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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 736 and 746

[Docket No. 150511438–5438–01]

RIN 0694–AG62

Updated Statements of Legal Authority for the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations (CFR) legal authority paragraphs in the Export Administration Regulations (EAR) to cite a Presidential notice extending an emergency declared pursuant to the International Emergency Economic Powers Act. This is a procedural rule that only updates authority paragraphs of the EAR. It does not alter any right, obligation or prohibition that applies to any person under the EAR.

DATES: The rule is effective May 22, 2015.

FOR FURTHER INFORMATION CONTACT: William Arvin, Regulatory Policy Division, Bureau of Industry and Security, Email *william.arvin@bis.doc.gov,* Telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

The authority for parts 730, 736 and 746 of the EAR (15 CFR parts 730, 736 and 744) rests, in part, on Executive Order 13338 of May 11, 2004—Blocking Property of Certain Persons and Prohibiting the Export of Certain Goods to Syria (69 FR 26751, 3 CFR, 2004 Comp., p. 168) and on annual notices by the President continuing that emergency. This rule updates the authority paragraphs in 15 CFR parts 730, 736 and 746 to cite the Notice of May 6, 2015 (80 FR 26815, May 8, 2015), which continues that emergency. This rule is purely procedural and makes no changes other than to revise CFR authority citations to make them current. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46959 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule does not involve any collection of information.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. It clarifies information and is non-discretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 736

Exports.

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 730, 736 and 746 of the EAR (15 CFR parts 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p.

256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014); Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015).

PART 736—[AMENDED]

■ 2. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015).

PART 746—[AMENDED]

■ 3. The authority citation for 15 CFR part 746 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Presidential Determination 2007–7 of December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015).

Dated: May 18, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–12453 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 738, 740, and 746

[Docket No. 150302205–5205–01]

RIN 0694–AG54

Russian Sanctions: Revisions and Clarifications for Licensing Policy for the Crimea Region of Ukraine

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) issues this final rule to amend the Export Administration Regulations (EAR) to facilitate Internet-based communications with persons in the Crimea region of Ukraine. This final rule allows exports or reexports without a license to the Crimea region of Ukraine of software that is necessary to enable the exchange of personal communications over the Internet, provided that such software is designated EAR99, or is classified as mass market software under Export Control Classification Number (ECCN) 5D992.c of the EAR, and provided further that such software is widely available to the public at no cost to the user. This final rule is being published simultaneously with the Department of the Treasury's Office of Foreign Assets Control (OFAC) issuance of General License No. 9, which authorizes the export or reexport from the United States or by U.S. persons to the Crimea region of Ukraine of certain services and software incident to the exchange of personal communications over the Internet. This action is consistent with the U.S. Government's policy to promote personal communications between the people in Crimea and the outside world.

Lastly, this final rule makes clarifications to the EAR with respect to the addition of the Crimea region of Ukraine provisions in a final rule published on January, 29, 2015, to the EAR. These clarifications are in response to requests that BIS received for guidance on applying these provisions.

DATES: This rule is effective May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Eileen Albanese, Director, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–0092, Fax: (202) 482–482–3355, Email: *rpd2@bis.doc.gov.* For emails, include ''Russia'' in the subject line.

SUPPLEMENTARY INFORMATION: On January 29, 2015, the Bureau of Industry and Security (BIS) published the final rule Russian Sanctions: Licensing Policy for the Crimea Region of Ukraine (80 FR 4776) (hereinafter the ''January 29 rule''). The January 29 rule imposed additional sanctions that implemented U.S. policy toward Russia.

Specifically, the January 29 rule imposed a license requirement for the export and reexport to the Crimea region of Ukraine, and the transfer within the Crimea region of Ukraine, of all items subject to the EAR, other than food and medicine designated as EAR99. The January 29 rule also added other provisions specific to the Crimea region of Ukraine. This action was consistent with the goals and objectives of Executive Order 13685.

Background for Executive Order 13685

This Order took additional steps to address the national emergency declared in Executive Order 13660 of March 6, 2014 (as expanded by Executive Order 13661 of March 16, 2014 and Executive Order 13662 of March 20, 2014), finding that the actions and policies of the Government of the Russian Federation with respect to Ukraine—including the deployment of Russian Federation military forces in the Crimea region of Ukraine—undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets, and thereby constitute an unusual and extraordinary threat to the national security and foreign policy of the United States.

In part, Executive Order 13685 prohibits certain transactions with respect to the Crimea region of Ukraine, including the export, reexport, sale or supply, directly or indirectly, from the United States, or by a U.S. person, of any goods, services or technology to the Crimea region of Ukraine. Under Section 10 of Executive Order 13685, all agencies of the United States Government are directed to take all appropriate measures within their authority to carry out the provisions of the Order.

Permitted Exports and Reexports of Certain Software to the Crimea Region of Ukraine

This final rule published today makes additional changes to the EAR for the Crimea region of Ukraine. Specifically, in § 746.6, this final rule revises paragraph (a) (license requirements) to

add an additional sentence that allows exports or reexports without a license to the Crimea region of Ukraine and transfers (in-country) within the Crimean region of Ukraine of certain software (described further below) that is necessary to enable the exchange of personal communications over the Internet.

This change to the license requirements, in addition to relieving a regulatory burden on exporters, reexporters, and transferors of such software, may also facilitate Internet-based communication between people located in the Crimea region of Ukraine and other people around the world. Facilitating such Internet-based communication with the people located in the Crimea region of Ukraine is in the United States' national security and foreign policy interests because it helps the people of the Crimea region of Ukraine communicate with the outside world. Persons in the Crimea region of Ukraine may use such Internet-based communication to describe their situation directly and counter any false messages being propagated by those currently exercising control over the Crimea region of Ukraine.

By creating an opportunity for the people of the Crimea region of Ukraine to draw attention to these issues, this final rule may reduce the ability of Russia, and those acting on Russia's behalf in the Crimea region of Ukraine, to control the narrative of local events. In addition, creating an opportunity for people in the Crimea region of Ukraine to draw attention to these issues may also encourage other countries to join with the United States and other like-minded countries currently imposing sanctions on Russia as a result of their activities in the Crimea region of Ukraine and other parts of eastern Ukraine, which is also in the national security and foreign policy interests of the United States.

This final rule is being published simultaneously with the Department of the Treasury's Office of Foreign Assets Control (OFAC) issuance of General License No. 9—*Exportation of Certain Services and Software Incident to Internet-Based Communications Authorized.* This general license authorizes the export or reexport, directly or indirectly, from the United States or by U.S. persons to the Crimea region of Ukraine of certain services incident to the exchange of personal communications over the Internet, such as instant messaging, chat and email, social networking, sharing of photos and movies, web browsing, and blogging, provided that such services are publicly available at no cost to the user, subject to certain exclusions. General License 9 further authorizes, in relevant part, the export or reexport, directly or indirectly, from the United States or by U.S. persons, wherever located, to persons in the Crimea region of Ukraine of software necessary to enable the services described above, provided that such software is designated as EAR99 or is classified as mass market software under ECCN 5D992.c of the EAR, and provided further that such software is widely available to the public at no cost to the user, subject to certain exclusions. See *http://www.treasury.gov/resource-center/sanctions/Programs/Documents/ukraine_gl9.pdf* BIS is publishing this rule to make § 746.6(a) of the EAR consistent with OFAC's new general license. This rule revises § 746.6(a) to allow license-free treatment of software that is necessary to enable the exchange of personal communications over the Internet only if such software is designated EAR99 or is classified as mass market software under ECCN 5D992.c of the EAR, and provided further that such software is widely available to the public at no cost to the user.

Other Clarifications To the EAR for the Crimea Region of Ukraine

In addition to the changes described above, this final rule also makes clarifications to the EAR with respect to the addition of the Crimea region of Ukraine provisions to the EAR. These clarifications are in response to requests that BIS received for guidance on applying these provisions. These clarifications do not change policy as it relates to the Crimea region of Ukraine provisions added to the EAR in the January 29 rule, but rather provide guidance on how BIS interprets them. These questions primarily arise because Crimea is not a country, so the public had questions in regards to how to apply certain EAR provisions that are generally tied to countries when they involve the Crimea region of Ukraine.

New Footnote To Clarify Application of Country Groups for Crimea Region of Ukraine

In Supplement No. 1 to part 740—Country Groups, this final rule adds a footnote 3 to the entry for Ukraine. The new footnote clarifies that for purposes of the Country Group provisions under the EAR, the Crimea region of Ukraine uses the same Country Group designations as the country of Ukraine. This is because the Crimea region of Ukraine is not a country. The Country Groups are also closely tied to the use of license exceptions, so the new footnote also clarifies that the only license exceptions that may be used for the Crimea region of Ukraine are those specified in § 746.6(c). Similar to footnote 8 that was added to the Commerce Country Chart in Supplement No. 1 to part 738 in the January 29 rule, footnote 3 makes the public aware of the additional requirements under § 746.6 that apply to the 'Crimea region of Ukraine,' including limitations on the use of license exceptions. The new footnote also includes the same definition of 'Crimea region of Ukraine' that appears in footnote 8 to the Commerce Country Chart and this rule's revision to § 746.6.

New Note To Clarify Application of Deemed Exports and Deemed Reexports for Crimea Region of Ukraine

In § 746.6 (Crimea region of Ukraine), this final rule adds a paragraph (a)(2) to clarify that for purposes of applying the EAR deemed export and deemed reexport requirements for foreign nationals located in or from the Crimea region of Ukraine, the nationality of the foreign national (as determined by accepted methods, such as looking to the passport or other nationality documents recognized by the United States Government) is what is used for purposes of determining whether a license is required under the EAR. For example, if a foreign national is in the United States and has a Ukrainian passport, the person releasing the technology or software source code would use Ukraine for purposes of determining the EAR license requirements and would not need to determine whether the person was from the Crimea region of Ukraine. For releases of technology in the Crimea region to foreign nationals of any country other than Ukraine, the nationality of the foreign national is used for determining deemed reexport license requirements. For example, a release of technology or software source code to a Russian national located in the Crimea region of Ukraine would use Russia for purposes of determining the EAR license requirements. BIS makes this clarification because of requests received from the public for guidance on how to apply the Crimea region of Ukraine license requirements in the deemed export and deemed reexport contexts. Note that nothing in this rule affects licensing requirements for the provision of goods and services under the OFAC regulations, 31 CFR parts 500–599.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order

13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46959 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable to the changes described above under the heading *Permitted exports and reexports of certain software to the Crimea region of Ukraine* because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). BIS implements this rule to advance U.S. policy toward Russia and therefore promote U.S. national security or foreign policy objectives by immediately facilitating Internet-based communications with persons in the Crimea region of Ukraine. Delay in publication and the rule's effective date to allow for notice and comment would frustrate those objectives. This change to the license requirements, in addition to relieving a regulatory burden of exporters, reexporters and transferors of such software, may also facilitate Internet-based communication between people located in the Crimea region of Ukraine and other people around the world. Facilitating such Internet-based communication with the people located in the Crimea region of Ukraine is in U.S. national security and foreign policy interests because it helps create a potentially uncontrolled access point to the outside world for the people of the Crimea region of Ukraine. They may use such Internet-based communication to highlight their plight and to counter any false messages being propagated by those currently exercising control over the Crimea region of Ukraine. By creating an opportunity for the people of the Crimea region of Ukraine to draw attention to these issues, this final rule may increase pressure on Russia and those acting on Russia's behalf in the Crimea region of Ukraine to stop such activities, or at least to allow a counter version of local events. In addition, creating an opportunity for people in the Crimea region of Ukraine to draw attention to these issues may also encourage other countries to join with the United States and other like-minded countries currently imposing sanctions on Russia as a result of their activities in the Crimea region of Ukraine and other parts of eastern Ukraine, which is also in the national security and foreign policy interests of the United States. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

5. The Department finds for the changes described under the heading *Other Clarifications to the EAR for the Crimea region of Ukraine* that there is good cause under 5 U.S.C. 553(b)(3)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. These changes included in this final rule are limited to clarifications to what was included in the final rule published on January 29, 2015. These revisions are non-substantive, or are limited to only clarifying the regulations to ensure consistency with the intent of the January 29 rule; therefore, providing an additional opportunity for public comment on these corrections is unnecessary.

In addition, BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3) because it will allow the clarifications to go into effect immediately, which will reduce the potential for confusion among the public and make sure all members of the public are aware of how BIS interprets these Crimea region of Ukraine provisions as they relate to other EAR provisions.

List of Subjects

15 CFR Part 738

Exports.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 746

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 738, 740, and 746 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 738—[AMENDED]

■ 1. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p.

228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 2. Supplement No. 1 to part 738 is amended by revising footnote 8 to read as follows:

Supplement No. 1 to Part 738—Commerce Country Chart

* * * * *

[8] See § 746.6 for additional license requirements for export and reexports to the Crimea region of Ukraine and transfers (in-country) within the Crimea region of Ukraine for all items subject to the EAR, other than food and medicine designated as EAR99 and certain EAR99 or ECCN 5D992.c software for Internet-based communications. The Crimea region of Ukraine includes the land territory in that region as well as any maritime area over which sovereignty, sovereign rights, or jurisdiction is claimed based on purported annexation of that land territory.

PART 740—[AMENDED]

■ 3. The authority citation for 15 CFR part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 4. Supplement No. 1 to part 740 is amended by:

■ a. Adding footnote designation ''3'' to ''Ukraine'' in Country Group A; and

■ b. Adding footnote 3 to Country Group A to read as follows:

Supplement No. 1 to Part 740—Country Groups

* * * * *

[3] For purposes of this supplement, as well as any other EAR provision that references the Country Groups, the designations for Ukraine also apply to the Crimea region of Ukraine. See § 746.6(c) for an exhaustive listing of license exceptions that are available for the Crimea region of Ukraine. No other EAR license exceptions are available for the Crimea region of Ukraine. The Crimea region of Ukraine includes the land territory in that region as well as any maritime area over which sovereignty, sovereign rights, or jurisdiction is claimed based on purported annexation of that land territory.

PART 746—[AMENDED]

■ 5. The authority citation for 15 CFR part 746 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Presidential Determination 2007–7 of December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015).

■ 6. Section 746.6 is amended by revising paragraph (a) to read as follows:

§ 746.6 Crimea region of Ukraine.

(a) *License requirements*—(1) *General prohibition.* As authorized by Section 6 of the Export Administration Act of 1979, a license is required to export or reexport any item subject to the EAR to the Crimea region of Ukraine and the transfer within the Crimea region of Ukraine except food and medicine designated as EAR99 or software that is necessary to enable the exchange of personal communications over the Internet (such as instant messaging, chat and email, social networking, sharing of photos and movies, Web browsing, and blogging), provided that such software is designated EAR99 or is classified as mass market software under Export Control Classification Number (ECCN) 5D992.c of the EAR, and provided further that such software is widely available to the public at no cost to the user. The 'Crimea region of Ukraine' includes the land territory in that region as well as any maritime area over which sovereignty, sovereign rights, or jurisdiction is claimed based on purported annexation of that land territory.

(2) For purposes of applying the EAR deemed export and deemed reexport requirements for foreign nationals located in or from the Crimea region of Ukraine, the nationality of the foreign national (as determined by accepted methods, such as looking to the passport or other nationality document(s) recognized by the United States Government) is what is used for purposes of determining whether a license is required for a deemed export or deemed reexport. For any other export, reexport or transfer (in-country), see the license requirements specified in paragraph (a).

* * * * *

Dated: May 14, 2015.

Eric L. Hirschhorn,

Under Secretary of Commerce for Industry and Security.

[FR Doc. 2015–12267 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0464]

Drawbridge Operation Regulation; Lake Washington Ship Canal, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Washington State Department of Transportation Montlake Bridge across the Lake Washington Ship Canal, mile 5.2, at Seattle, WA. The deviation is necessary to accommodate the University of Washington, and University of Washington Bothell commencement ceremony traffic. This deviation allows the bridge to remain in the closed-to-navigation position to accommodate the timely movement of vehicular traffic.

DATES: This deviation is effective from 9:30 a.m. on June 13, 2015 to 6:15 p.m. on June 14, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0464] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email *d13-pf-d13bridges@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The University of Washington, through the Washington Department of Transportation, has requested that the Montlake Bridge bascule span remain closed-to-navigation position, and need not open to vessel traffic to facilitate timely movement of commencement vehicular traffic.

The Montlake Bridge across the Lake Washington Ship Canal, at mile 5.2, in the closed position provides 30 feet of vertical clearance throughout the navigation channel, and 46 feet of vertical clearance throughout the center 60-feet of the bridge; vertical clearance references to the Mean Water Level of Lake Washington.

The normal operating schedule for Montlake Bridge operates in accordance with 33 CFR 117.1051(e) which requires the bridge to open on signal, except that the bridge need not open for vessels less than 1,000 gross tons between 7 a.m. and 9 a.m. and 3:30 p.m. and 6:30 p.m. Monday through Friday.

The deviation period is from 9:30 a.m. on June 13, 2015 to 6:15 p.m. on June 14, 2015. The deviation allows the bascule span of the Montlake Bridge to remain in the closed-to-navigation position from 9:30 a.m. to 12:30 p.m. and 4:30 p.m. to 6:30 p.m. on June 13, 2015, and from 11:45 a.m. to 1:45 p.m. and 4:15 p.m. to 6:15 p.m. on June 14, 2015. Waterway usage on the Lake Washington Ship Canal ranges from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 15, 2015.

Steven M Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015–12435 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2015–0463]

Drawbridge Operation Regulation; Duwamish Waterway, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Spokane Street Swing Bridge across the Duwamish Waterway, mile 0.3, at Seattle, WA. The deviation is necessary to enable timely completion of new electrical equipment. This deviation allows the drawbridge to remain in the closed-to-navigation position for marine traffic.

DATES: This deviation is effective from 8 a.m. to Noon on June 1, 2015.

ADDRESSES: The docket for this deviation, [USCG–2015–0463] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven M. Fischer, Thirteenth Coast Guard District Bridge Administrator; telephone 206–220–7282, email: *d13-pf-d13bridges@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Seattle Department of Transportation (SDOT) has requested a deviation from the operating schedule of Spokane Street Swing Bridge to install new electrical equipment. SDOT chose this date and time to coordinate a work day during a low tide to minimize any impacts with waterway traffic. The Spokane Street Bridge is located in the Duwamish Waterway, mile 0.3, at Seattle, WA, and provides 55 feet of vertical clearance at center span, and 44 feet of vertical clearance at the east and west sides of the navigation channel while in the closed position. Vessels have unlimited vertical clearance with the swing span in the fully open position. Vertical clearances are referenced to mean high-water elevation.

The deviation period is from 8 a.m. to Noon on June 1, 2015. The deviation allows the Spokane Street Swing Bridge across the Duwamish Waterway, mile 0.3, at Seattle, WA, to remain in the closed-to-navigation position and need not open for maritime traffic from 8 a.m. to Noon on June 1, 2015.

The normal operating schedule for the bridge is in 33 CFR 117.1041, which specifies that the draws of each bridge across the Duwamish Waterway shall open on signal. The deviation period is effective from 8 a.m. to Noon on June 1, 2015, and allows the drawbridge to remain in the closed-to-navigation position. Vessel traffic on the Duwamish waterway consists of vessels ranging from small pleasure craft, sailboats, small tribal fishing boats, and commercial tug and tow, and mega yachts.

Vessels able to pass through the bridge in the closed position may do so at any time, but are requested to transit at a minimum safe speed with no wake for worker safety. The bridge will not be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: May 15, 2015.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015–12434 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2011–0969; EPA–R05–OAR–2012–0991; EPA–R05–OAR–2013–0435; FRL–9927–94–Region–5]

Approval and Promulgation of Air Quality Implementation Plans; Illinois; Emission Limit Infrastructure SIP Requirements for the 2008 Ozone, 2010 NO_2, and 2010 SO_2 NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve some elements of state implementation plan (SIP) submissions from Illinois regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2008 ozone, 2010 nitrogen dioxide (NO_2), and 2010 sulfur dioxide (SO_2) National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. In this action, EPA is specifically approving infrastructure requirements concerning emission limits and other control measures. The proposed rulemaking associated with today's final action was published on February 27, 2015, and EPA received no comments during the comment period, which ended on March 30, 2015.

DATES: This final rule is effective on June 22, 2015.

ADDRESSES: EPA has established dockets for this action under Docket ID No. EPA–R05–OAR–2011–0969 (2008 ozone infrastructure SIP elements), Docket ID No. EPA–R05–OAR–2012–0991 (2010 NO_2 infrastructure SIP elements), and Docket ID No. EPA–R05–OAR–2013–0435 (2010 SO_2 infrastructure SIP elements). All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information 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 *www.regulations.gov* or in hard copy at the U.S. 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 Sarah Arra at (312) 886–9401 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Sarah Arra, Environmental Scientist, 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) 886–9401, *arra.sarah@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. What is the background of these SIP submissions?
II. What is our response to comments received on the proposed rulemaking?
III. What action is EPA taking?
IV. Statutory and Executive Order Reviews.

I. What is the background of these SIP submissions?

A. What state SIP submission does this rulemaking address?

This rulemaking addresses three submissions from December 31, 2012, and a January 9, 2015, clarification from the Illinois Environmental Protection Agency (Illinois EPA) intended to address all applicable infrastructure requirements for the 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS.

B. Why did the state make these SIP submissions?

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure that their SIPs provide for implementation, maintenance, and enforcement of the NAAQS, including the 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for the NAAQS already meet those requirements.

EPA has highlighted this statutory requirement in multiple guidance documents, including the most recent guidance document entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)'' issued on September 13, 2013.

C. What is the scope of this rulemaking?

EPA is acting upon the SIP submissions from Illinois that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

In this specific rulemaking, EPA is only taking action on the CAA 110(a)(2)(A) requirements of these submittals. The majority of the other infrastructure elements were finalized in an October 16, 2014 (79 FR 62042), rulemaking.

II. What is our response to comments received on the proposed rulemaking?

The proposed rulemaking associated with today's final action was published on February 27, 2015 (80 FR 10652), and EPA received no comments during the comment period, which ended on March 30, 2015.

III. What action is EPA taking?

To meet the infrastructure element under CAA section 110(a)(2)(A), IEPA has identified rules and regulations that provide control measures and limit emissions of pollutants relevant to the 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS. For the reasons discussed in our proposed rulemaking, EPA is taking final action to approve, as proposed, Illinois' submittal certifying that its current SIP is sufficient to meet the required infrastructure element under CAA section 110(a)(2)(A) for the 2008 ozone, 2010 NO_2, and 2010 SO_2 NAAQS.

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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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 July 21, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: May 13, 2015.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.745 is amended by revising paragraphs (e), (f), and (g) to read as follows:

§ 52.745 Section 110(a)(2) infrastructure requirements.

* * * * *

(e) Approval and Disapproval—In a December 31, 2012, submittal, Illinois certified that the State has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2008 ozone NAAQS except for 110(a)(2)(D)(i)(I). EPA is approving Illinois' submission addressing the infrastructure SIP requirements of section 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (D)(ii), (E) except for state board requirements, (F) through (H), (J) except for prevention of significant deterioration, and (K) through (M). EPA is disapproving Illinois' submission addressing the prevention of significant deterioration, in (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J). EPA is not taking action on the state board requirements of (E). Although EPA is disapproving portions of Illinois' submission addressing the prevention of significant deterioration, Illinois continues to implement the Federally promulgated rules for this purpose as they pertain to (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J).

(f) Approval and Disapproval—In a December 31, 2012, submittal, Illinois certified that the state has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2010 nitrogen dioxide (NO_2) NAAQS. EPA is approving Illinois' submission addressing the infrastructure SIP requirements of section 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(I), (D)(i)(II) with respect to visibility protection, (D)(ii), (E) except for state board requirements, (F) through (H), (J) except for prevention of significant deterioration, and (K) through (M). EPA is disapproving Illinois' submission addressing the prevention of significant deterioration, in (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J). EPA is not taking action on the state board requirements of (E). Although EPA is disapproving portions of Illinois' submission addressing the prevention of significant deterioration, Illinois continues to implement the Federally promulgated rules for this purpose as they pertain to (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J).

(g) Approval and Disapproval—In a December 31, 2012, submittal, Illinois certified that the state has satisfied the infrastructure SIP requirements of section 110(a)(2)(A) through (H), and (J) through (M) for the 2010 sulfur dioxide (SO_2) NAAQS except for 110(a)(2)(D)(i)(I). EPA is approving Illinois' submission addressing the infrastructure SIP requirements of section 110(a)(2)(A), (B), (C) with respect to enforcement, (D)(i)(II) with respect to visibility protection, (D)(ii), (E) except for state board requirements, (F) through (H), (J) except for prevention of significant deterioration, and (K) through (M). EPA is disapproving Illinois' submission addressing the prevention of significant deterioration, in (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J). EPA is not taking action on the state board requirements of (E).

Although EPA is disapproving portions of Illinois' submission addressing the prevention of significant deterioration, Illinois continues to implement the Federally promulgated rules for this purpose as they pertain to (C), (D)(i)(II), and the prevention of significant deterioration (PSD) portion of (J).

[FR Doc. 2015–12355 Filed 5–21–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[EPA–R2–OW–2014–0587; FRL–9928–04-Region 2]

Modification of the Designations of the Caribbean Ocean Dredged Material Disposal Sites

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Through this rulemaking, the U.S. Environmental Protection Agency (EPA) is modifying the designations for the five Ocean Dredged Material Disposal Sites (ODMDS) around Puerto Rico (San Juan Harbor, PR ODMDS; Yabucoa Harbor, PR ODMDS; Ponce Harbor, PR ODMDS; Mayaguez Harbor, PR ODMDS; Arecibo Harbor, PR ODMDS). Currently, each of the ODMDS is restricted to only allow disposal of dredged material from the specific harbor for which it is named. This modification removes the restriction that limits eligibility for disposal at each of the disposal sites based solely on the geographic origin of the dredged material. The modifications to the site designations do not actually authorize the disposal of any particular dredged material at any site. All proposals to dispose of dredged material at any of the designated sites will continue to be subject to project-specific reviews and must still be demonstrated to satisfy the criteria for ocean dumping before any material is authorized for disposal. This rulemaking was taken to provide long-term flexibility for management of any dredged material that may potentially be derived from maintenance, development, or emergency activities in areas outside those harbors provided for in the original designations. The modifications to the site designations are for an indefinite period of time. Each ODMDS will continue to be monitored to ensure that significant unacceptable, adverse environmental impacts do not occur as a result of dredged material disposal at the site.

DATES: This final rule is effective on June 22, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R02–OW–2014–0587. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy by appointment at the Dredging, Sediment and Oceans Section (CWD), U.S. Environmental Protection Agency, Region 2, 290 Broadway, New York, NY 10007. This Docket Facility is open from 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is 212–637–3799.

FOR FURTHER INFORMATION CONTACT: Mark Reiss, Clean Water Division Region 2 (24th Floor), Environmental Protection Agency, 290 Broadway New York, NY 10007; telephone number: 212–637–3799; fax number: 212–637–3891; email address: *reiss.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background
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I. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act (MPRSA) of 1972, as amended, 33 U.S.C. 1401 *et seq.,* gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean disposal sites to the Regional Administrator of the Region in which the sites are located. These modifications are being made pursuant to that authority. EPA is conducting this rulemaking to remove the geographic restrictions on the origin of the dredged material that can be disposed from the designations of the San Juan Harbor, PR Ponce Harbor, PR, Yabucoa Harbor, PR, Mayaguez Harbor, PR and Arecibo Harbor, PR ODMDSs.

The site modifications in this action provide the Corps, Commonwealth of Puerto Rico, municipal, and private entities with greater long term flexibility in managing dredged materials outside the specific harbors provided for in the original designations.

The background for today's action is discussed in detail in EPA's October 14, 2014, proposal (79 FR 61591). The EPA received two comments on the proposed rule that supported the rulemaking. One of the letters raised some general concerns about the need to ensure that sensitive marine habitats are not adversely impacted by activities allowed by this rulemaking.

Modification of the designation of ocean disposal sites under 40 CFR part 228 is essentially a preliminary, planning measure. The practical effect of such a designation is only to require that if future ocean disposal activity is permitted and/or authorized (in the case of Corps projects) under 40 CFR part 227, then such disposal should normally be consolidated at the designated sites (see 33 U.S.C. 1413(b).) Modification of the designation of an ocean disposal site does not authorize any actual disposal and does not preclude EPA or the Corps from finding available and environmentally preferable alternative means of managing dredged materials, or from finding that certain dredged material is not suitable for ocean disposal under the applicable regulatory criteria.

This modification provides flexibility for management of dredged material from areas outside the harbors provided for in the original designations. However, it should be emphasized that modification of the designations of the ODMDS does not constitute or imply Corps' or EPA's approval of open water disposal of dredged material from any specific project. Before disposal of dredged material at any site may commence, Essential Fish Habitat and Endangered Species Act consultations must be completed, and EPA and the Corps must evaluate the proposal and authorize disposal according to the ocean dumping regulatory criteria (40 CFR part 227). All projects proposed for disposal at the ODMDS will be subject to review and comment by the relevant resource agencies and the public to ensure that any concerns regarding potential impacts associated with transport of material from the project area to the ODMDS are addressed before they are authorized for disposal. All transport and disposal activities must adhere to the strict provisions and restrictions laid out for each site in its Site Monitoring and Management Plan, which include specific monitoring and management requirements to avoid impacts to sensitive habitats. Finally, EPA has the right to disapprove the actual disposal, if it determines that

environmental requirements under the MPRSA (including required Essential Fish Habitat and Endangered Species Act consultations) have not been met.

Enabling management of the additional dredged materials at monitored designated sites restricts impacts to those areas and minimizes the potential for using other near shore discharge strategies with potentially greater impacts to the marine environment. As such, this rulemaking would afford additional protection of aquatic organisms at individual, population, community, or ecosystem levels of ecological structures and sensitive marine habitats will not be adversely impacted by activities allowed by this rulemaking.

II. Final Action

The EPA hereby modifies the designations of Arecibo Harbor PR Ocean Disposal Site, Mayaguez Harbor PR Ocean Disposal Site, Ponce Harbor PR Ocean Disposal Site, San Juan Harbor PR Ocean Disposal Site and Yabucoa Harbor PR Ocean Disposal Site by removing the geographic restrictions on the origin of dredged material that can be managed at each site. This modification is made pursuant to MPRSA section 102(c). These ocean disposal sites are located in ocean waters off Puerto Rico outside the harbors corresponding to their names.

III. Regulatory Reviews

Details of the regulatory requirements of this rule are in EPA's October 14, 2014, proposed rule, 79 FR 61591. To summarize, this final rule complies as follows:

—It complies with the National Environmental Policy Act of 1969 (42 U.S.C. 4332) under the doctrine of functional equivalency; the EPA has relied on information from the final Environmental Impact Statement in its consideration and application of ocean dumping criteria to modification of the designations of the San Juan Harbor, PR Ponce Harbor, PR, Yabucoa Harbor, PR, Mayaguez Harbor, PR and Arecibo Harbor, PR dredged material sites;

—It complies with the Endangered Species Act (16 U.S.C. 1536(a)(2), regarding consultations with the U.S. Fish and Wildlife Service and National Marine Fisheries Service in that modification of the designations of the ocean disposal sites is not expected to adversely affect any threatened or endangered species or their critical habitat;

—It complies with the Magnuson-Stevens Fishery Conservation and Management Act of 1996 regarding consultation with the National Marine Fisheries Service in that modification of the designations of the ocean disposal sites is not expected to have significant impacts to marine fishery resources; and

—It complies with the Coastal Zone Management Act, regarding federal activities that affect a state's coastal zone in that the Corps will submit Coastal Zone Consistency determinations to the Commonwealth of Puerto Rico for individual projects proposing to dispose at the sites.

IV. Statutory and Executive Order Reviews

Details of the applicability of executive orders and statutory provisions to this rule are in EPA's October 14, 2014, proposed rule, 79 FR 61591. To summarize, this final rule complies with applicable executive orders and statutory provisions as follows:

—It is not a ''significant regulatory action'' subject to Office of Management and Budget (OMB) review under Executive Order 12866 (58 FR 51735, October 4, 1993);

—It does not impose an information collection burden under the provisions of the Paperwork Reduction Act 44 U.S.C. 3501 *et seq;*

—It 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);

—It does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);

—It does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

—It is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

—It has no Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000);

—It is not an economically significant regulatory action subject to Executive Order 12866 (62 FR 19885, April 23, 1997), and does not present a disproportionate risk to children;

—It is not a significant regulatory action under Executive Order 12866 and so is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001) ;

—It is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113, 12(d) (15 U.S.C. 272 note) as it does not involve technical standards;

—It will not have a disproportionately high and adverse human health or environmental effects on minority or low-income populations subject to Executive Order 12898 (59 FR 7629);

— EPA has written this rulemaking in plain language to be consistent with the Plain Language Directive of Executive Order 12866; and

— It will provide additional protection of aquatic organisms and therefore advances the objective of Executive Order 13158 (65 FR 34909, May 31, 2000) to protect marine areas.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as amended 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. The 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**.

List of Subjects in 40 CFR Part 228

Environmental protection, Water pollution control.

Authority: 33 U.S.C. 1412 and 1418.

Dated: April 20, 2015.

Judith A. Enck,

Regional Administrator, Region 2.

In consideration of the foregoing, EPA hereby amends part 228, chapter I of title 40 of the Code of Federal Regulations as follows:

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

■ 2. Section 228.15 is amended by revising paragraphs (d)(10)(vi), (d)(11)(vi), (d)(12)(vi), (d)(13)(vi), and (d)(14)(vi) to read as follows:

§ 228.15 Dumping sites designated on a final basis.

* * * * *

(d) * * *

(10) * * *

(vi) *Restriction:* Disposal shall be limited to dredged material.

(11) * * *

(vi) *Restriction:* Disposal shall be limited to dredged material.

(12) * * *

(vi) *Restriction:* Disposal shall be limited to dredged material.

(13) * * *

(vi) *Restriction:* Disposal shall be limited to dredged material.

(14) * * *

(vi) *Restriction:* Disposal shall be limited to dredged material.

* * * * *

[FR Doc. 2015–12335 Filed 5–21–15; 8:45 am]

BILLING CODE 6560–50–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

40 CFR Part 1850

[Docket Number: 105002015–1111–05]

Procedures for Disclosure of Records Under the Freedom of Information Act and Privacy Act

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Final rule.

SUMMARY: This rule sets forth the Gulf Coast Ecosystem Restoration Council's (Council) regulations regarding the Freedom of Information Act (FOIA), Privacy Act (PA), and declassification and public availability of national security information. The FOIA and PA require each agency to promulgate regulations implementing the provisions of those laws and this Final Rule fulfills that mandate, facilitating public access to Council records.

DATES: This rule becomes effective on June 22, 2015.

ADDRESSES: The Council posted all comments on the proposed FOIA and PA regulations on its Web site, *http://www.restorethegulf.gov/,* without change, including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. All comments received are part of the public record and subject to public disclosure.

FOR FURTHER INFORMATION CONTACT: Jeffrey Roberson at 202–482–1315.

SUPPLEMENTARY INFORMATION:

I. Background

The RESTORE Act, Public Law 112–141 (July 6, 2012), codified at 33 U.S.C. 1321(t) and note, makes funds available for the restoration and protection of the Gulf Coast Region through a new trust fund in the Treasury of the United States, known as the Gulf Coast Restoration Trust Fund (Trust Fund). The Trust Fund will contain 80 percent of the administrative and civil penalties paid by the responsible parties after July 6, 2012, under the Federal Water Pollution Control Act in connection with the *Deepwater Horizon* oil spill. These funds will be invested and made available through five components of the RESTORE Act.

Two of the five components, the Comprehensive Plan and Spill Impact Components, are administered by the Council, an independent federal entity created by the RESTORE Act. Under the Comprehensive Plan Component (33 U.S.C. 1321(t)(2)), 30 percent of funds in the Trust Fund (plus interest) are available to develop a Comprehensive Plan to restore the ecosystem and the economy of the Gulf Coast Region. Under the Spill Impact Component (33 U.S.C. 1321(t)(3)), 30 percent of funds in the Trust Fund will be disbursed to the five Gulf Coast States (Alabama, Florida, Louisiana, Mississippi, and Texas) or their administrative agents based on an allocation formula established by the Council by regulation based on criteria in the RESTORE Act.

II. Public Comments and Summary of Changes to Final Rule

On February 9, 2015, the Council proposed a draft rule implementing its obligations to make records available under the Freedom of Information Act (FOIA) and Privacy Act (PA). 80 FR 6934. The FOIA regulations govern third-party requests for information controlled by the Council. The PA regulations govern first-party requests for his or her own information. The Council provided a public comment period of 30 days and received comments from four separate commenters, three citizens and one Federal agency. The recommendations contained in the four comments are summarized below section by section, along with the Council's responses to the recommendations. The Council also posted all comments on its Web site, *http://www.restorethegulf.gov/,* without change, including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. All comments received are part of the public record and subject to public disclosure.

Section-by-Section Analysis

Section 1850.1 Purpose and Scope

The agency commenter suggested that the Council include language clarifying the intersection of FOIA and the PA. The Council accepts this comment and the suggested language can be found in the last paragraph of section 1850.1.

Section 1850.2 Definitions

The agency commenter suggested adding three new definitions: FOIA public liaison, requester category, and fee waiver. The Council accepts this comment and the definitions can be found at new paragraphs 1850.2(i), (j), and (s).

Section 1850.4 Public Reading Room

One commenter asked whether documents will be placed online for the public to access without request. The Council is committed to making documents of interest to the public available online in its public reading room on its Web site, *http://www.restorethegulf.gov.* This commitment is documented in section 1850.4 of these regulations. No change was made to the regulations in response to this comment.

Section 1850.5 Requirements for Making Requests

The agency commenter suggested that the Council's wording of paragraph 1850.5(b) where the Council describes its process for contacting a requester to narrow the scope of a request has a negative connotation. The agency commenter suggested alternative text that the Council has incorporated into paragraph 1850.5(b).

The agency commenter also suggested adding two paragraphs to the end of section 1850.5 to help explain the interaction of the Council's FOIA and PA regulations and the effect on a request for Council records pertaining to another individual of submitting proof of death or a notarized authorization to access records by that individual. The Council accepts this comment and the paragraphs can be found at new paragraphs 1850.5(e) and (f).

Section 1850.6 Responding to Records

The agency commenter suggested consistency edits to paragraph 1850.6(a) to keep the terminology of simple and complex track processing consistent. The Council accepts this comment and the revised language can be found in paragraph 1850.6(a).

The agency commenter recommended that the Council modify paragraph 1850.6(c)(1) to include a requirement that the Council Records Management Officer provide the requester with a unique tracking number, an estimated date of completion (once the request is perfected) and a fee estimate (when applicable). The agency commenter also suggested that the Council include in its acknowledgment to the requester a brief description of the subject of the request to aid both the requester and the Council in keeping track of multiple

pending requests. The Council accepts these comments and revised language can be found in the final two sentences of paragraph 1850.6(c)(1).

The agency commenter recommended that the Council include in the list of required elements in a denial letter a description of the exemption(s) applied. The Council accepts this comment and the revised language can be found at 1850.6(e)(1).

The agency commenter also recommended adding a new subsection to paragraph 1850.6(e) that addresses requirements under the FOIA to indicate, if technically feasible, the precise amount of information deleted at the place in the record where the deletion was made, and to indicate the exemption under which a deletion is made on the released portion of the record unless including that information would harm an interest protected by the exemption. The Council accepts this comment and the new subsection can be found at 1850.6(e)(3).

One commenter suggested broadening the language of paragraph 1850.6(h) to provide more leeway to respond to a request electronically rather than only by mail. The Council accepts this comment and paragraph 1850.6(h) has been modified accordingly.

The same commenter suggested revising subsection 1850.6(h)(3) to clarify that retrieving data from a database or running a report from a database is permissible. The Council accepts this comment and subsection 1850.6(h)(3) has been modified accordingly.

One commenter asked whether records will be transferred to another agency in the future and how the public will be informed of any such transfer. Section 1850.6(f) of these regulations discusses the Council's procedures for referring documents to another agency when that other agency is the originating agency. Whenever the Council refers any part of the responsibility for responding to a request to another agency, it will notify the requester of the referral and inform the requester of the name of the agency to which the record was referred, including that agency's FOIA contact information. No change was made to the regulations in response to this comment.

Section 1850.7 Appeals

One commenter suggested that the Council remove requirements that an appellant include in his/her appeal a copy of the original request and the initial determination. The commenter suggested that these additional requirements are beyond the strict requirements of the statute and could create unnecessary burdens on potential appellants, including possibly leading to the rejection of an appeal based on the failure to include such documentation. The commenter also pointed out that this sort of requirement is rare among agencies. In the alternative, the commenter suggested that the Council could include language encouraging but not requiring the inclusion of such additional documentation in an appeal. The Council accepts this comment and has revised section 1850.7(c) to remove this requirement; instead the Council has included language encouraging submission of the original request and initial determination when filing an appeal. The Council is also clarifying in section 1850.7(c) that the appellant may submit as much or as little information as he/she wishes, so long as the determination that is being appealed is clearly identified.

The agency commenter suggested that the Council amend section 1850.7 to add language discussing the Office of Government Information Services (OGIS) and the services provided by that office. The Council accepts this comment and has added a new paragraph (3) to section 1850.7(f) that contains language recommended by the commenter and the Department of Justice's Office of Information Policy. See *http://www.justice.gov/oip/blog/foia-post-2010-oip-guidance-notifying-requesters-mediation-services-offered-ogis.*

Section 1850.9 Maintenance of Files

The agency commenter suggested including language explaining how long the Council will retain records related to FOIA requests and why. The agency commenter also suggested clarifying that material responsive to a FOIA request may not be disposed of or destroyed while the request or related appeal or lawsuit is pending even if otherwise authorized for disposition under an approved records retention schedule. The Council accepts this comment and new language was incorporated into 1850.9.

One commenter asked whether Council record schedules will be clear for the public to understand. While these regulations do not establish any record retention schedules, the Council does endeavor to make all its regulations and internal processes clear to the public. At this time the Council uses the government-wide record retention schedules promulgated by the National Archives and Records Administration (*http://www.archives.gov/records-mgmt/grs.html*). No change was made to the regulations in response to this comment.

Section 1850.10 Fees

One commenter noted that the rate the Council intends to charge as a fee when conducting reviews of records includes the actual salary rate of the employee involved plus 16 percent to cover benefits and wondered whether this was affordable for most U.S. citizens. The review fee is only applicable to commercial use requests so most individual U.S. citizens would not be subject to the fee. See section 1850.10(b)(4). Further, the FOIA directs agencies to develop fee schedules that reflect direct costs of search, duplication, or review. The Council's review fee rate is based on the actual time an employee spends reviewing documents potentially responsive to a request. These costs include salary and attendant benefits. The Council has calculated that 16 percent reasonably represents the benefit costs of its employees. No change was made to the regulations in response to this comment.

One commenter asked whether the Council would charge fees if the Council does not process the FOIA request in a timely manner. Consistent with 5 U.S.C. 552(a)(4)(viii), no search fee will be charged to a requester if the Council does not comply with the statutory time limits of the FOIA (5 U.S.C. 552(a)(6)) unless unusual or exceptional circumstances apply to the processing of the request. Further, no duplication fees will be charged to requesters in the fee category of a representative of the news media or an educational or noncommercial scientific institution when the Council does not comply with the statutory time limits of the FOIA (5 U.S.C. 552(a)(6)) unless unusual or exceptional circumstances apply to the processing of the request. Language related to not charging fees in this these circumstances is already included at section 1850.10(b)(5)(vi) and (vii). No change was made to the regulations in response to this comment.

Other

The Council also received one comment that expressed general support for the proposed regulations and noted that the regulations strike a balance between permitting access to government records and protecting potentially national security information. No change was made to the regulations in response to this comment.

In addition to the modifications discussed above, the Council has made minor formatting changes and corrected typographical errors in the zip code for the Council, the citation for one of the

authorities under which the Council is issuing this rule, and an internal cross-reference in section 1850.6(f).

After considering public comments, the Council now issues the regulations as a final rule. The rule will take effect on June 22, 2015.

III. Procedural Requirements

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that this Interim Final Rule will not have a significant economic impact on a substantial number of small entities. The Council hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. Under the FOIA, agencies may recover only the direct costs of searching for, reviewing, and duplicating the records processed for requesters. Thus, the fees the Council assesses are typically nominal. Further, the number of ''small entities'' that make FOIA requests is relatively small compared to the number of individuals who make such requests.

B. Paperwork Reduction Act

This rule does not contain a ''collection of information'' as defined by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

C. Regulatory Planning and Review (Executive Orders 12866 and 13563)

As an independent federal entity that is composed of, in part, six federal agencies, including the Departments of Agriculture, Army, Commerce, and Interior, the Department in which the Coast Guard is operating, and the Environmental Protection Agency, the requirements of Executive Orders 12866 and 13563 are inapplicable to this rule.

List of Subjects in 40 CFR Part 1850

Administrative practice and procedure, Freedom of Information, Privacy, Public information, Classified information.

For the reasons set forth in the preamble, the Gulf Coast Ecosystem Restoration Council adds part 1850 to 40 CFR chapter VIII, to read as follows:

PART 1850—AVAILABILITY OF RECORDS

Sec.

Subpart A—Production or Disclosure Under the Freedom of Information Act

1850.1 Purpose and scope.
1850.2 Definitions.
1850.3 General provisions.
1850.4 Public reading room.
1850.5 Requirements for making requests.
1850.6 Responding to requests.
1850.7 Appeals.
1850.8 Authority to determine.
1850.9 Maintenance of files.
1850.10 Fees.
1850.11 Requests for confidential treatment of business information.
1850.12 Requests for access to confidential commercial or financial information.
1850.13 Classified information.

Subpart B—Production or Disclosure Under the Privacy Act

1850.31 Purpose and scope.
1850.32 Definitions.
1850.33 Procedures for requests pertaining to individual records in a record system.
1850.34 Times, places, and requirements for identification of individuals making requests.
1850.35 Disclosure of requested information to individuals.
1850.36 Special procedures: Medical records.
1850.37 Request for correction or amendment to record.
1850.38 Council review of request for correction or amendment to record.
1850.39 Appeal of initial adverse agency determination on correction or amendment.
1850.40 Disclosure of record to person other than the individual to whom it pertains.
1850.41 Fees.
1850.42 Penalties.

Authority: 33 U.S.C. 1321(t); 5 U.S.C. 552; 5 U.S.C. 552a.

Subpart A—Production or Disclosure Under the Freedom of Information Act

§ 1850.1 Purpose and scope.

This subpart contains the regulations of the Gulf Coast Ecosystem Restoration Council (Council) implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended. These regulations supplement the FOIA, which provides more detail regarding requesters' rights and the records the Council may release.

The regulations of this subpart provide information concerning the procedures by which records may be obtained from the Council. Official records of the Council made available pursuant to the requirements of the FOIA shall be furnished to members of the public only as prescribed by this subpart. Information routinely provided to the public as part of a regular Council activity (for example, press releases) may be provided to the public without following this subpart.

The FOIA applies to third-party requests for documents concerning the general activities of the Government, and of the Council in particular. When a U.S. citizen or an individual lawfully admitted for permanent residence requests access to his or her own records, he/she is making a first-person Privacy Act request, not a FOIA request, subject to subpart B of these rules. The Council maintains records about individuals under the individual's name or personal identifier. Although the Council determines whether a request is a FOIA request or a Privacy Act request, the Council processes requests in accordance with both laws. This provides the greatest degree of lawful access to requesters while safeguarding individuals' personal privacy.

§ 1850.2 Definitions.

(a) *Commercial Use Request* means a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made.

(b) *Confidential Commercial Information* means commercial or financial information, obtained by the Council from a submitter, that may contain information exempt from release under Exemption 4 of FOIA, 5 U.S.C. 552(b)(4).

(c) *Council* means to the Gulf Coast Ecosystem Restoration Council.

(d) *Days,* unless stated as ''calendar days,'' are business days and do not include Saturday, Sunday, or federal holidays.

(e) *Direct costs* means those expenses the Council actually incurs in searching for and duplicating (and, in the case of commercial requesters, reviewing) documents in response to a request made under § 1850.5. Direct costs include, for example, the labor costs of the employee performing the work (the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating duplicating machinery. Not included in direct costs are overhead expenses such as costs of space and heating or lighting of the facility in which the documents are stored.

(f) *Duplication* means the making a copy of a document, or other information contained in it, necessary to respond to a FOIA request. Copies may take the form of paper, microfilm, audio-visual materials, or electronic records, among others. The Council shall honor a requester's specified preference of form or format of disclosure if the record is readily

reproducible with reasonable efforts in the requested form or format.

(g) *Educational institution* means a preschool, a public or private elementary or secondary school, or an institution of undergraduate higher education, graduate higher education, professional education, or an institution of vocational education that operates a program of scholarly research.

(h) *Fee category* means one of the three categories that agencies place requesters in for the purpose of determining whether a requester will be charged fees for search, review and duplication. The three fee categories are:

(1) Commercial requesters;

(2) Non-commercial scientific or educational institutions or news media requesters; and

(3) All other requesters.

(i) *Fee waiver* means the waiver or reduction of processing fees if a requester can demonstrate that certain statutory standards are satisfied, including that the information is in the public interest and is not requested for a commercial interest.

(j) *FOIA Public Liaison* means an agency official who is responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes.

(k) *News* means information about current events or that would be of current interest to the public.

(l) *Noncommercial scientific institution* means an institution that is not operated on a ''commercial'' basis (as that term is used in this section) and which is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(m) *Perfected request* means a written FOIA request that meets all of the criteria set forth in § 1850.5.

(n) *Reading room* means a location where records are available for review pursuant to 5 U.S.C. 552(a)(2).

(o) *Records* under the FOIA include all Government records, regardless of format, medium or physical characteristics, and electronic records and information, audiotapes, videotapes, Compact Disks, DVDs, and photographs.

(p) *Records Management Officer* means the person designated by the Executive Director of the Council to oversee all aspects of the Council's records management program, including FOIA.

(q) *Representative of the news media, or news media requester,* means any person or entity organized and operated to publish or broadcast news to the public that actively gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes the work to an audience. Examples of news-media entities are television or radio stations broadcasting to the public at large, and publishers of periodicals that disseminate ''news'' and make their products available through a variety of means to the general public including news organizations that disseminate solely on the Internet. To be in this category, a requester must not be seeking the requested records for a commercial use. A request for records that supports the news-dissemination function of the requester shall not be considered to be for a commercial use. A ''freelance journalist'' shall be regarded as working for a news-media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A publication contract would be the clearest proof, but the Council shall also look to the past publication record of a requester in making this determination. The Council's decision to grant a requester media status will be made on a case-by-case basis based upon the requester's intended use of the material.

(r) *Requester* means any person, partnership, corporation, association, or foreign or State or local government, which has made a request to access a Council record under FOIA.

(s) *Requester category* means one of the three categories in which agencies place requesters to determine whether the agency will charge a requester fees for search, review, and duplication. The categories include commercial requesters, non-commercial scientific or educational institutions or news media requesters, and all other requesters.

(t) *Review* means the examination of a record located in response to a request in order to determine whether any portion of it is exempt from disclosure. Review time includes processing any record for disclosure, such as doing all that is necessary to prepare the record for disclosure, including the process of redacting it and marking any applicable exemptions. Review costs are recoverable even if a record ultimately is not disclosed. Review time includes time spent obtaining and considering any formal objection to disclosure made by a business submitter under § 1850.12 but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(u) *Search* means the process of looking for and retrieving documents or information that is responsive to a request. Search time includes page-by-page or line-by-line identification of information within documents and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format.

(v) *Submitter* means any person or entity from whom the Council obtains confidential commercial information, directly or indirectly.

(w) *Unusual circumstances* include situations in which the Council must:

(1) Search for and collect the requested agency records from field facilities or other establishments that are separate from the office processing the request;

(2) Search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are the subject of a single request; or

(3) Consult with another Federal agency having a substantial interest in the determination of the FOIA request.

§ 1850.3 General provisions.

The Council shall prepare an annual report to the Attorney General of the United States regarding its FOIA activities in accordance with 5 U.S.C. 552(e).

§ 1850.4 Public reading room.

The Council maintains an electronic public reading room on its Web site, *http://www.restorethegulf.gov,* which contains the records FOIA requires the Council to make available for public inspection and copying, as well as additional records of interest to the public.

§ 1850.5 Requirements for making requests.

(a) *Type of records made available.* The Council shall make available upon request, pursuant to the procedures in this section and subject to the exceptions set forth in FOIA, all records of the Council that are not available under § 1850.4. The Council's policy is to make discretionary disclosures of records or information otherwise exempt from disclosure under FOIA unless the Council reasonably foresees that such disclosure would harm an interest protected by one or more FOIA exemptions, or otherwise prohibited by law. This policy does not create any enforceable right in court.

(b) *Procedures for requesting records.* A request for records shall reasonably describe the records in a way that enables Council staff to identify and produce the records with reasonable effort. The requester should include as much specific information as possible regarding dates, titles, and names of

individuals. In cases where the request requires production of voluminous records, or is not reasonably described, a Council representative may suggest the requester, or the individual acting on the requester's behalf, to verify the scope of the request and, if possible, narrow the request. Once narrowed, the Council will process the request. All requests must be submitted in writing (including by email, fax or mail) to the Council's Records Management Officer. Requesters shall clearly mark a request as a ''Freedom of Information Act Request'' or ''FOIA Request'' on the front of the envelope or in the subject line of the email.

(c) *Contents of request.* The request, at minimum, shall contain the following information:

(1) The name, telephone number, and non-electronic address of the requester;

(2) Whether the requested information is intended for commercial use, or whether the requester represents an education or noncommercial scientific institution, or news media; and

(3) A statement agreeing to pay the applicable fees, identifying any fee limitation desired, or requesting a waiver or reduction of fees that satisfies § 1850.10(j)(1) to (3).

(d) *Perfected requests.* The requester must meet all the requirements in this section to perfect a request. The Council will only process perfected requests.

(e) *Requests by an individual for Council records pertaining to that individual.* An individual who wishes to inspect or obtain copies of Council records that pertain to that individual must file a request in accordance with subpart B of this part.

(f) *Requests for Council records pertaining to another individual.* Where a request for records pertains to a third party, a requester may receive greater access by submitting a notarized authorization signed by that individual or a declaration by that individual made in compliance with the requirements set forth in 28 U.S.C. 1746, authorizing disclosure of the records to the requester, or by submitting proof the individual is deceased (*e.g.* a copy of the death certificate or an obituary). The Council may require a requester to supply additional information if necessary to verify that a particular individual has consented to disclosure.

(g) Requesters may submit a request for records, expedited processing or waiver of fees by writing directly to the Records Management Officer via email at *FOIArequest@restorethegulf.gov,* or first class United States mail at 500 Poydras Street, Suite 1117, New Orleans, LA 70130.

(h) Any Council officer or employee who receives a written Freedom of Information Act request shall promptly forward it to the Records Management Officer. Any Council officer or employee who receives an oral request under the Freedom of Information Act shall inform the person making the request that it must be in writing and also inform such person of the provisions of this subpart.

§ 1850.6 Responding to requests.

(a) *Receipt and processing.* The date of receipt for any request, including one that is addressed incorrectly or that is referred to the Council by another agency, is the date the Council actually receives the request. The Council normally will process requests in the order they are received. However, in the Records Management Officer's discretion, the Council may use two or more processing tracks by distinguishing between simple and more complex requests based on the number of pages involved, or some other measure of the amount of work and/or time needed to process the request, and whether the request qualifies for expedited processing as defined by paragraph (d) of this section. When using multi-track processing, the Records Management Officer may provide requesters in the complex track(s) with an opportunity to limit the scope of their requests to qualify for the simple track and faster processing.

(b) *Authorization.* The Records Management Officer and other persons designated by the Council's Executive Director are solely authorized to grant or deny any request for Council records.

(c) *Timing.* (1) When a requester submits a request in accordance with § 1850.5, the Records Management Officer shall inform the requester of the determination concerning that request within 20 days from receipt of the request, unless ''unusual circumstances'' exist, as defined in § 1850.2(w). The Records Management Officer also shall provide requesters with a unique tracking number, an estimated date of completion (once the request is perfected), and a fee estimate (when applicable). The Records Management Officer shall also include in the Council's acknowledgment letter a brief description of the subject of the request.

(2) When additional time is required as a result of ''unusual circumstances,'' as defined in § 1850.2(w), the Records Management Officer shall, within the statutory 20 day period, issue to the requester a brief written statement of the reason for the delay and an indication of the date on which it is expected that a determination as to disclosure will be forthcoming. If more than 10 additional days are needed, the requester shall be notified and provided an opportunity to limit the scope of the request or to arrange for an alternate time frame for processing the request.

(3) The Council may toll the statutory time period to issue its determination on a FOIA request one time during the processing of the request to obtain clarification from the requester. The statutory time period to issue the determination on disclosure is tolled until the Council receives the information reasonably requested from the requester. The Council may also toll the statutory time period to issue the determination to clarify with the requester issues regarding fees. There is no limit on the number of times the agency may request clarifying fee information from the requester.

(d) *Expedited processing.* (1) A requester may request expedited processing by submitting a statement, certified to be true and correct to the best of that person's knowledge and belief, that demonstrates a compelling need for records, as defined in 5 U.S.C. 552(a)(6)(E)(v).

(2) The Records Management Officer will notify a requester of the determination to grant or deny a request for expedited processing within ten days of receipt of the request. If the Records Management Officer grants the request for expedited processing, the Council staff shall process the request as soon as practicable subject to § 1850.10(d) and (e). If the Records Management Officer denies the request for expedited processing, the requester may file an appeal in accordance with the process described in § 1850.7.

(3) The Council staff will give expedited treatment to a request when the Records Management Officer determines the requester has established one of the following:

(i) Circumstances in which the lack of expedited treatment reasonably could be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged Federal Government activity, if made by an individual primarily engaged in disseminating information;

(iii) The loss of substantial due process rights;

(iv) A matter of widespread and exceptional media interest raising possible questions about the Federal government's integrity which affects public confidence; or

(4) These procedures for expedited processing also apply to requests for

expedited processing of administrative appeals.

(e) *Denials.* If the Records Management Officer denies the request in whole or part, the Records Management Officer will inform the requester in writing and include the following:

(1) A brief statement of the reason(s) for the denial, including applicable FOIA exemption(s) and a description of those exemptions;

(2) An estimate of the volume of records or information withheld;

(3) If technically feasible, the precise amount of information deleted at the place in the record where the deletion was made, and the exemption under which a deletion is made on the released portion of the record, unless including that information would harm an interest protected by the exemption;

(4) The name and title or position of the person responsible for the denial of the request;

(5) The requester's right to appeal any such denial and the title and address of the official to whom such appeal is to be addressed; and

(6) The requirement that the appeal be received within 45 days of the date of the denial.

(f) *Referrals to another agency.* (1) When the Council receives a request for a record (or a portion thereof) in its possession that originated with another Federal agency subject to the FOIA, the Council shall, except as provided in paragraph (f)(4) of this section, refer the record to that agency for direct response to the requester. However, if the Council and the originating agency jointly agree that the Council is in the best position to respond regarding the record, then the record may be handled as a consultation.

(2) Whenever the Council refers any part of the responsibility for responding to a request to another agency, it shall document the referral, maintain a copy of the record that it refers, and notify the requester of the referral and inform the requester of the name of the agency to which the record was referred, including that agency's FOIA contact information.

(3) The Council's response to an appeal will advise the requester that the 2007 FOIA amendments created the Office of Government Information Services (OGIS) to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. A requester may contact OGIS in any of the following ways: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road—OGIS, College Park, MD 20740, *ogis.archives.gov,* Email: *ogis@nara.gov,* Telephone: 202–741–5770, Facsimile: 202–741–5769, Toll-free: 1–877–684–6448.

(4) The referral procedure is not appropriate where disclosure of the identity of the agency, typically a law enforcement agency or Intelligence Community agency, to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy and national security interests. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the Council shall coordinate with the originating agency to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination shall then be conveyed to the requester by the Council.

(g) *Consulting with another agency.* In instances where a record is requested that originated with the Council and another agency has a significant interest in the record (or a portion thereof), the Council shall consult with that agency before responding to a requester. When the Council receives a request for a record (or a portion thereof) in its possession that originated with another agency that is not subject to the FOIA, the Council shall consult with that agency before responding to the requester.

(h) *Providing responsive records.* (1) Council staff shall send a copy of records or portions of records responsive to the request to the requester by regular United States mail to the address indicated in the request or by email to the email address provided by the requester, unless the requester makes other acceptable arrangements or the Council deems it appropriate to send the records by other means. The Council shall provide a copy of the record in any form or format requested if the record is readily reproducible in that form or format. The Council need not provide more than one copy of any record to a requester.

(2) The Records Management Officer shall provide any reasonably segregable portion of a record that is responsive to the request after redacting those portions that are exempt under FOIA or this section.

(3) The Council is not required to create, compile, prepare or obtain from outside the Council a record to satisfy a request. Retrieving data from a Council database or running a report from a database is permissible.

(i) *Prohibition against disclosure.* Except as provided in this subpart, no member or employee of the Council shall disclose or permit the disclosure of any non-public information of the Council to any person (other than Council members, employees, or agents properly entitled to such information for the performance of their official duties), unless required by law to do so.

§ 1850.7 Appeals.

(a) Requesters may administratively appeal an adverse determination regarding a request by writing directly to the General Counsel via email at *GeneralCounsel@restorethegulf.gov* or first class United States mail at 500 Poydras Street, Suite 1117, New Orleans, LA 70130. Administrative appeals sent to other individuals or addresses are not considered perfected. An adverse determination is a denial of a request and includes decisions that: The requested record is exempt, in whole or in part; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has previously been destroyed; or the requested record is not readily reproducible in the form or format sought by the requester. Adverse determinations also include denials involving fees or fee waiver matters or denials of requests for expedited processing.

(b) FOIA administrative appeals must be in writing and should contain the phrase ''FOIA Appeal'' on the front of the envelope or in the subject line of the electronic mail.

(c) Appellants are encouraged to include a copy of the original request and the initial denial (if any) in the appeal. The appeal letter may include as much or as little related information as the appellant wishes, as long as it clearly identifies the component determination (including the assigned request number, if known) that is being appealed.

(d) Requesters submitting an administrative appeal of an adverse determination must ensure that the Council receives the appeal within 45 days of the date of the denial letter.

(e) Upon receipt of an administrative appeal, Council staff shall inform the requester within 20 days of the determination on that appeal.

(f) The determination on an appeal shall be in writing and, when it denies the appeal, in whole or in part, the letter to the requester shall include:

(1) A brief explanation of the basis for the denial, including a list of the applicable FOIA exemptions and a description of how they apply;

(2) A statement that the decision is final for the Council;

(3) Notification that judicial review of the denial is available in the district court of the United States in the district in which the requester resides, or has his or her principal place of business, or in which the agency records are located, or in the District of Columbia; and

(4) The name and title or position of the official responsible for denying the appeal.

§ 1850.8 Authority to determine.

The Records Management Officer or Council Executive Director, when receiving a request pursuant to these regulations, shall grant or deny such request. That decision shall be final, subject only to administrative appeal as provided in § 1850.7. The Council General Counsel shall deny or grant an administrative appeal requested under § 1850.7.

§ 1850.9 Maintenance of files.

The Records Management Officer shall maintain files containing all material required to be retained by or furnished to them under this subpart. The Council shall preserve all correspondence pertaining to the FOIA requests that it receives, as well as copies of all requested records, until a General Records Schedule (GRS) published by the National Archives and Records Administration (NARA) or another NARA-approved records schedule authorizes the office to dispose of or destroy the records. All materials identified as responsive to a FOIA request will be retained while the request or a related appeal or lawsuit is pending even otherwise authorized for disposal or destruction under a GRS or other NARA-approved records schedule. The material shall be filed by a unique tracking number.

§ 1850.10 Fees.

(a) *Generally.* Except as provided elsewhere in this section, the Records Management Officer shall assess fees where applicable in accordance with this section for search, review, and duplication of records requested. The Records Management Officer shall also have authority to furnish documents without any charge or at a reduced charge if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(b)(1) *Fee schedule; waiver of fees.* The fees applicable to a request for Council records pursuant to § 1850.5 are set forth in the following uniform fee schedule:

Service	Rate
(i) Manual search	Actual salary rate of employee involved, plus 16 percent of salary rate to cover benefits.
(ii) Computerized search	Actual direct cost, including operator time.
(iii) Duplication of records:	
(A) Paper copy reproduction	$0.05 per page.
(B) Other reproduction (*e.g.,* computer disk or printout, microfilm, microfiche, or microform).	Actual direct cost, including operator time.
(iv) Review of records (including redaction)	Actual salary rate of employee involved, plus 16 percent of salary rate to cover benefits.

(2) *Search.* (i) The Council shall charge search fees for all requests, subject to the limitations of paragraph (b)(5) of this section. The Records Management Officer shall charge for time spent searching for responsive records, even if no responsive record is located or if the Records Management Officer withholds records located as entirely exempt from disclosure. Search fees shall equal the direct costs of conducting the search by the Council employee involved, plus 16 percent of the salary rate to cover benefits.

(ii) For computer searches of records, the Council will charge requesters the direct costs of conducting the search. In accordance with paragraph (f) of this section, however, the Council will charge certain requesters no search fee and certain other requesters are entitled to the cost equivalent of two hours of manual search time without charge. These direct costs include the costs attributable to the salary of an operator/programmer performing a computer search.

(3) *Duplication.* The Council will charge duplication fees to all requesters, subject to the limitations of paragraph (b)(5) of this section. The fee for a paper photocopy of a record (no more than one copy of which need be supplied) is 5 cents per page. The Records Management Officer will charge the requester for the direct costs, including operator time, of making copies produced by computer, such as tapes or printouts. The Records Management Officer will charge a requester the direct costs of providing other forms of duplication.

(4) *Review.* The Council will charge review fees to requesters who make a commercial use request. Review fees generally are limited to the initial record review, *i.e.,* the review done when the Records Management Officer determines whether an exemption applies to a particular record at the initial request level. The Council will not charge a requester for additional review at the administrative appeal level. Review fees consist of the direct costs of conducting the review by the Council employee involved, plus 16 percent of the salary rate to cover benefits.

(5) *Limitations on charging fees.* (i) The Council will not charge a search fee for requests from educational institutions, noncommercial scientific institutions, or representatives of the news media.

(ii) The Council will not charge a search fee or review fee for a quarter-hour period unless more than half of that period is required for search or review.

(iii) The Council will not charge a fee to a requester whenever the total fee calculated under this paragraph is $25 or less for the request.

(iv) Except for requesters seeking records for a commercial use, the Council will provide without charge the first 100 pages of duplication (or the cost equivalent) and the first two hours of search.

(v) The provisions of paragraphs (b)(5)(iii) and (iv) of this section work together. This means that for requesters other than those seeking records for a commercial use, no fee shall be charged unless the cost of search is in excess of two hours plus the cost of duplication in excess of 100 pages totals more than $25.

(vi) No search fees shall be charged to a requester when the Council does not comply with the statutory time limits at 5 U.S.C. 552(a)(6) in which to respond to a request, unless unusual or exceptional circumstances (as those terms are defined by the FOIA) apply to the processing of the request.

(vii) No duplication fees shall be charged to requesters in the fee category of a representative of the news media or an educational or noncommercial scientific institution when the Council does not comply with the statutory time limits at 5 U.S.C. 552(a)(6) in which to respond to a request, unless unusual or exceptional circumstances (as those terms are defined by the FOIA) apply to the processing of the request.

(c) *Payment procedures.* All requesters shall pay the applicable fee before the Council sends copies of the requested records, unless the Records Management Official grants a fee waiver. Requesters must pay fees by check or money order made payable to the ''Treasury of the United States.'' Checks and money orders should be mailed to 500 Poydras Street, Suite 1117, New Orleans, LA 70130.

(d) *Advance notification of fees.* If the estimated charges exceed $25, the Records Management Officer shall notify the requester of the estimated amount, unless the requester has indicated a willingness to pay fees as high as those anticipated. Upon receipt of such notice, the requester may confer with the Records Management Officer to reformulate the request to lower the costs. Council staff shall suspend processing the request until the requester provides the Records Management Officer with a written guarantee that the requester will make payment upon completion of processing (*i.e.,* upon completion of the search, review and duplication, but prior the Council sending copies of the requested records to the requester).

(e) *Advance payment.* The Records Management Officer shall require advance payment of any fee estimated to exceed $250. The Records Management Officer also shall require full payment in advance where a requester has previously failed to pay a fee in a timely fashion. If an advance payment of an estimated fee exceeds the actual total fee by $1 or more, the Council shall refund the difference to the requester. The Council shall suspend the processing of the request and the statutory time period for responding to the request until the Records Management Officer receives the required payment.

(f) *Categories of uses.* The fees assessed depend upon the fee category. In determining which category is appropriate, the Records Management Officer shall look to the identity of the requester and the intended use set forth in the request for records. Where a requester's description of the use is insufficient to make a determination, the Records Management Officer may seek additional clarification before categorizing the request.

(1) *Commercial use requester:* The fees for search, duplication, and review apply.

(2) *Educational institutions, non-commercial scientific institutions, or representatives of the news media requesters:* The fees for duplication apply. The Council will provide the first 100 pages of duplication free of charge.

(3) *All other requesters:* The fees for search and duplication apply. The Council will provide the first two hours of search time and the first 100 pages of duplication free of charge.

Category	Chargeable fees
(i) Commercial Use Requesters	Search, Review, and Duplication.
(ii) Education and Non-commercial Scientific Institution Requesters	Duplication (excluding the cost of the first 100 pages).
(iii) Representatives of the News Media	Duplication (excluding the cost of the first 100 pages).
(iv) All Other Requesters	Search and Duplication (excluding the cost of the first 2 hours of search and first 100 pages of duplication).

(g) *Nonproductive search.* The Council may charge fees for search even if no responsive documents are found.

(h) *Interest charges.* The Records Management Officer may assess interest charges on any unpaid bill starting on the 31st calendar day following the date the Council sent the bill to the requester. The Council will charge interest at the rate prescribed in 31 U.S.C. 3717 on fees payable in accordance with this section. The Council will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(i) *Aggregated requests.* A requester may not file multiple requests at the same time solely in order to avoid payment of fees. If the Council reasonably believes that a request, or a group of requesters acting in concert, is attempting to break down a request into a series of requests for the purpose of evading the assessment of fees, the Council may aggregate any such requests and charge accordingly. The Records Management Officer may reasonably presume that one requester making multiple requests on the same topic within a 30-day period has done so to avoid fees.

(j) *Waiver or reduction of fees.* To seek a waiver, a requester shall include the request for waiver or reduction of fees, and the justification for such based on the factors set forth in this paragraph, with the request for records to which it pertains. If a requester requests a waiver or reduction and has not indicated in writing an agreement to pay the applicable fees, the time for responding to the request for Council records shall not begin until the Records Management Officer makes a determination regarding the request for a waiver or reduction of fees.

(1) Records responsive to a request shall be furnished without charge, or at a reduced rate below that established in paragraph (b) of this section, where the Council determines, after consideration of all available information, that the requester has demonstrated that:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) In deciding whether disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government, the Council will consider the following factors:

(i) The subject of the request: Whether the subject of the requested records concerns the operations or activities of the Government. The subject of the requested records must concern identifiable operations or activities of the Federal government, with a connection that is direct and clear, not remote or attenuated.

(ii) The informative value of the information to be disclosed: Whether the disclosure is ''likely to contribute'' to an understanding of Government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be ''likely to contribute'' to an increased public understanding of those operations or activities. The disclosure

of information that already is in the public domain, in either the same or a substantially identical form, would not be likely to contribute to such an understanding.

(iii) The contribution to an understanding of the subject by the public: Whether disclosure of the requested information will contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as his or her ability and intention to effectively convey information to the public shall be considered. It shall be presumed that a representative of the news media will satisfy this consideration. Merely providing information to media sources is insufficient to satisfy this consideration.

(iv) The significance of the contribution to public understanding: Whether the disclosure is likely to contribute ''significantly'' to public understanding of Government operations or activities. The public's understanding of the subject in question prior to disclosure must be significantly enhanced by the disclosure.

(3) To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, the Council will consider the following factors:

(i) The existence and magnitude of a commercial interest: Whether the requester has a commercial interest that would be furthered by the requested disclosure. The Council shall consider any commercial interest of the requester (with reference to the definition of ''commercial use request'' in § 1850.2(b)), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters shall be given an opportunity to provide explanatory information regarding this consideration.

(ii) The primary interest in disclosure: Whether any identified commercial interest of the requester is sufficiently great, in comparison with the public interest in disclosure, that disclosure if ''primarily in the commercial interest of the requester.'' A fee waiver or reduction is justified if the public interest standard (paragraph (j)(1)(i) of this section) is satisfied and the public interest is greater than any identified commercial interest in disclosure. The Council shall presume that if a news media requester has satisfied the public interest standard, the public interest is the primary interest served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market Government information for direct economic return shall not be presumed to primarily serve the public interest.

(4) A request for a waiver or reduction of fees shall include a clear statement of how the request satisfies the criteria set forth in paragraphs (j)(2) and (3) of this section, insofar as they apply to each request. The burden shall be on the requester to present evidence or information in support of a request for a waiver or reduction of fees.

(5) Where only some of the records to be released satisfy the requirements for a fee waiver, a waiver shall be granted for those records.

(6) The Records Management Officer shall make a determination on the request for a waiver or reduction of fees and shall notify the requester accordingly. A denial may be appealed to the General Counsel in accordance with § 1850.7.

§ 1850.11 Requests for confidential treatment of business information.

(a) *Submission of request.* Any submitter of information to the Council who desires confidential treatment of business information pursuant to 5 U.S.C. 552(b)(4) shall file a request for confidential treatment with the Council at the time the information is submitted or within a reasonable time after submission. These designations will expire ten years after the date of submission unless the submitter requests, and provides justification for, a longer period.

(b) *Form of request.* Each request for confidential treatment of business information shall state in reasonable detail the facts supporting the commercial or financial nature of the business information and the legal justification under which the business information should be protected. Conclusory statements indicating that release of the information would cause competitive harm generally are not sufficient to justify confidential treatment.

(c) *Designation and separation of confidential material.* A submitter shall clearly mark all information it considers confidential as ''PROPRIETARY'' or ''BUSINESS CONFIDENTIAL'' in the submission and shall separate information so marked from other information submitted. Failure by the submitter to segregate confidential commercial or financial information from other material may result in release of the nonsegregated material to the public without notice to the submitter.

§ 1850.12 Requests for access to confidential commercial or financial information.

(a) *Notice to submitters.* The Council shall provide a submitter with prompt notice of a FOIA request or administrative appeal that seeks its business information whenever required under paragraph (b) of this section, except as provided in paragraph (e) of this section, in order to give the submitter an opportunity under paragraph (c) of this section to object to disclosure of any specified portion of that information. The notice shall either describe the business information requested or include copies of the requested records containing the information. If notification of a large number of submitters is required, notification may be made by posting or publishing the notice in a place reasonably likely to accomplish notification.

(b) *When notice is required.* Notice shall be given to the submitter whenever:

(1) The submitter has designated the information in good faith as protected from disclosure under FOIA exemption (b)(4); or

(2) The Council has reason to believe that the information may be protected from disclosure under FOIA exemption (b)(4).

(c) *Opportunity to object to disclosure.* The Council shall allow a submitter seven days from the date of receipt of the written notice described in paragraph (a) of this section to provide the Council with a statement of any objection to disclosure. The statement must identify any portions of the information the submitter requests to be withheld under FOIA exemption (b)(4), and describe how each qualifies for protection under the exemption: That is, why the information is a trade secret, or commercial or financial information that is privileged or confidential. If a submitter fails to respond to the notice within the time frame specified, the submitter will be considered to have no objection to disclosure of the information. Information a submitter provides under this paragraph may itself be subject to disclosure under the FOIA.

(d) *Notice of intent to disclose.* The Council shall consider a submitter's objections and specific grounds under the FOIA for nondisclosure in deciding whether to disclose business information. If the Council decides to disclose business information over a submitter's objection, the Council shall give the submitter written notice via certified mail, return receipt requested, or similar means, which shall include:

(1) A statement of reason(s) why the submitter's objections to disclosure were not sustained;

(2) A description of the business information to be disclosed; and

(3) A statement that the Council intends to disclose the information seven days from the date the submitter receives the notice.

(e) *Exceptions to notice requirements.* The notice requirements of paragraphs (a) and (d) of this section shall not apply if:

(1) The Council determines that the information is exempt and will be withheld under a FOIA exemption, other than exemption (b)(4);

(2) The information has been lawfully published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with Executive Order 12600; or

(4) The designation made by the submitter under this section or § 1850.11 appears obviously frivolous, except that, in such a case, the Council shall provide the submitter written notice of any final decision to disclose the information seven days from the date the submitter receives the notice.

(f) *Notice to requester.* The Council shall notify a requester whenever it provides the submitter with notice and an opportunity to object to disclosure; whenever it notifies the submitter of its intent to disclose the requested information; and whenever a submitter files a lawsuit to prevent the disclosure of the information.

(g) *Notice of lawsuits.* Whenever a requester files a lawsuit seeking to compel the disclosure of confidential commercial information, the Council shall promptly notify the submitter.

§ 1850.13 Classified information.

In processing a request for information classified under Executive Order 13526 or any other Executive Order concerning the classification of records, the information shall be reviewed to determine whether it should remain classified. Ordinarily the Council or other Federal agency that classified the information should conduct the review, except that if a record contains information that has been derivatively classified by the Council because it contains information classified by another agency, the Council shall refer the responsibility for responding to the request to the agency that classified the underlying information. Information determined to no longer require classification shall not be withheld on the basis of FOIA exemption (b)(1) (5 U.S.C. 552(b)(1)), but should be reviewed to assess whether any other FOIA exemption should be invoked. Appeals involving classified information shall be processed in accordance with § 1850.7.

Subpart B—Production or Disclosure Under the Privacy Act

§ 1850.31 Purpose and scope.

This subpart contains the regulations of the Gulf Coast Ecosystem Restoration Council (Council) implementing the Privacy Act of 1974, 5 U.S.C. 552a. It sets forth the basic responsibilities of the Council under the Privacy Act (the Act) and offers guidance to members of the public who wish to exercise any of the rights established by the Act with regard to records maintained by the Council. Council records that are contained in a government-wide system of records established by the U.S. Office of Personnel Management (OPM), the General Services Administration (GSA), the Merit Systems Protection Board (MSPB), the Office of Government Ethics (OGE), Equal Employment Opportunity Commission (EEOC) or the Department of Labor (DOL) for which those agencies have published systems notices are subject to the publishing agency's Privacy Act regulations. Where the government-wide systems notices permit access to these records through the employing agency, an individual should submit requests for access to, for amendment of or for an accounting of disclosures to the Council in accordance with § 1850.33.

§ 1850.32 Definitions.

(a) For purposes of this subpart, the terms *individual, maintain, record,* and *system of records* shall have the meanings set forth in 5 U.S.C. 552a(a).

(b) *Working days* are business days and do not include Saturday, Sunday, or federal holidays.

§ 1850.33 Procedures for requests pertaining to individual records in a record system.

(a) Any person who wishes to be notified if a system of records maintained by the Council contains any record pertaining to him or her, or to request access to such record or to request an accounting of disclosures made of such record, shall submit a written request, either in person or by mail, in accordance with the instructions set forth in the system notice published in the **Federal Register**. The request shall include:

(1) The name of the individual making the request;

(2) The name of the system of records (as set forth in the system notice to which the request relates);

(3) Any other information specified in the system notice;

(4) When the request is for access to records, a statement indicating whether the requester desires to make a personal inspection of the records or be supplied with copies by mail; and

(5) Any additional information required by § 1850.34 for proper verification of identity or authority to access the information.

(b) Requests pertaining to records contained in a system of records established by the Council and for which the Council has published a system notice should be submitted to the person or office indicated in the system notice. Requests pertaining to Council records contained in the government-wide systems of records listed below should be submitted as follows:

(1) For systems OPM/GOVT–1 (General Personnel Records), OPM/GOVT–2 (Employee Performance File System Records), OPM/GOVT–3 (Records of Adverse Actions and Actions Based on Unacceptable Performance), GSA/GOVT–4 (Contracted Travel Services Program), OPM/GOVT–5 (Recruiting, Examining and Placement Records), OPM/GOVT–6 (Personnel Research and Test Validation Records), OPM/GOVT–7 (Applicant Race, Sex, National Origin, and Disability Status Records), OPM/GOVT–9 (Files on Position Classification Appeals, Job Grading Appeals and Retained Grade or Pay Appeals), OPM/GOVT–10 (Employee Medical File System Records) and DOL/ESA–13 (Office of Workers' Compensation Programs, Federal Employees' Compensation File), or any other government-wide system of record not specifically listed, to the *restorecouncil@restorethegulf.gov*]; and

(2) For systems OGE/GOVT–1 (Executive Branch Public Financial Disclosure Reports and Other Ethics Program Records), OGE/GOVT–2 (Confidential Statements of Employment and Financial Interests) and MSPB/GOVT–1 (Appeal and Case Records), to the General Counsel at *restorecouncil@restorethegulf.gov.*

(c) Any person whose request for access under paragraph (a) of this section is denied, may appeal that denial in accordance with § 1850.39.

§ 1850.34 Times, places, and requirements for identification of individuals making requests.

(a) If a person submitting a request for access under § 1850.33 has asked that

the Council authorize a personal inspection of records pertaining to that person, and the appropriate Council official has granted that request, the requester shall present himself or herself at the time and place specified in the Council's response or arrange another, mutually convenient time with the appropriate Council official.

(b) Prior to personal inspection of the records, the requester shall present sufficient personal identification (*e.g.,* driver's license, employee identification card, social security card, credit cards). If the requester is unable to provide such identification, the requester shall complete and sign in the presence of a Council official a signed statement asserting his or her identity and stipulating that he or she understands that knowingly or willfully seeking or obtaining access to records about another individual under false pretenses is a misdemeanor punishable by fine up to $5,000.

(c) Any person who has requested access under § 1850.3 to records through personal inspection, and who wishes to be accompanied by another person or persons during this inspection, shall submit a written statement authorizing disclosure of the record in such person's or persons' presence.

(d) If an individual submitting a request by mail under § 1850.33 wishes to have copies furnished by mail, he or she must include with the request a signed and notarized statement asserting his or her identity and stipulating that he or she understands that knowingly or willfully seeking or obtaining access to records about another individual under false pretenses is a misdemeanor punishable by fine up to $5,000.

(e) A request filed by the parent of any minor or the legal guardian of any incompetent person shall: State the relationship of the requester to the individual to whom the record pertains; present sufficient identification; and, if not evident from information already available to the Council, present appropriate proof of the relationship or guardianship.

(f) A person making a request pursuant to a power of attorney must possess a specific power of attorney to make that request.

(g) No verification of identity will be required where the records sought are publicly available under the Freedom of Information Act.

§ 1850.35 Disclosure of requested information to individuals.

(a) Upon receipt of request for notification as to whether the Council maintains a record about an individual and/or request for access to such record:

(1) The appropriate Council official shall acknowledge such request in writing within 10 working days of receipt of the request. Wherever practicable, the acknowledgement should contain the notification and/or determination required in paragraph (a)(2) of this section.

(2) The appropriate Council official shall provide, within 30 working days of receipt of the request, written notification to the requester as to the existence of the records and/or a determination as to whether or not access will be granted. In some cases, such as where records have to be recalled from the Federal Records Center, notification and/or a determination of access may be delayed. In the event of such a delay, the Council official shall inform the requester of this fact, the reasons for the delay, and an estimate of the date on which notification and/or a determination will be forthcoming.

(3) If access to a record is granted, the determination shall indicate when and where the record will be available for personal inspection. If a copy of the record has been requested, the Council official shall mail that copy or retain it at the Council to present to the individual, upon receipt of a check or money order in an amount computed pursuant to § 1850.41.

(4) When access to a record is to be granted, the appropriate Council official will normally provide access within 30 working days of receipt of the request unless, for good cause shown, he or she is unable to do so, in which case the requester shall be informed within 30 working days of receipt of the request as to those reasons and when it is anticipated that access will be granted.

(5) The Council shall not deny any request under § 1850.33 concerning the existence of records about the requester in any system of records it maintains, or any request for access to such records, unless that system is exempted from the requirements of 5 U.S.C. 552a.

(6) If the Council receives a request pursuant to § 1850.33 for access to records in a system of records it maintains which is so exempt, the appropriate Council official shall deny the request.

(b) Upon request, the appropriate Council official shall make available an accounting of disclosures pursuant to 5 U.S.C. 552a(c)(3), unless that system is exempted from the requirements of 5 U.S.C. 552a.

(c) If a request for access to records is denied pursuant to paragraph (a) or (b) of this section, the determination shall specify the reasons for the denial and advise the individual how to appeal the denial in accordance with § 1850.39. All appeals must be submitted in writing to the General Counsel at *GeneralCounsel@restorethegulf.gov.*

(d) Nothing in 5 U.S.C. 552a or this subpart allows an individual access to any information compiled in reasonable anticipation of a civil action or proceeding.

§ 1850.36 Special procedures: Medical records.

In the event the Council receives a request pursuant to § 1850.33 for access to medical records (including psychological records) and the appropriate Council official determines disclosure could be harmful to the individual to whom they relate, he or she may refuse to disclose the records directly to the requester but shall transmit them to a physician designated by that individual.

§ 1850.37 Request for correction or amendment to record.

(a) Any person who wishes to request correction or amendment of any record pertaining to him or her that is contained in a system of records maintained by the Council, shall submit that request in writing in accordance with the instructions set forth in the system notice for that system of records. If the request is submitted by mail, the envelope should be clearly labeled ''Personal Information Amendment.'' The request shall include:

(1) The name of the individual making the request;

(2) The name of the system of records as set forth in the system notice to which the request relates;

(3) A description of the nature (*e.g.,* modification, addition or deletion) and substance of the correction or amendment requested; and

(4) Any other information specified in the system notice.

(b) Any person submitting a request pursuant to paragraph (a) of this section shall include sufficient information in support of that request to allow the Council to apply the standards set forth in 5 U.S.C. 552a(e) requiring the Council to maintain accurate, relevant, timely, and complete information.

(c) All requests to amend pertaining to personnel records described in § 1850.33(b) shall conform to the requirements of paragraphs (a) and (b) of this section and may be directed to the appropriate officials as indicated in § 1850.33(b). Such requests may also be directed to the system manager specified in the OPM's systems notices.

(d) Any person whose request under paragraph (a) of this section is denied may appeal that denial in accordance with § 1850.39.

§ 1850.38 Council review of request for correction or amendment to record.

(a) When the Council receives a request for amendment or correction under § 1850.37(a), the appropriate Council official shall acknowledge that request in writing within 10 working days of receipt. He or she shall promptly either:

(1) Determine to grant all or any portion of a request for correction or amendment; and:

(i) Advise the individual of that determination;

(ii) Make the requested correction or amendment; and

(iii) Inform any person or agency outside the Council to whom the record has been disclosed, and where an accounting of that disclosure is maintained in accordance with 5 U.S.C. 552a(c), of the occurrence and substance of the correction or amendments; or

(2) Inform the requester of the refusal to amend the record in accordance with the request; the reason for the refusal; and the procedures whereby the requester can appeal the refusal to the General Counsel of the Council in accordance with § 1850.39.

(b) If the Council official informs the requester of the determination within the 10-day deadline, a separate acknowledgement is not required.

(c) In conducting the review of a request for correction or amendment, the Council official shall be guided by the requirements of 5 U.S.C. 552a(e).

(d) In the event that the Council receives a notice of correction or amendment from another agency that pertains to records maintained by the Council, the Council shall make the appropriate correction or amendment to its records and comply with paragraph (a)(1)(iii) of this section.

(e) Requests for amendment or correction of records maintained in the government-wide systems of records listed in § 1850.35(c) shall be governed by the appropriate agency's regulations cited in that paragraph.

§ 1850.39 Appeal of initial adverse agency determination on correction or amendment.

(a) If a request for correction or amendment of a record in a system of records maintained by the Council is denied, the requester may appeal the determination in writing to the General Counsel at *GeneralCounsel@restorethegulf.gov.*

(b) The General Counsel shall make a final determination with regard to an appeal submitted under paragraph (a) of this section not later than 30 working days from the date on which the individual requests a review, unless for good cause shown, this 30-day period is extended and the requester is notified of the reasons for the extension and of the estimated date on which a final determination will be made. Such extensions will be used only in exceptional circumstances and will not normally exceed 30 working days.

(c) In conducting the review of an appeal submitted under paragraph (a) of this section, the General Counsel shall be guided by the requirements of 5 U.S.C. 552a(e).

(d) If the General Counsel determines to grant all or any portion of a request on an appeal submitted under paragraph (a) of this section, he or she shall so inform the requester, and the appropriate Council official shall comply with the procedures set forth in § 1850.38(a)(1)(ii) and (iii).

(e) If the General Counsel determines in accordance with paragraphs (b) and (c) of this section not to grant all or any portion of a request on an appeal submitted under paragraph (a) of this section, he or she shall inform the requester:

(1) Of this determination and the reasons for it;

(2) Of the requester's right to file a concise statement of reasons for disagreement with the determination of the General Counsel;

(3) That such statements of disagreement will be made available to anyone to whom the record is subsequently disclosed, together with (if the General Counsel deems it appropriate) a brief statement summarizing the General Counsel's reasons for refusing to amend the record;

(4) That prior recipients of the disputed record will be provided with a copy of the statement of disagreement together with (if the General Counsel deems it appropriate) a brief statement of the General Counsel's reasons for refusing to amend the record, to the extent that an accounting of disclosure is maintained under 5 U.S.C. 552a(c); and

(5) Of the requester's right to file a civil action in Federal district court to seek a review of the determination of the General Counsel in accordance with 5 U.S.C. 552a(g).

(f) The General Counsel shall ensure that any statements of disagreement submitted by a requester are made available or distributed in accordance with paragraphs (e)(3) and (4) of this section.

§ 1850.40 Disclosure of record to person other than the individual to whom it pertains.

The Counsel shall not disclose any record which is contained in a system of records it maintains, by any means of communication to any person or to another agency, except pursuant to a written request by, or with the prior written consent of the individual to whom the record pertains, unless the disclosure is authorized by one or more provisions of 5 U.S.C. 552a(b).

§ 1850.41 Fees.

(a) No fee shall be charged for searches necessary to locate records. No charge shall be made if the total fees authorized are less than $1.00. Fees shall be charged for services rendered under this subpart as follows:

(1) For copies made by photocopy—$0.05 per page (maximum of 10 copies). For copies prepared by computer, such as tapes or printouts, the Council will charge the direct cost incurred by the agency, including operator time. For other forms of duplication, the Council will charge the actual costs of that duplication.

(2) For attestation of documents—$25.00 per authenticating affidavit or declaration.

(3) For certification of documents—$50.00 per authenticating affidavit or declaration.

(b) All required fees shall be paid in full prior to issuance of requested copies of records. Requesters must pay fees by check or money order made payable to the ''Treasury of the United States.''

§ 1850.42 Penalties.

The criminal penalties which have been established for violations of the Privacy Act of 1974 are set forth in 5 U.S.C. 552a(i). Penalties are applicable to any officer or employee of the Council; to contractors and employees of such contractors who enter into contracts with the Council, and who are considered to be employees of the Council within the meaning of 5 U.S.C. 552a(m); and to any person who knowingly and willfully requests or obtains any record concerning an individual from the Council under false pretenses.

Will D. Spoon,

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Proposed Rules

Federal Register
Vol. 80, No. 99
Friday, May 22, 2015

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 COMMERCE

Bureau of Industry and Security

15 CFR Part 758

[Docket No. 150107020–5160–01]

RIN 0694–AG47

Export Administration Regulations (EAR): Harmonization of the Destination Control Statements

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the destination control statement in the Export Administration Regulations (EAR) to harmonize the statement required for the export of items subject to the EAR with the destination control statement in the International Traffic in Arms Regulations (ITAR).

This proposed rule is published in conjunction with the publication of a Department of State, Directorate of Defense Trade Controls proposed rule revising the destination control statement in the ITAR. Both proposed rules being published today by the Departments of Commerce and State are part of the President's Export Control Reform Initiative. This proposed rule is also part of Commerce's retrospective regulatory review plan under Executive Order (E.O.) 13563 (see the **SUPPLEMENTARY INFORMATION** for availability of the plan).

DATES: The Bureau of Industry and Security will accept comments on this proposed rule until July 6, 2015.

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

- By the Federal eRulemaking Portal: *http://www.regulations.gov.* The identification number for this rulemaking is BIS–2015–0013.
- By email directly to *publiccomments@bis.doc.gov.* Include RIN 0694–AG47 in the subject line.
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Refer to RIN 0694–AG47.

FOR FURTHER INFORMATION CONTACT: For questions about this rule, contact Timothy Mooney, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, at 202–482–2440 or email: *timothy.mooney@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EAR currently requires exporters to include a destination control statement, specified in § 758.6 (Destination control statement and other information furnished to consignees) of the EAR, on certain export control documents that accompany a shipment for most exports. The purpose of this statement is to alert other parties outside the United States that receive the item that the item is subject to the EAR, the item was exported in accordance with the EAR, and that diversion contrary to U.S. law is prohibited.

The ITAR, under § 123.9(b)(1), also includes the same type of destination control statement requirement, but specific to the ITAR context and with slightly different text than what is used under the EAR, although the purpose of the destination control statement requirements is the same under both sets of export control regulations. As a general principle under the Export Control Reform (ECR) implementation that is currently underway, wherever the ITAR and EAR have provisions that are intended to achieve the same purpose, the U.S. Government is making an effort to harmonize those provisions, except when circumstances exist that require that those provisions remain different. The destination control statement requirements under the ITAR and the EAR are an example of requirements that can and should be harmonized to reduce the burden on exporters, improve compliance, and ensure the regulations are achieving their intended purpose for use under the U.S. export control system, specifically under the transactions ''subject to the ITAR'' and ''subject to the EAR.'' The proposed harmonization changes to be made to the EAR are described below under the heading ''*Harmonization of destination control statement.*''

Harmonization of Destination Control Statement

This proposed rule would revise § 758.6 of the EAR to harmonize the destination control statement requirement text with § 123.9(b)(1) of the ITAR. This change would be made to facilitate implementation of the President's Export Control Reform Initiative, which has transferred thousands of formerly ITAR controlled defense article parts and components, along with other items, to the Commerce Control List in the EAR under the jurisdiction of the Department of Commerce.

This change in jurisdiction for many of the parts and components for military systems has increased incidence of exporters' shipping articles subject to both the ITAR and the EAR in the same shipment. Both regulations have a mandatory destination control statement that must be on the export control documents for shipments that include items subject to those regulations. This has caused confusion to exporters as to which statement to include on such mixed shipments, or whether to include both. Harmonizing these statements is intended to ease the regulatory burden on exporters.

This change is also being made to harmonize the two sets of regulations, the EAR and the ITAR, per the President's instructions. While the creation of a single export control list and licensing agency would require legislation, the President has directed BIS and the Directorate of Defense Trade Controls at the Department of State to undertake all available actions to prepare for consolidation as a single agency with a single set of regulations. Harmonization, to the extent possible, is one important step for preparing both regulators and the regulated public.

The harmonization of the destination control statement would include the following proposed changes to the EAR. The heading of § 758.6 of the EAR would remain the same. However, the provisions currently under paragraph (b) would be moved to a new paragraph (a)(2).

Further, regarding proposed new paragraph (a)(2), this paragraph would specify that the ECCN for each 9x515 or ''600 series'' item being exported must be included, which is the same requirement that is currently in paragraph (b), although it would be

slightly shortened because the introductory text of paragraph (a) would specify some of the requirements that previously were included in paragraph (b), specifically the documents for which the 9x515 and ''600 series'' classification must be included on under this section. These documents are the same as those documents that the destination control statement would be included on, so this change would shorten and simplify this section by moving the text of paragraph (b) to paragraph (a)(2). This change would reduce the number of documents that this classification would need to be included on to conform with the destination control statement changes described below.

The proposed new introductory text paragraph (a) would specify that the exporter shall incorporate the information specified under paragraph (a)(1) (destination control statement) and (a)(2) (ECCN for each 9x515 or ''600 series'' item being exported) as an integral part of the commercial invoice and contractual documentation, when such contractual documentation exists. This proposed change would mean this section of the EAR would no longer include a requirement to include the destination control statement on the air waybill, bill of lading or other export control documents, and would instead focus the requirement on the two documents—the commercial invoice and contractual documentation. This rule proposes requiring the destination control statement on the commercial invoice and contractual documentation because these two documents are the most likely to travel with the item from its time of export from the United States to its ultimate destination and ultimate consignee. The intent of the destination control statement requirement is to ensure that the statement reaches the ultimate destination and ultimate consignee of the item, so requiring the destination control statement to be included on such documentation, when it exists, would be more likely to achieve the intended purpose of this provision. At the same time, the requirement would have the added benefit of reducing the number of documents on which exporters would be responsible for entering the destination statement. Consistent with the current destination control statement provisions, this rule would not require an EAR destination control statement for exports of EAR99 items or items exported under License Exception BAG or GFT. Any other export from the United States of any item on the CCL would require the destination statement as specified in paragraph (a)(1) and any export of a 9x515 or ''600 series'' ECCN would also need to be specified on those two documents as specified in paragraph (a)(2), when they exist.

The text of the harmonized destination control statement would be specified under revised paragraph (a)(1) of § 758.6 of the EAR. The new destination control statement would not include EAR-specific language, but rather would adopt language that would be equally applicable under the ITAR as well as the EAR. The first sentence of the statement would specify that ''these items are controlled and authorized by the U.S. Government for export only to the specified country of ultimate destination for use by the end-user herein identified.'' This first sentence is intended to alert the person outside the United States receiving the item that the item is subject to U.S. export laws and regulations and was authorized by the U.S. Government for export. In addition, the first sentence would specify that the U.S. Government only authorized the export to the specified country of ultimate destination and for use by the specified end-user. The new destination control statement would use the term authorized, but in the context of this EAR paragraph ''authorized'' would also include exports that were designated under No License Required (NLR).

The second sentence of the new harmonized destination control statement would focus on alerting the persons receiving the items that they may not be resold, transferred, or otherwise be disposed of, to any other country or to any person other than the authorized end-user or consignee(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations. Similar to the first sentence, this proposed second sentence adopts common language that can be used under the ITAR and the EAR. The application of this second sentence would be different under the ITAR and the EAR due to the different types of authorizations and other approvals in the respective regulations, as well as other differences, such as the de minimis requirements in the EAR, which is not provided for in the ITAR. But the advantage of the proposed text is that it would adopt a new harmonized destination control statement, while at the same time still being flexible enough to not impact other ITAR or EAR provisions that do warrant differentiation, such as the availability of de minimis provisions, which are available under the EAR, but because of statutory limitations in the Arms Export Control Act are not available under the ITAR.

Adoption of a new harmonized destination control statement would simplify export clearance requirements for exporters because they would not have to decide which destination control statement to include, especially for mixed shipments containing both ITAR and EAR items.

An exporter would still need to go through all of the steps to determine jurisdiction, classification, license requirements, and to obtain and use the proper authorization under the respective regulations, prior to moving on to the respective export clearance requirements under the ITAR or EAR. This is important to remember when evaluating these proposed changes because the regulations need to be reviewed and evaluated in the context in which they are intended to be applied, including the steps for determining the applicable export control requirements under the ITAR and the EAR. For those parties outside the United States that would be receiving items under this new destination control statement, although the new destination control statement is not ITAR or EAR specific, in the case of the USML the classification of the USML items would be required on the documentation. This classification would alert the parties that the items are subject to the ITAR. For military items under the EAR, because of the proposed requirement in paragraph (a)(2)(which is currently required under paragraph (b)) of § 758.6 of the EAR, anyone receiving a ''600 series'' military item or an ECCN 9x515 item would know that specific item was subject to the EAR because the classification information would also need to be included on the same documentation. For other EAR items, there would not be a requirement to include the classification information, although BIS does encourage the inclusion of that information as a good export compliance practice.

Removal of Paragraph (c)

BIS proposes removing paragraph (c) of § 758.6 in this rule. Paragraph (c) was added recently (January 23, 2015, 80 FR 3463) and requires a special DCS for items controlled under ECCNs for crime control columns 1 and 3 or regional stability column 2 reasons when those items are destined to India. BIS proposes removing this requirement because the benefit for this requirement in paragraph (c) is outweighed by the added complexity to the EAR of including this country specific requirement. Therefore, consistent with

the purpose of the retrospective regulatory review, BIS proposes removing paragraph (c).

As required by Executive Order (EO) 13563, BIS intends to review this rule's impact on the licensing burden on exporters. Commerce's full retrospective regulatory review plan is available at: *http://open.commerce.gov/news/2011/08/23/plan-retrospective-analysis-existing-rules*. Data are routinely collected on an ongoing basis, including through the comments to be submitted and through new information and results from Automated Export System data. These results and data have formed, and will continue to form, the basis for ongoing reviews of the rule and assessments of various aspects of the rule. As part of its plan for retrospective analysis under E.O. 13563, BIS intends to conduct periodic reviews of this rule and to modify, or repeal, aspects of this rule, as appropriate, and after public notice and comment. With regard to a number of aspects of this rule, assessments and refinements will be made on an ongoing basis. This is particularly the case with regard to possible modifications that will be considered based on public comments described above.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46959 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This regulation involves collections previously approved by the OMB under control numbers 0694–0122, ''Licensing Responsibilities and Enforcement.'' This rule does not alter any information collection requirements; therefore, total burden hours associated with the PRA and OMB control number 0694–0122 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities.

Number of Small Entities

BIS does not collect data on the size of entities that apply for and are issued export licenses. Although BIS is unable to estimate the exact number of small entities that would be affected by this rule, it acknowledges that this rule would affect some unknown number.

Economic Impact

This proposed rule is part of the Administration's Export Control Reform (ECR) Initiative. The destination control statement is an existing regulatory requirement under the EAR that exporters must use for export clearance purposes for most export transactions that are subject to the EAR.

The improvements to the export control system being implemented under ECR have resulted in reduced burdens on exporters, including small businesses, because the military items moved to the CCL now have the availability of more flexible EAR authorizations and availability of de minimis provisions among other advantages for exporters of items that have moved from the USML to the CCL. However, the existing destination control statement requirements impose an unnecessary burden on exporters of mixed shipments (shipments that include items subject to the EAR and ITAR). The current provisions create ambiguity for exporters on which destination control statement to use for such mixed shipments, which imposes unnecessary administrative costs and burdens on such exporters. The proposed changes in this rule would relieve this burden by adopting a harmonized destination control statement under the EAR. The corresponding Department of State proposed rule would adopt a harmonized destination control statement under the ITAR. This proposed harmonized destination control statement would result in time savings for exporters when they determine their export clearance requirements. These proposed changes would also reduce the economic impact on exporters, including small businesses, because it would make it easier for exporters to comply with this export clearance requirement under the EAR and the ITAR for specific transactions and would also simplify the export control clearance requirements associated with mixed transactions.

In practice, the greatest impact of this rule on small entities would likely be reduced administrative costs and reduced delay for exports of items. Therefore, this proposed rule would not cause any economic impact and would result in no additional compliance cost. On the contrary, this proposed rule would reduce compliance costs.

Conclusion

BIS is unable to determine the precise number of small entities that would be affected by this rule. Based on the facts and conclusions set forth above, BIS believes that any burdens imposed by this rule would be offset by the improvements made to harmonization of the destination control statement under the EAR and the ITAR. For these reasons, the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule, if adopted in final form, would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 758

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, Part 758 of the Export Administration Regulations (15 CFR parts 730–774) is proposed to be amended as follows:

PART 758—[AMENDED]

■ 1. The authority citation for 15 CFR part 758 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 2. Section 758.6 is revised to read as follows:

§ 758.6 Destination control statement and other information furnished to consignees.

(a) The exporter shall incorporate the following information as an integral part of the commercial invoice and contractual documentation, when such contractual documentation exists, whenever items on the Commerce Control List are exported, unless the export may be made under License Exception BAG or GFT (see part 740 of the EAR):

(1) For any item on the Commerce Control List being exported, the following statement: ''These items are controlled and authorized by the U.S. Government for export only to the specified country of ultimate destination for use by the end-user herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized end-user or consignee(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations'' and

(2) The ECCN for each 9x515 or ''600 series'' item being exported.

(b) [Reserved]

Dated: May 13, 2015.

Kevin J. Wolf,

Assistant Secretary of Commerce for Export Administration.

[FR Doc. 2015–12298 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 758

[Docket No. 150220163–5163–01]

RIN 0694–AG51

Additional Improvements and Harmonization of Export Clearance Provisions

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Bureau of Industry and Security (BIS) in this advanced notice of proposed rulemaking (ANPR) requests comments for how the export clearance requirements under the Export Administration Regulations (EAR) can be improved, including how the EAR export clearance provisions can be better harmonized with the export clearance requirements under the International Traffic in Arms Regulations (ITAR). This ANPR is part of Commerce's retrospective regulatory review and ongoing harmonization efforts being undertaken by Commerce and State as part of Export Control Reform (ECR) implementation. This ANPR is also part of Commerce's retrospective regulatory review plan under Executive Order (EO) 13563 (see the **SUPPLEMENTARY INFORMATION** for availability of the plan).

DATES: The Bureau of Industry and Security will accept comments on this advanced notice of proposed rulemaking until July 6, 2015.

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

- By the Federal eRulemaking Portal: *http://www.regulations.gov.* The identification number for this rulemaking is BIS–2015–0012.
- By email directly to *publiccomments@bis.doc.gov.* Include RIN 0694–AG51 in the subject line.
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Refer to RIN 0694–AG51.

FOR FURTHER INFORMATION CONTACT: For questions about this ANPR, contact Timothy Mooney, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, at 202–482–2440 or email: *timothy.mooney@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) in this advanced notice of proposed rulemaking (ANPR) requests comments for how the requirements under part 758 (Export clearance) of the Export Administration Regulations (EAR) (15 CFR parts 730–774) can be improved, including how the EAR export clearance provisions can be better harmonized with the export clearance requirements under the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). This ANPR is part of Commerce's retrospective regulatory review and ongoing harmonization efforts being undertaken by Commerce and State as part of Export Control Reform (ECR) implementation. Commerce's full retrospective regulatory review plan is available at: *http://open.commerce.gov/news/2011/08/23/commerce-plan-analysis-existing-rules.*

Harmonization of Export Clearance Provisions

The President's Export Control Reform (ECR) Initiative has transferred thousands of formerly ITAR controlled defense article parts and components, along with other items, to the Commerce Control List in the EAR under the jurisdiction of the Department of Commerce. The EAR includes part 758, which specifies requirements for export clearance under the EAR. As part of ECR implementation, BIS has made certain changes to part 758 to address the addition of the 9x515 and ''600 series'' ECCNs to the CCL (see the EAR final rules published on April 16, 2013 (78 FR 22660), May 13, 2014 (79 FR 27418) and November 12, 2014 (79 FR 67055)), along with other changes to the EAR to account for the 9x515 and ''600 series'' ECCNs being added to the EAR.

As a general principle, under the ECR implementation that is currently underway, wherever the ITAR and EAR have provisions that are intended to achieve the same purpose the U.S. Government is making an effort to harmonize those provisions, except when there is a reason why those provisions should remain different. The export clearance requirements under the

ITAR and the EAR are an example of requirements that may for certain provisions be harmonized to reduce the burden on exporters, improve compliance with the export clearance requirements, and ensure the export clearance requirements are achieving their intended purpose for use under the U.S. export control system, specifically under the transactions ''subject to the ITAR'' and ''subject to the EAR.''

Request for Comments on Additional Improvement and Harmonization of Export Clearance Provisions

BIS is considering further revisions to part 758 of the EAR as part of Commerce's retrospective regulatory review and ongoing harmonization efforts being undertaken by Commerce and State as part of ECR implementation. As part of this review effort for how part 758 can be improved to make these provisions more effective and to assist BIS in developing regulatory changes to improve these provisions of the EAR, BIS requests comments on these potential future changes described under paragraphs (A) through (E). Export control documents in paragraphs (A) through (C) include the commercial invoice and contractual documentation.

A. *Require ECCNs on export control documents.* The ECCN for all 9x515 and ''600 series'' items is currently required to be identified on the export control documents, along with the destination control statement. BIS is considering requiring that the ECCN be identified for all items on the Commerce Control List. This would not include items that are designated EAR99.

B. *Require identification of country of ultimate destination on export control documents.* BIS is considering requiring that the country of ultimate destination be identified on the export control documents. This requirement would mirror the requirement in the ITAR and BIS believes that this would only impact a small number of exports where additional actions would be needed by exporters, because in most cases, the export control documents already identify the country of ultimate destination.

C. *Require license number or export authorization symbol on export control documents.* BIS is also considering requiring that the license number or export authorization symbol be identified on export control documents. This proposed revision would require that the license number, license exception code, or no license required designation be entered on the export control documents. BIS specifically requests comments on the application of this requirement to mixed authorization and mixed jurisdiction shipments.

D. *Require AES filing for exports to Canada for items controlled for NS, MT, NP and CB.* BIS seeks comments on the potential impact and feasibility of changing section 758.1 under paragraph (b) to require EEI filing in the AES for all exports to Canada of items controlled for National Security (NS), Missile Technology (MT), Nuclear Nonproliferation (NP), and Chemical & Biological Weapons (CB) reasons, regardless of license requirements (meaning regardless of whether the export was authorized under a license, license exception, or designated as no license required). Because of the AES filing exemption for non-licensed items to Canada, BIS currently has little visibility into the movement of these items into Canada, except for exports to Canada that involve a licensed item (see paragraph (b)(2) of section 758.1), a 9x515 or ''600 series'' item (see paragraph (b)(3) of section 758.1) or are to be transhipped to a third country (see paragraph (b)(6) of section 758.1) which do require EEI filing in the AES. Therefore, BIS is seeking information that would help us determine:

—The volume of trade that would be impacted by this filing requirement;
—if this filing requirement would be beneficial and practical or detrimental and burdensome for industry;
—if this filing requirement would have a commercial impact on exporters; *and*
—if there are alternative methods to collecting or accessing this data.

E. *Other suggestions for improving and harmonizing export clearance requirements.* Any other suggestions for improving the EAR export clearance requirements, including suggestions where additional harmonization should be considered for the export clearance requirements under the EAR and ITAR to ease the regulatory burden on exporters and make the provisions more effective would be helpful to receive in response to this ANPR. These suggestions can apply to any export clearance provision under part 758 of the EAR or any other EAR provisions that relate to export clearance requirements.

Comments should be submitted to BIS as described in the **ADDRESSES** section of this ANPR by July 6, 2015. BIS will consider all comments submitted in response to this ANPR that are received before the close of the comment period. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. BIS will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. BIS will return such comments and materials to the persons submitting the comments and will not consider them. All public comments in response to this ANPR must be in writing and will be a matter of public record, and will be available for public inspection and copying on the BIS Freedom of Information Act (FOIA) Reading Room at *http://efoia.bis.doc.gov/index.php/electronic-foia/index-of-documents.*

Dated: May 13, 2015.

Kevin J. Wolf,

Assistant Secretary of Commerce for Export Administration.

[FR Doc. 2015–12296 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–33–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1201

[CPSC Docket No. CPSC–2012–0049]

Safety Standard for Architectural Glazing Materials

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (''CPSC'' or ''Commission'') is proposing an amendment to the Safety Standard for Architectural Glazing Materials (16 CFR part 1201) to clarify certain test procedures specified in the standard. The CPSC proposes to replace the testing procedures for glazing materials in certain architectural products, set forth in 16 CFR 1201.4, with the testing procedures contained in the voluntary standard, ANSI Z97.1–2009$^{\varepsilon 2}$, *American National Standard for Safety Glazing Materials Used in Buildings—Safety Performance Specifications and Methods of Test.*

DATES: Written comments must be received by July 21, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2012–0049, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The Commission encourages you to submit electronic

comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2012–0049, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

Brian Baker, Project Manager, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301–987–2289; *bbaker@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Safety Standard for Architectural Glazing Materials

On January 6, 1977 (42 FR 1427), as amended on June 20, 1977 (42 FR 31164), the Commission issued the Safety Standard for Architectural Glazing Materials under the Consumer Product Safety Act (''CPSA'') to reduce or eliminate risks of injuries associated with walking, running, or falling through or against glazing materials (''CPSC standard''). The standard applies to glazing materials used or intended for use in any of the following architectural products:

(1) Storm doors or combination doors;
(2) Doors (both exterior and interior);
(3) Bathtub doors and enclosures;
(4) Shower doors and enclosures; and
(5) Sliding glass doors (patio-type).

The standard applies to glazing materials and architectural products incorporating glazing materials that are produced or distributed for sale to or for the personal use, consumption or enjoyment of consumers in or around a permanent or temporary household or residence or in recreational, school, public, or other buildings or parts thereof. The standard was codified at 16 CFR part 1201.

The standard exempts the following products, materials, and uses:

(1) Wired glass used in doors or other assemblies to retard the passage of fire where required by federal, state, local, or municipal fire ordinance;
(2) Louvers of jalousie doors;
(3) Openings of doors which a 3 inch diameter sphere is unable to pass;
(4) Carved glass (as defined in section 1201.2(a)(36)), dalle glass (as defined in § 1201.2(a)(37)), or leaded glass (as defined in section 1201.2(a)(14)), which is used in doors and glazed panels (as defined in sections 1201.2(a)(7) and (a)(10)) if the glazing material meets all of the following criteria:
(i) The coloring, texturing, or other design qualities or components of the glazing material cannot be removed without destroying the material; and
(ii) The primary purpose of such glazing is decorative or artistic; and
(iii) The glazing material is conspicuously colored or textured so as to be plainly visible and plainly identifiable as aesthetic or decorative rather than functional (other than for the purpose of admitting or controlling admission of light components or heat and cold); and
(iv) The glazing material, or assembly into which it is incorporated, is divided into segments by conspicuous and plainly visible lines.
(5) Glazing materials used as curved glazed panels in revolving doors; and
(6) Commercial refrigerator cabinet glazed doors. 16 CFR 1201.1(c).

On September 27, 1978, (43 FR 43704), the Commission amended the standard to clarify the definitions, description of test apparatus, and test procedures in the standard. The Commission stated that under the CPSA, when an amendment to a consumer product safety rule involves a material change, the procedures in section 7 and 9 apply. 15 U.S.C. 2058(h). The Commission determined, however, that the amendments to the definitions, test apparatus, and test procedures did not involve a material change to the standard because they did not affect the basic purpose and provisions of the standard. (42 FR 53798, 53799 (Oct. 3, 1977); 43 FR 43704 (Sept. 27, 1978.) Accordingly, the Commission did not apply the provisions of sections 7 and 9 of the CPSA. However, the Commission provided notice and comment under the informal rulemaking procedures of the Administrative Procedure Act (''APA''), 5 U.S.C. 553, before issuing a final rule.

The Commission subsequently revoked portions of the standard that prescribed requirements for ''glazed panels'' (45 FR 67383, August 28, 1980); an accelerated environmental durability test for plastic glazing materials intended for outdoor exposure (45 66002, October 6, 1980); and a modulus of elasticity test, a harness test, and an indoor aging test applicable to plastic glazing materials (47 FR 27853, June 28, 1982). 16 CFR 1201.1(d) n.1. Tempered glass, wired glass, and annealed glass are also exempt from the accelerated environmental durability tests. 16 CFR 1201.4(a)(2).

The testing procedures currently set forth in 16 CFR 1201.4 require impact tests and accelerated environment durability tests for non-exempted materials, which are intended to determine if glazing materials used in these architectural products meet safety requirements designed to reduce or eliminate unreasonable risks of death or serious injury to consumers when glazing material is broken by human contact. The testing procedures further describe the testing equipment and apparatus required to be used, and the test result interpretation methodology to be employed in determining if the glazing materials being tested meet the safety requirements of the standard.

B. Petition Request

On June 26, 2012, the Commission received a petition from the Safety Glazing Certification Council (''SGCC'' or ''petitioner''), requesting that the Commission initiate rulemaking to replace the testing procedures for glazing materials in certain architectural products, as set forth in 16 CFR 1201.4, with the testing procedures contained in the voluntary standard, ANSI Z97.1–2009$^{\varepsilon 2}$, *American National Standard for Safety Glazing Materials Used in Buildings—Safety Performance Specifications and Methods of Test* (the ANSI standard). SGCC stated that consumers and the glazing industry would be better served if the test procedures for glazing materials used in architectural products set forth in 16 CFR 1201.4 were replaced with the ANSI standard test procedures because the ANSI test procedures are more efficient and modern. The petitioner asserts that the testing procedures set forth in section 1201.4 were promulgated in 1977, and they have not been updated or clarified, as necessary. The petitioner stated that the ANSI standard for glazing materials has been updated periodically (in 1984, 1994,

2004, and 2009), unlike the CPSC standard, and that these updates include modifications in testing equipment and procedures. Petitioner asserted that the absence of updates to the CPSC standard during a period in which the ANSI standard was revised four times has resulted in different testing methods and qualifying procedures that have created confusion in the industry regarding which test methodology must be used in what circumstance. Petitioner claimed that the existence of overlapping but divergent CPSC and voluntary standards has resulted in manufacturers paying for duplicative testing.

On August 30, 2012, notice of the petition was published in the **Federal Register** (77 FR 52625). The Commission received five comments, all supporting the petitioner's request to amend the existing test procedures with the ANSI standard. The petition was referred to the Commission's staff for evaluation. On April 3, 2013, CPSC staff submitted a briefing package to the Commission evaluating the petition, including the feasibility of integrating the test procedures of the ANSI standard into the CPSC standard.[1] On April 9, 2013, the Commission voted to grant the petition.

On May 6, 2015, CPSC staff submitted a briefing package to the Commission recommending that the Commission issue a proposed amendment to 16 CFR 1201.4 that would replace the testing procedures set forth in the CPSC mandatory standard for glazing materials in certain architectural products, with the testing procedures contained in the voluntary standard, ANSI Z97.1–2009$^{\varepsilon 2}$. The staff's briefing package is available on the CPSC's Web site at: *http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/Proposed-Rule-to-Amend-the-Safety-Standard-for-Architectural-Glazing-Material.pdf.*

C. Statutory Authority

The proposed amendment to the CPSC standard would clarify certain test procedures specified in the mandatory standard. Under section 9 (h) of the CPSA, if an amendment of a consumer product safety rule ''involves a material change,'' 15 U.S.C. 2058(h), the Commission must make certain findings, including a finding that the amendment is ''reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product''; the expected benefits of the amended rule ''bear a reasonable relationship to its costs''; and the amended rule imposes ''the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.'' *Id.* §§ 2056(a); 2058(a)–(g). If the amendment does not constitute ''a material change'' for purposes of section 9(h) of the CPSA, the Commission is not required to make the findings that are otherwise required for the amendment of a consumer product safety rule.

When the Commission previously amended the CPSC standard to clarify the definitions and the description of test apparatus and test procedures in the architectural glazing standard, the Commission determined that the amendments to the definitions, test apparatus, and test procedures did not involve a material change to the standard because the changes did not affect the basic purpose and provisions of the standard. (43 FR 43704, September 27, 1978). However, the Commission did not elaborate on what changes might affect the basic purpose of a standard.

To assess what types of changes may result in a material change for the proposed amendment, the Commission looked to other statutory language for guidance. The Consumer Product Safety Improvement Act (''CPSIA'') directed the Commission to establish protocols and standards to test children's products for testing and certification purposes ''when there has been a material change in the product's design or manufacturing process.'' 15 U.S.C. 2063(d)(2)(B). The Commission's regulation implementing this provision defines ''material change'' as: ''any change in the product's design, manufacturing process or sourcing of component parts that . . . could affect a product's ability to comply with the applicable rules, bans, standards or regulations.'' 16 CFR 1107.2. This definition contemplates that certain changes would not be considered ''material'' if changes are not significant enough to potentially impact the product's ability to comply with applicable standards and regulations.

The basis for the Commission's findings in promulgating the standard for architectural glazing was that unreasonable risks of injury are associated with architectural glazing materials used in certain architectural glazing products. In assessing the question of whether unreasonable risks of injury or injury potential are associated with architectural glazing materials, the Commission balanced the degree, nature, and frequency of injury against the potential effect of the standard on the ability of architectural glazing materials to meet the need of the public and the effect of the standard on the cost, utility, and availability of architectural glazing materials to meet that need. 16 CFR 1201.1(d)(5).

Consistent with this prior analysis, for the proposed amendment, the Commission has reviewed whether the proposed amendment would alter the original basic purpose of the rule addressing an unreasonable risk of injury associated with architectural glazing materials, including whether the proposed amendment would have an important or significant impact on the safety of consumers or on the burdens imposed on the regulated industry. In particular, to assess whether the basic purpose and provisions of the standard would be altered, the Commission compared the existing CPSC test procedures in the mandatory standard with the ANSI test procedures. The basic purpose of 16 CFR 1201.4 is to provide test procedures that will assess the safety of architectural glazing materials. The mandatory standard was promulgated to reduce or eliminate risks of injuries associated with walking, running, or falling through or against glazing materials in storm doors, doors (both exterior and interior), shower and bathtub doors and enclosures, and sliding or patio-type doors. The adoption of the ANSI test procedures will not alter that purpose. As discussed in section II below, the proposed amended testing procedures will clarify the existing test procedures and update references to current test methods.

In addition, the Commission reviewed whether there would be an important or significant impact on the safety of consumers. As discussed in section IV below, CSPC staff's review showed that almost all of the samples tested both to 16 CFR 1201.1 and the ANSI standard passed both standards; only a small number of samples tested (5 out of more than 3,500) failed the CPSC standard testing, but passed when tested to the voluntary standard. Thus, the proposed amendment is unlikely to have an important or significant impact on the safety of consumers because testing to either standard provided consistent and comparable test results.

The Commission also reviewed whether there would be any important or significant impact on the burdens imposed on the regulated industry. As discussed in section V below, CPSC staff's review showed existing widespread compliance with the ANSI standard. Therefore, the data did not show that adoption of the ANSI test procedures would impose any

[1] *http://www.cpsc.gov//Global/Newsroom/FOIA/CommissionBriefingPackages/2013/ArchitecturalGlazingPetitionBriefingPackage.pdf.*

additional burdens on the regulated industry. In fact, a slight reduction in the burdens imposed on the regulated industry is likely because the proposed amendment would reduce confusion in the industry regarding applicable test procedures. Moreover, adoption of the ANSI test procedures likely will make testing of the architectural glazing materials more efficient, less costly, and reduce redundant testing for manufacturers who currently comply with the ANSI standard, as well as the CPSC mandatory standard.

Accordingly, as provided under section 9(h) of the CPSA, the Commission believes that the proposed amendment replacing the test procedures specified in the CPSC mandatory standard with the test procedures in the ANSI standard would not involve a material change requiring the procedures under sections 7 and 9 of the CPSA. However, because the proposed amendment would make revisions to an existing standard, the Commission is providing notice and comment under the informal rulemaking procedures of the APA, 5 U.S.C. 553, before issuing a final rule.

II. The Proposed Amendment

A. No Change in Scope

The proposed amendment would replace the test procedures in the CPSC standard at 16 CFR 1201.4 with the ANSI test procedures. The ANSI standard covers certain products, materials, and uses that are exempt from the CPSC standard. The proposed amendment would not change the scope of products, materials, or uses covered by the CPSC standard.

The CPSC standard currently exempts: Wired glass used in doors or other assemblies to retard the passage of fire where required by federal, state, local, or municipal fire ordinance; louvers of jalousie doors; openings of doors which a 3 inch diameter sphere is unable to pass; carved glass, dalle glass, or leaded glass; glazing materials used as curved glazed panels in revolving doors; and commercial refrigerator cabinet glazed doors. 16 CFR 1201.1(c). In addition, the test procedures at 16 CFR 1201.4(a)(2) do not provide for accelerated environmental durability testing of plastic glazing materials because those tests were removed from 16 CFR part 1201 by the Commission in the early 1980s. (45 FR 66002, October 6, 1980). Moreover, tempered glass, wired glass, and annealed glass are not required to be subjected to the accelerated environmental durability tests. *Id.* at § 1201.4(a)(2).

In contrast, the ANSI standard does not exempt any specific glazing materials. The ANSI testing procedures include testing for materials and products that are not covered by the CPSC standard: Plastic glazing and fire-resistant wire-glass. Accordingly, the ANSI standard includes tests for certain items, such as fire-resistant wired glass and accelerated environmental durability testing for plastic glazing, which are otherwise exempt from the CPSC standard. Although the ANSI standard does not specifically exempt tempered glass, wired glass, and annealed glass from the accelerated environmental durability tests, the ANSI standard only requires plastic glazing and organic coated glass to be subjected to the accelerated environmental durability test. Tests in the ANSI standard that apply to materials, products, or uses that are exempt from the CPSC standard would not be included in the proposed amendment.

In the proposed amendment, the Commission does not propose to alter the scope or exemptions provided in the CPSC standard; materials that are exempt from 16 CFR part 1201 would continue to be exempt, and those exempt materials would not be subject to the ANSI test procedures. The proposed amendment, however, would adopt the ANSI standard for the remaining test procedures in the CPSC standard.

B. Test Procedures for Glazing Materials

The proposed amendment replacing the CPSC test procedures in 16 CFR 1201.4 with the ANSI test procedures will clarify the existing test procedures and update references to current test methods.

1. Obsolete References Will Be Replaced With Updated Test Methods

Currently, 16 CFR 1201.4(b)(3)(ii) refers to obsolete ASTM standard practices and equipment, which have been replaced in the ANSI standard (5.4.1.1, 5.4.1.2). For example, the simulated weathering test in the CPSC standard references two outdated ASTM standards:

- ASTM G26–70—*Practice for Operating Light Exposure Apparatus (Xenon-Arc Type) With and Without Water for Exposure of Nonmetallic Materials,* was withdrawn by ASTM in 2000, and replaced with ASTM G155—*Practice for Operating Xenon Arc Light Apparatus for Exposure of Non-Metallic Materials.*
- The obsolete 1970 edition of ASTM D2565–70—*Practice for Xenon-Arc Exposure of Plastics Intended for Outdoor Applications,* has been revised over the years; its current edition is ASTM D2565–99 (2008).

For manufacturers who test to both the 16 CFR 1201.4 and the ANSI standard, using these withdrawn and obsolete versions of current standards can result in increased costs and duplication of testing if manufacturers are required to test to the earlier versions of these editions to meet the regulation and also test to the current versions of these standard practice test procedures to meet the voluntary standard. Furthermore, the old standards referenced in 16 CFR 1201.4(b)(3)(ii) require obsolete test equipment that is currently not manufactured. By replacing the CPSC testing procedures with the updated references in the ANSI standard, the proposed amendment would allow the use of currently manufactured test equipment rather than the obsolete and outdated equipment referenced in section 1201.4(b)(3)(ii). The updated references would not involve a material change to the standard because changing these references to reflect current test methods would not alter the basic purpose of the CPSC standard.

2. The ANSI Impact Tests Are Similar to the Impact Tests in Section 1201.4(b)

Although ANSI Z97.1–2009$^{\varepsilon 2}$ has been modified several times since the CPSC standard was published, the impact tests of 16 CFR 1201.4(b) and ANSI Z97.1–2009$^{\varepsilon 2}$ (5) are similar. The CPSC standard shows drawings of a Glass Impact Test Structure (Figures 1–5) that is similar to the drawing of the Impact Test Frame drawing in ANSI Z97.1–2009$^{\varepsilon 2}$ (Figures 1–7), except for differences in the descriptive terms used for naming the parts of the test apparatus, *i.e.,* Main Frame and Sub-Frame in ANSI Z97.1–2009,$^{\varepsilon 2}$ versus 16 CFR 1201.4's Impact Test Structure and Test Specimen Mounting Frame. ANSI Z97.1–2009$^{\varepsilon 2}$ provides enlarged drawings of the Impact Test Frame. Overall, the Glass Impact Test Structure of 16 CFR 1201.4 appears to be of similar construction to the ANSI Z97.1–2009$^{\varepsilon 2}$ Impact Test Frame, except that ANSI Z97.1–2009$^{\varepsilon 2}$ provides clearer assembly drawings.

The ANSI drawings are larger and clearer to use, which would benefit manufacturers. In addition, if the ANSI impact test procedures were adopted, manufacturers who currently test to both the CPSC standard and ANSI standard could avoid duplicative testing because the manufacturers would not need to conduct impact tests for both the CPSC standard and the ANSI standard. The proposed amendment adopting the ANSI test procedures

would not involve a material change to the standard because the ANSI impact tests are comparable to the CPSC impact tests, but clearer construction drawings are provided in the ANSI standard.

3. The ANSI Test Procedures Clarify Specimen Categories, Methodology, and Quantity

The CPSC standard provides two impact categories, 150 foot-pound impact test (Category I) and 400 foot-pound impact test (Category II). 16 CFR 1201.4(d). The ANSI standard provides three impact categories (5.1.2.1): A 400 foot-pound impact test (Class A); a 150 foot-pound impact test (Class B); and a 100 foot-pound impact test (Class C) for fire-resistant wired glass. The proposed amendment would not result in a material change because the impact categories in the CPSC standard would remain the same and still include the 150 foot-pound impact test and 400 foot-pound impact test. The 100 foot-pound test in the ANSI standard only applies to fire-resistant wired glass, a product that is exempt from the CPSC standard. The Commission is not proposing to change the scope of the materials covered by the CPSC standard. Thus, manufacturers would not be required to follow the ANSI standard 100 foot-pound impact test (Class C) for fire-resistant wired glass because these materials remain exempt under the proposed amendment.

Both 16 CFR 1201.4(e)(1) and ANSI Z97.1–2009$^{\varepsilon 2}$ (5.1.4 (1)) permit using a 3-inch diameter steel sphere for evaluating any hole remaining in an impact tested specimen after the impact test for flat specimens. However, the standards differ because the CPSC standard requires that the specimen be evaluated in a horizontal position after the vertical test is completed. ANSI Z97.1–2009$^{\varepsilon 2}$ requires that the impacted specimen remain in the vertical, upright as-impact tested position while being evaluated with the 3-inch diameter steel sphere. Adopting the ANSI test procedure does not constitute a material change in the test method because the basic purpose of the requirement is not altered; rather, the test procedure is clarified. Leaving the specimen in the vertical position makes it less likely that gravity or human error will contribute to the potential failure of a product.

In addition, the requirements for size classification of impact specimens at 16 CFR 1201.4(c)(2) does not specify the number of specimens to be impact tested; rather, the standard requires only that the largest size and each thickness offered by the manufacturer are to be tested. However, ANSI Z97.1–2009$^{\varepsilon 2}$ (4.4) requires that four specimens of each size and thickness are to be impact tested. Specifying the number of specimens to be tested would not involve a material change to the standard because the proposed amendment would not alter the basic purpose of the requirement; rather, the ANSI test method would clarify the number of specimens to be tested, which would help reduce confusion on the number of specimens to be tested and provide a clearer test for manufacturers.

4. The ANSI Test Procedures Clarify Procedures for Evaluating Tempered Glass Specimens

ANSI Z97.1–2009$^{\varepsilon 2}$ (5.2) has more specific procedures for evaluating tempered glass specimens than 16 CFR 1201.4(d). The ANSI standard specifies a procedure to evaluate tempered glass specimens that did not fracture as a result of the 400 foot-pound Class A impact test. In the CPSC standard, fragmented pieces of glass were evaluated, by size and weight, only if the specimen failed the impact test. The ANSI standard requires that all samples that have been impacted be subjected to a ''Center Punch Fragmentation Test,'' which requires purposely fracturing the unbroken impact-tested tempered glass specimen with a center punch and hammer. In both cases, the fractured pieces of the tempered glass specimen are evaluated by weighing the 10 largest fragments. A tempered glass specimen is considered to conform to both the CPSC standard and ANSI Z97.1–2009$^{\varepsilon 2}$ as acceptable for use as safety glazing, if the 10 largest fragments weigh no more than the equivalent of 10 in^2 of the original unbroken specimen; however, ANSI Z97.1–2009$^{\varepsilon 2}$ requires that the pieces selected be no longer than 4 inches in length. Adopting the ANSI test procedures for evaluating tempered glass would not alter the basic purpose of the CPSC standard; rather, the ANSI Center Punch Fragmentation Test provides a more accurate and efficient way of measuring potential failures, which would further clarify the impact test for tempered glass for manufacturers.

5. Other Provisions

There are other testing procedures in the CPSC standard and the ANSI standard that are similar. Both standards have a boil test for laminated glass and similar requirements for testing for failure (1201.4(c)(3)(i); ANSI Z97.1–2009$^{\varepsilon 2}$ (5.3)). Both standards provide for accelerated environmental durability testing for organic coated glass (1201.4(d)(2)(B); ANSI Z97.1–2009$^{\varepsilon 2}$ (5.4)); adhesion tests for organic coated glass (1201.4(e)(ii)(B)(1); ANSI Z97.1–2009$^{\varepsilon 2}$ (5.4.2.2.1)); tensile strength tests for organic coated glass (1201.4(e)(ii)(B)(2); ANSI Z97.1–2009$^{\varepsilon 2}$ (5.4.2.2.2)); and impact testing of organic coated glazing materials for indoor service (1201.4(c)(3)(iii); ANSI Z97.1–2009$^{\varepsilon 2}$ (5.4.3)). The similarities in the testing procedures between the two standards further support the adoption of the proposed ANSI testing procedures. The proposed amendment would not result in a material change because the tests are comparable; however, manufacturers who currently test to both the CPSC standard and ANSI standard could reduce confusion regarding which standard to follow, and avoid duplicative testing, if the Commission specified the use of the ANSI test procedures.

III. Injury Information

CPSC Staff reviewed the Injury and Potential Injury Incident (IPII), In-Depth Investigation IDI), and Death Certificate databases for injuries reported to the Commission and identified 430 incidents for the period from 1978 to 2014. Since 1978, 98 architectural glazing-related fatalities were reported to the CPSC. Shower doors and enclosures accounted for 64 percent of the injuries and deaths. Glass or partial glass storm doors accounted for 15 percent of the reported injuries and deaths, and ''sliding glass'' doors or doors only specified as ''glass doors'' accounted for 8 percent each of the reported injuries and deaths. At least two of the incidents involved wired glass, which is exempt from the CPSC standard.

In addition to reviewing the CPSC databases, CSPC staff also identified 9,942 cases that occurred during the period from 1991 through 2013, which involved injuries from architectural glazing products treated in the emergency departments of CPSC's National Electronic Injury Surveillance System (''NEISS'') member hospitals. Staff determined that due to design changes within NEISS, estimates made before 1991 are not comparable. Based on these cases, staff computed a national estimate of 420,000 emergency department-treated injuries, with a coefficient of variance of 0.0648 percent. The 95 percent confidence interval for this estimate is 366,000 to 473,000. Ninety-six percent of the cases during the 1992 to 2013 period, which were reviewed by staff, involved lacerations. During this 20-year time period, the estimated number of emergency department-treated architectural glazing breakage incidents has declined.

Injury severity ranged from minor lacerations, abrasions, and contusions, to more severe laceration, puncture, and penetration injuries. The body part most often involved in these incidents was the arm (46.8%), followed by hand (30.1%), and head (8.6%). The incidents captured in NEISS suggest that the most severe injuries (*i.e.,* injuries that necessitated transfer to another hospital or admission to the hospital where emergency room treatment was provided) represented approximately 5 percent of the total. Lacerations are the most common hazard associated with glazing failures, and can range from superficial to extreme in their severity. Severe injuries often require surgery and rehabilitation, which may result in the loss of motion, loss of sensation, or permanent disfigurement.

Although many incident reports lacked detailed information about the injury, a review of the incidents from the CPSC databases suggests that many of the injuries and deaths resulted from products that did not meet the CPSC standard; the deep laceration injuries and puncture and penetration wounds reported in these incidents, some of which were fatal, most likely resulted from large glass fragments from broken pieces of non-safety glass.

IV. Impact on Consumer Safety

To assess the potential effect of the proposed amendment on consumer safety, in January 2014, CPSC staff collected information on sample data from 16 SGCC-approved testing laboratories to assess the relative compliance of architectural glazing companies with 16 CFR 1201.4 and the ANSI standard. The 16 laboratories represented approximately 70 percent of the third party testing laboratories responsible for testing architectural glazing products. Specifically, the companies were asked if specimens that pass 16 CFR 1201.4 were ever noncompliant with ANSI standard, and if so, the frequency of such occurrence. Ninety percent of all responses stated that there had never been an instance in which a specimen that complied with the ANSI standard did not also comply with the requirements of 16 CFR 1201.4.

These data indicate that replacing the CPSC standard testing procedures with the testing procedures in the ANSI standard would not have an important or significant impact on consumer safety because only a small number of samples tested (5 out of more than 3,500) failed the CPSC standard testing, but passed when tested to the voluntary standard. Accordingly, the data show that testing to either standard provides consistent testing results, and adopting the ANSI standard would not significantly affect the testing results.

V. Burdens on Industry Generally

As discussed in section II, replacing the test procedures in 16 CFR 1201.4 with the ANSI standard test procedures will make product testing more efficient and avoid potentially redundant tests for manufacturers who currently comply with the voluntary and the CPSC standard. Moreover, there is already substantial compliance with the ANSI standard.

CPSC staff's review showed that there are about 250 manufacturers of architectural glazing materials and roughly 2,500 glazing material products certified annually. SGCC manages the certification testing for about 70 percent of the market. The remaining manufacturers conduct in-house testing or they contract testing through labs outside of SGCC. All but a small proportion of these manufacturers currently test to both the CPSC mandatory standard and the ANSI voluntary standard.

Most manufacturers in the architectural glazing industry certify their products to ANSI Z97.1–2009$^{\varepsilon 2}$ and 16 CFR part 1201. Of the products certified through SGCC, 99 percent or 1,855 products were certified to both ANSI Z97.1–2009$^{\varepsilon 2}$ and 16 CFR part 1201. Only 12 products (0.6%) were certified solely to ANSI Z97.1–2009$^{\varepsilon 2}$; seven products (0.4%) were certified solely to 16 CFR part 1201. CPSC staff's review of manufacturers from the Glass Association of North America (''GANA''), which consists of members that both do and do not participate in the SGCC program, indicated that of the 35 manufacturers that test their products outside of SGCC and provided certification information, 32 manufacturers certified to both standards, and only three manufacturers listed certification to just 16 CFR part 1201.

Based on CPSC staff's review, if the ANSI standard test procedures were adopted, the proposed amendment would not have an important or significant impact on the burdens imposed on the regulated industry. Almost all of the manufacturers already certify to the ANSI standard. Manufacturers currently testing to both the ANSI standard and the CPSC standard will probably experience a decrease in testing and certification costs because they would only need to follow one testing protocol to be certified to both standards. This reduces the number of samples that a manufacturer needs to fabricate for testing, which will directly reduce certification costs. In addition, for manufacturers who contract out their testing, shipping costs will be reduced, due to the smaller number of samples shipped. SGCC estimates that its customers each would save an average of $1,284 per product tested annually. Thus, the proposed amendment likely would lessen the impact on the burdens imposed on industry to meet the requirements of the CPSC standard.

VI. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (''RFA'') requires that proposed rules be reviewed for the potential economic impact on small entities, including small businesses. 5 U.S.C. 601–612. Section 603 of the RFA requires agencies to prepare and make available for public comment an Initial Regulatory Flexibility Analysis (''IRFA''), describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. The requirement to prepare an IRFA does not apply if the agency certifies that the rulemaking will not have a significant economic impact on a substantial number of small entities. *Id.* 605. Because the Commission expects that the economic effect on all entities will be minimal, the Commission certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Small Entities to Which the Proposed Rule Would Apply

The U.S. Small Business Administration (''SBA'') guidelines categorize manufacturers of flat glass as ''small'' if they have fewer than 1,000 employees; and they categorize manufacturers of products made with purchased glass as ''small'' if they have fewer than 500 employees. In cases where firms fall under both categories, the size standard for flat glass manufacturers is applied to classify the firm. Based upon these criteria, the number of small manufacturers and importers identified in the architectural glazing market is 104, including 10 firms of undetermined size. Of the 104 small manufacturers known to produce architectural glass, 84 certify their products through the SGCC and 20 certify their products through other in-house testing, or they contract the testing.

The expected impact of the proposed rule is to reduce the costs of certification for most manufacturers. The 102 of 104 small manufacturers currently testing to both the ANSI standard and the CPSC standard also will probably experience a decrease in

testing and certification costs because they would only need to follow one testing protocol to be certified to both standards. This reduces the number of samples a manufacturer needs to fabricate for testing, thus directly reducing certification costs. In addition, for manufacturers who contract out their testing, shipping costs will be reduced, due to the smaller number of samples shipped.

SGCC estimates that its customers would each save an average of $1,284 per product tested annually. Two manufacturers outside SGCC's membership who currently test to both standards will also likely see cost savings. However, if these two manufacturers currently conduct their testing in-house, they do not incur the costs of shipping samples to SGCC; thus, the cost savings will be limited to the savings from fabricating fewer testing samples.

One of the two small domestic manufacturers that does not certify to both standards is listed under SGCC's certified products directory and tests products only to 16 CFR part 1201. SGCC's fees are structured so that testing to ANSI Z97.1–2009$^{\varepsilon 2}$ and 16 CFR part 1201 currently cost the manufacturer the same. Thus, this manufacturer should not experience an increase in testing fees from aligning 16 CFR 1201.4's testing protocol with ANSI Z97.1–2009 [2]. However, there will probably be an increase in cost associated with the shipping and fabrication of the higher number of CPSC samples required to be tested under ANSI Z97.1–2009$^{\varepsilon 2}$.

Of those small manufacturers identified outside of SGCC, only one was found to have products tested only to 16 CFR 1201.4, according to certification information readily available. This small manufacturer contracts out to a lab for certification and the lab tests to both standards. Therefore, this small manufacturer should not incur any significant increase due to testing fees. However, this manufacturer could experience some increase in shipping and fabricating costs, as identified above.

In summary, 102 of 104 small architectural glazing producers (or about 98 percent of the small producers) would experience some slight cost savings, or no impact, due to the proposed amendment. Consequently, the Commission certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the RFA.

VII. Environmental Considerations

Generally, the Commission's regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. See 16 CFR 1021.5(a). The proposed rule is not expected to have an adverse impact on the environment and is considered to fall within the ''categorical exclusion'' for the purposes of the National Environmental Policy Act. 16 CFR 1021.5(c). However, the proposed rule will decrease the number of samples that most manufacturers are required to test, and will likely lead to a small, beneficial effect on the environment because waste produced by the manufacture of excess samples, and the transport of those samples, will be reduced.

VIII. Paperwork Reduction Act

Currently, there is no paperwork collection burden associated with 16 CFR part 1201, and the proposed amendment to the regulation does not create any new paperwork collection burdens. Thus, no paperwork burden is associated with the proposed rule, and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) does not apply.

IX. Executive Order 12988 (Preemption)

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no state or political subdivision of a state may either establish or continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product, which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the federal standard. Section 9(h) of the CPSA provides that the Commission may by rule amend any consumer product safety rule. Therefore, the preemption provision of section 26(a) of the CPSA would apply to any rule issued under section 9(h).

X. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). Accordingly, if a final rule is issued, the amendment will go into effect 30 days after publication of a final rule.

XI. Incorporation by Reference

The Commission proposes to incorporate by reference ANSI Z97.1–2009$^{\varepsilon 2}$. The Office of the Federal Register (''OFR'') has regulations concerning incorporation by reference. 1 CFR part 51. The OFR recently revised these regulations to require that, for a proposed rule, agencies must discuss in the preamble to the NPR, ways that the materials that the agency proposes to incorporate by reference are reasonably available to interested persons, or how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the material. 1 CFR 51.5(a).

In accordance with the OFR's requirements, section II of this preamble summarizes the ANSI Z97.1–2009$^{\varepsilon 2}$ standard that the Commission proposes to incorporate by reference into 16 CFR part 1201. Interested persons may purchase a copy of ANSI Z97.1–2009$^{\varepsilon 2}$ from the following address. Attn: ANSI Customer Service Department, 25 W 43rd Street, 4th Floor, New York, NY 10036. The standard is also available for purchase from ANSI's Web site: *http://webstore.ansi.org/RecordDetail.aspx?sku=ANSI+Z97.1-2009.* A copy of the standard can also be inspected at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923.

XII. Request for Comments

The Commission invites interested persons to submit their comments to the Commission on any aspect of the proposed amendment. Comments should be submitted as provided in the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects in 16 CFR Part 1201

Administrative practice and procedure, Consumer protection, Imports, Labeling, Law enforcement, Incorporation by reference.

For the reasons stated in the preamble, the Consumer Product Safety Commission proposes to amend 16 CFR part 1201 as follows:

PART 1201—SAFETY STANDARD FOR ARCHITECTURAL GLAZING MATERIALS

■ 1. The authority citation for part 1201 continues to read as follows:

Authority: Secs. 2, 3, 7, 9, 14, 19. Pub.L. 92–573, 86 Stat. 1212–17; (15 U.S.C. 2051, 2052, 2056, 2058, 2063, 2068).

§ 1201.4 [Amended]

■ 2. Revise § 1201.4 to read as follows:

(a) Except as provided in § 1201.1(c) and (d), architectural glazing products shall be tested in accordance with all of the applicable test provisions of ANSI Z97.1–2009[ε2] ''*American National Standard for Safety Glazing Materials Used in Building—Safety Performance Specifications and Methods of Test.*'' The Director of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ANSI Customer Service Department, 25 W 43rd Street, 4th Floor, New York NY, 10036. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) [Reserved]

■ 3. Remove Figures 1 through 5 to Subpart A of Part 1201.

Dated: May 19, 2015.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2015–12438 Filed 5–21–15; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM15–18–000]

Commencement of Assessment of Annual Charges

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to revise its regulations regarding when the Commission will commence assessing annual charges to hydropower licensees and exemptees, other than state or municipal entities, with respect to licenses and exemptions authorizing unconstructed projects and new capacity. Specifically, the Commission proposes to commence assessing annual charges two years from the effective date of the project license, exemption, or amendment authorizing new capacity, rather than on the date that project construction starts. The proposed revisions will provide administrative efficiency and promote certainty among licensees, exemptees, and Commission staff as to when annual charges will commence.

DATES: Comments are due July 21, 2015.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways:

- Electronic filing through *http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format, rather than in a scanned format.
- Mail/Hand Delivery. Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: For detailed instructions for submitting comments and additional information on the rulemaking process, see the Comment Procedures section of this document.

FOR FURTHER INFORMATION CONTACT:

Tara DiJohn (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8671, *tara.dijohn@ferc.gov.*

Norman Richardson (Technical Information), Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6219, *norman.richardson@ferc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

1. Section 10(e)(1) of the Federal Power Act (FPA),[1] and section 3401 of the Omnibus Budget Reconciliation Act of 1986,[2] require the Federal Energy Regulatory Commission (Commission) to, among other things, collect annual charges from licensees in order to reimburse the United States for the costs of administering Part I of the FPA. The Commission assesses these annual charges against licensees and exemptees of projects with more than 1.5 megawatts (MW) of installed capacity under section 11.1 of its regulations.[3]

2. Currently, the Commission begins assessing these annual charges against licensees and exemptees with original licenses or exemptions authorizing unconstructed projects on the date project construction starts.[4] The Commission also begins assessing annual charges for new capacity, authorized by a relicense[5] or an amendment of a license or exemption, on the date that the construction to enable such capacity starts.[6] Because this proposed rule affects only projects with respect to which annual charges are assessed when project construction starts, we will not further discuss state or municipal projects, projects that do not have installed capacity that exceeds 1.5 MW, or constructed projects without newly authorized capacity.[7]

[1] 16 U.S.C. 803(e)(1) (2012).

[2] 42 U.S.C. 7178 (2012).

[3] 18 CFR 11.1 (2014).

[4] *Id.* (c)(5).

[5] We use the term ''relicense'' to refer to any new or subsequent license.

[6] 18 CFR 11.1(c)(5) (2014). We refer to the addition of capacity and a reduction of capacity (on occasion, capacity is reduced as a result of construction, in which case annual charges are lowered) as ''new capacity.''

[7] Licensees or exemptees that are state or municipal entities are already not assessed annual

3. Recently, to determine when project construction starts for annual charges purposes, the Commission has included language in its orders requiring the licensee or exemptee to notify the Commission when project construction begins.[8] Otherwise, the Commission has to contact the licensee or exemptee to determine that date.

4. Annual charges assessment should typically commence within two years of the effective date of the order issuing a license, exemption, or amendment adding capacity.[9] Original licenses and relicenses require a licensee to start construction no later than two years from the effective license date pursuant to section 13 of the FPA.[10] Similarly, exemptions of unconstructed projects include standard exemption Article 3, which allows the Commission to revoke an exemption if actual construction of the proposed generating facilities has not begun within two years.[11] Amendments adding new capacity include an ordering paragraph that typically requires the licensee or exemptee to start construction within two years of the amendment's issuance date.[12]

5. In some cases, construction may not begin by the two-year deadline and therefore annual charges assessment may begin more than two years after the effective date (*e.g.,* when a license's start of construction deadline is extended by the Commission for an additional period of no more than two years as permitted by section 13 of the FPA).[13] In rare cases, the Commission has granted requests for stay of a license's start of construction deadline, or of an entire license, in certain narrowly circumscribed circumstances.[14] On average, the Commission grants extensions and stays of a license's start of construction deadline 3.4 and zero [15] times per year, respectively.

6. Similarly, exemptees may not begin construction by the deadline, and may request that the Commission extend the deadline to start construction. The Commission expects the prompt development of exemption projects and that exemption applicants will anticipate and solve problems that affect construction either before or during the time that they seek their exemptions.[16] From 2010 through 2014, the Commission granted two extensions of start of construction deadlines, or on average 0.4 times per year, to exemptees.

7. Licensees and exemptees can experience delays and may request an extension of an amendment order's start of construction deadline as well. From 2010 through 2014, the Commission granted six initial extensions of a start of construction deadline, or an average of 1.2 extensions per year, to licensees granted amendments authorizing new capacity.

II. Proposed Revisions

8. The Commission proposes to revise section 11.1(c)(5) of its regulations regarding when it will commence assessing annual charges with respect to hydropower licenses and exemptions authorizing unconstructed projects and new capacity. Specifically, the Commission proposes to commence assessing annual charges two years from the effective date of an order issuing a license, exemption, or an amendment authorizing additional capacity, rather than on the date project construction starts.

9. The Commission anticipates the proposed rule will provide administrative efficiency and foster certainty among licensees, exemptees, and Commission staff as to when annual charges will commence. Licensees and exemptees will no longer need to notify the Commission when project construction starts for the purpose of assessing annual charges and, in turn, the Commission will not have to contact the licensee or exemptee for this purpose.

10. This proposed change, however, will affect those licensees and exemptees that do not start construction within two years. Annual charges will be assessed two years from the effective date of an order issuing a license, exemption, or an amendment authorizing additional capacity, regardless of whether the Commission has granted an extension of time for construction or a stay of the construction deadline.[17] As noted above, on average, 5 (3.4 licenses + 0.4 exemptions + 1.2 license amendments) affected projects each year receive extensions of the start of construction deadline, and zero receive a stay of the start of construction deadline.[18]

11. In addition, licensees and exemptees that do not start construction by the deadline established in their license or exemption, or as extended by the Commission, will be affected. If a licensee fails to start construction within two years of its license's effective date or as extended by the Commission, the Commission must terminate the license pursuant to section 13 of the FPA.[19] Similarly, as noted above, standard exemption Article 3 states that the Commission may revoke an exemption if the exemptee fails to start construction within the time prescribed by the Commission. From 2010 through 2014, the Commission terminated one license, or an average of 0.2 licenses per year, and no exemptions. Therefore, we estimate that annually 0.2 licenses would have been assessed annual charges after the two-year deadline until their termination for failure to construct.

12. In sum, we anticipate that, on average, 5.2 (5 extensions + 0.2 terminations) licensees and/or exemptees per year will begin paying annual charges before starting construction or before the Commission terminates its license or revokes its exemption under the proposed rule.

charges until project operation commences. 18 CFR 11.1(d)(6) (2014). As noted above, the Commission does not assess annual charges with respect to projects with installed capacity of less than or equal to 1.5 MW. Licensees or exemptees of constructed projects without new capacity are assessed annual charges immediately, because their entire capacity is already in place. *See* 18 CFR 11.1(c)(5) (2014).

[8] *See, e.g., Eagle Crest Energy Company,* 147 FERC ¶ 61,220, at Article 207 (2014) (requiring the licensee to notify the Commission of the date when it starts construction of the unconstructed project); *Wisconsin Electric Power Co.,* 144 FERC ¶ 62,268, at ordering para. (G) (2013) (requiring the licensee to notify the Commission of the date when it starts construction of the newly authorized capacity).

[9] Unless otherwise specified, orders are effective on the date of issuance. 18 CFR 385.2007(c)(1) (2014). On occasion, a relicense is issued before the expiration of the prior license. In that circumstance, the effective date would not be the date of issuance and would instead be established in the order to coincide with the expiration of the prior license.

[10] *See* 16 U.S.C. 806 (2012).

[11] 18 CFR 4.94(c) (2014).

[12] *See, e.g., Northern States Power Co.,* 138 FERC ¶ 62,022, at ordering para. (E) (2012).

[13] 16 U.S.C. 806 (2012).

[14] Such circumstances may exist where there are preconditions to construction that are beyond a licensee's control but will likely be resolved within a definitive period of time. *See City of Broken Bow, Oklahoma,* 142 FERC ¶ 61,118, at PP 8–9 (2013) (staying the start of construction deadline where City presented sufficient proof it would not be able to timely start project construction for reasons outside of its control).

[15] From 2010 through 2014, the Commission granted three requests for stays of construction deadlines to municipal licensees with projects at U.S. Army Corps of Engineers' dams.

[16] *Ralph and Raleigh Coppedge,* 28 FERC ¶ 61,363, at 61,654 & n.11 (1984) (citing, *FERC Stats. & Regs.,* Regulations Preambles 1977–1981 ¶ 30,204, at 31,368 (1980). *Exemption from All or Part of Part I of the Federal Power Act of Small Hydroelectric Power Projects With an Installed Capacity of Five Megawatts or Less, Order No. 106.*

[17] Additionally, this proposed change may affect any licensees and exemptees that utilize a phase-in approach for adding capacity.

[18] Stays of entire licenses, however, will continue to stay the assessment of annual charges.

[19] 16 U.S.C. 806 (2012).

III. Regulatory Requirements

A. Information Collection Statement

13. The Paperwork Reduction Act [20] requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB regulations require approval of certain information collection requirements contemplated by proposed rules.[21] The proposed revisions discussed above do not impose or alter existing reporting or recordkeeping requirements on applicable entities as defined by the Paperwork Reduction Act.[22] Therefore, the Commission will submit this proposed rule to OMB for informational purposes only.

B. Environmental Analysis

14. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[23] Commission actions concerning annual charges are categorically exempt from this requirement.[24]

C. Regulatory Flexibility Act

15. The Regulatory Flexibility Act of 1980 (RFA) [25] generally requires a description and analysis of proposed and final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and minimize any significant economic impact on a substantial number of small entities.[26]

16. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[27] The SBA revised its size standard for electric utilities (effective January 22, 2014) from a standard based on megawatt hours to a standard based on the number of employees, including affiliates.[28] Under SBA's current size standards, a hydroelectric generator is small if, including its affiliates, it employs 500 or fewer people.[29] The Commission, however, currently does not require information regarding the number of individuals employed by hydroelectric generators to administer Part I of the FPA, and therefore, is unable to estimate the number of small entities using the new SBA definitions. Regardless, the Commission anticipates that the proposed rule will affect few small hydroelectric generators.

17. As noted earlier, the proposed rule will only affect non-state or municipal licensed projects with an installed capacity exceeding 1.5 MW that are unconstructed or have newly authorized capacity. From 2010 through 2014, the Commission issued on average 3.6 original licenses and 0.4 exemptions per year authorizing unconstructed projects to affected licensees and exemptees, and 1.6 relicenses and 5 license amendments per year authorizing new capacity. In sum, on average a total of 10.6 licensees and exemptees may be affected by the proposed rule annually.

18. Of the 10.6 total entities, only those that do not start construction within two years, or receive a stay of their license, will be negatively affected by the acceleration of annual charges. As noted above, on average, 5.2 affected licensees and/or exemptees per year do not start construction within two years. Conversely, small entities that would otherwise start construction before the two year mark after their effective date will benefit from the proposed rule as it delays the commencement of their annual charges.

19. Accordingly, pursuant to section 605(b) of the RFA, the Commission certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

D. Comment Procedures

20. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due July 21, 2015. Comments must refer to Docket No. RM15–18–000, and must include the commenter's name, the organization they represent, if applicable, and their address.

21. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

22. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

23. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

E. Document Availability

24. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

25. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

26. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

List of Subjects in 18 CFR Part 11

Electric power, Reporting and recordkeeping requirements.

By direction of the Commission.

Issued: May 14, 2015

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend Part 11, Chapter I, Title 18, *Code of Federal Regulations,* as follows:

[20] 44 U.S.C. 3501–3521 (2012).

[21] *See* 5 CFR 1320.11 (2014).

[22] 44 U.S.C. 3502(2)–(3) (2012).

[23] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, 52 FR 47,897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (1987).

[24] *See* 18 CFR 380.4 (a)(11) (2014).

[25] 5 U.S.C. 601–612 (2012).

[26] 5 U.S.C. 603(c) (2012).

[27] 13 CFR 121.101 (2014).

[28] SBA Final Rule on ''Small Business Size Standards: Utilities,'' 78 FR 77,343 (Dec. 23, 2013).

[29] 13 CFR 121.201, Sector 22, Utilities (2014).

PART 11—ANNUAL CHARGES UNDER PART I OF THE FEDERAL POWER ACT

■ 1. The authority citation for Part 11 continues to read as follows:

Authority: 16 U.S.C. 792–828c; 42 U.S.C. 7101–7352.

■ 2. Revise § 11.1(c)(5) to read as follows:

§ 11.1 Costs of administration.

* * * * *

(c) * * *

(5) For unconstructed projects, the assessments start two years after the effective date of the license or exemption. For constructed projects, the assessments start on the effective date of the license or exemption, except for any new capacity authorized therein. The assessments for new authorized capacity start two years after the effective date of the license, exemption, or amendment, authorizing such new capacity. In the event that assessment commences during a fiscal year, the charges will be prorated based on the date of commencement.

* * * * *

[FR Doc. 2015–12432 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF STATE

22 CFR Parts 120, 123, 124, 125, and 126

RIN 1400–AC88

[Public Notice 9139]

Amendment to the International Traffic in Arms Regulations: Exports and Temporary Imports Made to or on Behalf of a Department or Agency of the U.S. Government; Procedures for Obtaining State Department Authorization To Export Items Subject to the Export Administration Regulations; Revision to the Destination Control Statement; and Other Changes

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: As part of the President's Export Control Reform (ECR) effort, the Department of State is proposing to amend the International Traffic in Arms Regulations (ITAR) to: clarify regulations pertaining to the export of items subject to the Export Administration Regulations (EAR); revise the licensing exemption for exports made to or on behalf of an agency of the U.S. government; revise the destination control statement in ITAR § 123.9 to harmonize the language with the EAR; and make several minor edits for clarity. The proposed revisions contained in this rule are part of the Department of State's retrospective plan under E.O. 13563.

DATES: The Department of State will accept comments on this proposed rule until July 6, 2015.

ADDRESSES: Interested parties may submit comments by one of the following methods:

- Email: *DDTCPublicComments@state.gov* with the subject line, ''ITAR Amendment—To or on behalf of'';
- Internet: At *www.regulations.gov,* search for this proposed rule by using this proposed rule's RIN (1400–AC88).

Comments received after that date will be considered if feasible, but consideration cannot be assured. Those submitting comments should not include any personally identifying information they do not desire to be made public or information for which a claim of confidentiality is asserted because those comments and/or transmittal emails will be made available for public inspection and copying after the close of the comment period via the Directorate of Defense Trade Controls Web site at *www.pmddtc.state.gov.* Parties who wish to comment anonymously may do so by submitting their comments via *www.regulations.gov,* leaving the fields that would identify the commenter blank and including no identifying information in the comment itself. Comments submitted via *www.regulations.gov* are immediately available for public inspection.

FOR FURTHER INFORMATION CONTACT: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email *DDTCPublicComments@state.gov.* ATTN: ITAR Amendment—To or on behalf of. The Department of State's full retrospective plan can be accessed at *http://www.state.gov/documents/organization/181028.pdf.*

SUPPLEMENTARY INFORMATION: The Department proposes to make the following revisions in this rule:

Items subject to the EAR: This proposed rule adds clarifying language to various provisions of the ITAR pertaining to the export of items subject to the EAR pursuant to a Department of State authorization, when such exports are made in conjunction with items subject to the ITAR. These revisions include guidance on the use of licensing exemptions for export of such items, as well as clarification that items subject to the EAR are not considered defense articles, even when exported under a license or other approval (to include exemptions, *see* § 120.20) issued by the Department of State.

Items exported to or on behalf of an agency of the U.S. government: This proposed rule revises the licensing exemption language in ITAR § 126.4 to clarify when exports may be made to or on behalf of an agency of the U.S. government without a license. Additionally, the scope of this exemption is expanded in that it will allow for permanent exports, rather than only temporary exports. The Department seeks comments from the public on whether the proposed revision adequately eliminates ambiguity as to when the exemption may be applied, and whether it creates any unintended compliance burden.

Revision to the Destination Control Statement: This proposed rule revises the destination control statement in ITAR § 123.9 to harmonize its language with the EAR. This change is being made to facilitate the President's Export Control Reform initiative, which has transferred thousands of formerly ITAR-controlled defense article parts and components, along with other items, to the Commerce Control List in the EAR under the jurisdiction of the Department of Commerce.

This change in jurisdiction for many parts and components, along with other items, for military systems has increased the incidence of exporters shipping articles subject to both the ITAR and the EAR in the same shipment. Both regulations have a mandatory destination control statement that must be on the export control documents for shipments that include items subject to both sets of regulations. This has caused confusion to exporters as to which statement to include on mixed shipments, or whether to include both. Harmonizing these statements will ease the regulatory burden on exporters.

Procedures for Obtaining State Department Authorization to Export Items Subject to the EAR: This proposed rule revises the ITAR in a number of places to clarify how parties may obtain authorization from the Department to export or retransfer items subject to the EAR. Section 120.5 is revised to clarify that items subject to the EAR may be authorized pursuant to an exemption with certain conditions. A new paragraph (d) is added to ITAR § 123.9 to clarify the requirements for retransferring items subject to the EAR pursuant to a letter of General Correspondence. Section 124.16 is revised to clarify that the special retransfer authorization of this section may be used for items subject to the EAR with certain conditions.

Other changes in this rule: The Department proposes to make a number of minor edits to the ITAR that will address erroneous or outdated reporting requirements. This rule would remove the requirement to provide seven paper copies for various export license requests in §§ 124.7, 124.12, 124.14, 125.2, 125.7 and 126.9, which has not been necessary for many years due to the use of electronic license submissions, change the identification of the agency responsible for permanent import authorizations in § 123.4 from the Department of the Treasury to Department of Justice, and impose the Code of Federal Regulations paragraph structure on § 124.8. Additionally, the Department proposes removing the pilot filing requirement found in § 123.13, given that it does not take into account the practices of modern airport operations and is no longer necessary.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States government and that rules implementing this function are exempt from §§ 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act (APA). Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department is publishing this rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function.

Regulatory Flexibility Act

Since the Department of State is of the opinion that this proposed rule is exempt from the provisions of 5 U.S.C. 553, there is no requirement for an analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This proposed rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

The Department does not believe this rulemaking is a major rule as defined in 5 U.S.C. 804.

Executive Orders 12372 and 13132

This proposed rulemaking 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. Therefore, in accordance with Executive Order 13132, it is determined that this proposed rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this proposed rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These executive orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. These rules have been designated ''significant regulatory actions,'' although not economically significant, under Executive Order 12866. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

The Department of State has reviewed this proposed rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this proposed rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the provisions of Executive Order 13175 do not apply to this proposed rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35. This rule removes provisions that previously required the applicant to provide seven additional copies for various export license requests. The Department believes that there will be little or no practical burden reduction since the use of electronic methods of filing has made the requirement for ''seven copies'' obsolete.

The following information collections are affected by this rulemaking:

1. Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data, OMB Control No. 1405–0003;
2. Application/License for Temporary Import of Unclassified Defense Articles, OMB Control No. 1405–0013;
3. Application/License for the Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Classified Technical Data, OMB Control No. 1405–0022;
4. Application/License for Temporary Export of Unclassified Defense Articles, OMB Control No. 1405–0023;
5. Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Technical Data OMB Control No. 1405–0092;
6. Request for Approval of Manufacturing License Agreements, Technical Assistance Agreements, and Other Agreements, OMB Control No. 1405–0093;
7. Request to Change End User, End Use and/or Destination of Hardware, OMB Control No. 1405–00173; and
8. Request for Advisory Opinion, OMB Control No. 1405–0174.

The Department is requesting public comment on its estimate that there will be little or no change in the burdens associated with these information collections as a result of this rulemaking.

Date: Comments will be accepted until July 21, 2015.

Addresses: Interested parties may submit comments within 60 days of the date of publication by one of the following methods:

- *Email: DDTCPublicComments@state.gov,* with the subject line ''AC88 PRA Burden Reduction'';
- *Internet: At www.regulations.gov;* please search for this proposed rule by using this proposed rule's RIN (1400–AC88) and indicate that you are commenting on the paperwork burden change in any (or all) of the eight information collections identified above.

List of Subjects

22 CFR Parts 120 and 125

Arms and munitions, Classified information, Exports.

22 CFR Part 123

Arms and munitions, Exports, Reporting and recordkeeping requirements.

22 CFR Part 124

Arms and munitions, Exports, Technical assistance.

22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, parts 120, 123, 124, 125, and 126 are proposed to be amended as follows:

PART 120—PURPOSE AND DEFINITIONS

■ 1. The authority citation for part 120 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920; Pub. L. 111–266; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 2. Section 120.5 is amended by revising the section heading and paragraph (b) to read as follows:

§ 120.5 Relation to regulations of other agencies; export of items subject to the EAR.

* * * * *

(b) A license or other approval (*see* § 120.20) from the Department of State granted in accordance with this subchapter may also authorize the export of items subject to the EAR (*see* § 120.42). Items subject to the EAR may be exported pursuant to an exemption (*see* parts 124, 125, and 126 of this subchapter), provided the items subject to the EAR are for use in or with defense articles authorized under a license or other approval. Separate approval from the Department of Commerce is not required for these items when approved for export under a Department of State license or other approval. Those items subject to the EAR exported pursuant to a Department of State license or other approval would remain under the jurisdiction of the Department of Commerce for any subsequent transactions. The inclusion of items subject to the EAR on a Department of State license or other approval does not change the licensing jurisdiction of the items. (*See* § 123.1(b) of this subchapter for guidance on identifying items subject to the EAR in a license application to the Department of State.)

PART 123—LICENSES FOR THE EXPORT AND TEMPORARY IMPORT OF DEFENSE ARTICLES

■ 3. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261, 112 Stat. 1920; Sec. 1205(a), Pub. L. 107–228; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 4. Section 123.4 is amended by revising paragraph (a)(4) to read as follows:

§ 123.4 Temporary import license exemptions.

(a) * * *

(4) Has been rejected for permanent import by the Department of Justice and is being returned to the country from which it was shipped; or

* * * * *

■ 5. Section 123.9 is amended by revising paragraphs (b)(1) and (2), and adding paragraph (d) to read as follows:

§ 123.9 Country of ultimate destination and approval of reexports or retransfers.

* * * * *

(b) * * *

(1) The exporter must incorporate the following information as an integral part of the bill of lading, air waybill, or other shipping document, and the purchase documentation or invoice whenever defense articles are to be exported, retransferred, or reexported pursuant to a license or other approval under this subchapter:

(i) The country of ultimate destination;

(ii) The end-user;

(iii) The license or other approval number or exemption citation; and

(iv) The following statement: ''These items are controlled and authorized by the U.S. government for export only to the country of ultimate destination for use by the end-user herein identified. They may not be resold, transferred, or otherwise be disposed of, to any other country or to any person other than the authorized end-user or consignee(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations.''

(2) When exporting items subject to the EAR (see §§ 120.42 and 123.1(b) of this subchapter) pursuant to a Department of State license or other approval, the U.S. exporter must also provide the end-user and consignees with the appropriate EAR classification information for each item exported pursuant to a U.S. Munitions List ''(x)'' paragraph. This includes the Export Control Classification Number (ECCN) or EAR99 designation.

* * * * *

(d) The Directorate of Defense Trade Controls may authorize reexport or retransfer of an item subject to the EAR provided that:

(1) The item was initially exported, reexported or transferred pursuant to a Department of State license or other approval;

(2) The item is for end-use in or with a defense article; and,

(3) All requirements of paragraph (c) of this section are satisfied for the item subject to the EAR, as well as for the associated defense article.

* * * * *

■ 6. Revise § 123.13 to read as follows:

§ 123.13 Domestic aircraft shipments via a foreign country.

A license is not required for the shipment by air of a defense article from one location in the United States to another location in the United States via a foreign country.

PART 124—AGREEMENTS, OFF SHORE PROCUREMENT, AND OTHER DEFENSE SERVICES

■ 7. The authority citation for part 124 continues to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 8. Section 124.7 is amended by designating the introductory text as paragraph (a), adding and reserving paragraph (b), and revising paragraph (a)(1) to read as follows:

§ 124.7 Information required in all manufacturing license agreements and technical assistance agreements.

(a) * * *

(1) The agreement must describe the defense article to be manufactured and all defense articles to be exported, including any test and support equipment or advanced materials. They should be described by military nomenclature, contract number, National Stock Number, nameplate data, or other specific information. Only defense articles listed in the agreement will be eligible for export under the exemption in § 123.16(b)(1) of this subchapter. * * *

(b) [Reserved]

■ 9. Section 124.8 is amended by designating the introductory text as paragraph (a) and adding and reserving paragraph (b), as follows:

§ 124.8 Clauses required both in manufacturing license agreements and technical assistance agreements.

* * * * *

(b) [Reserved]

* * * * *

■ 10. Section 124.12 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 124.12 Required information in letters of transmittal.

(a) An application for the approval of a manufacturing license or technical assistance agreement with a foreign person must be accompanied by an explanatory letter. The explanatory letter shall contain:

* * * * *

■ 11. Section 124.14 is amended by revising the introductory text of paragraph (e) to read as follows:

§ 124.14 Exports to warehouses or distribution points outside the United States.

* * * * *

(e) *Transmittal letters.* Requests for approval of warehousing and distribution agreements with foreign persons must be made by letter. The letter shall contain:

* * * * *

■ 12. Section 124.16 is revised to read as follows:

§ 124.16 Special retransfer authorizations for unclassified defense articles and defense services to member states of NATO and the European Union, Australia, Japan, New Zealand, and Switzerland.

(a) The provisions of § 124.8(a)(5) notwithstanding, the Department may approve access to unclassified defense articles and items subject to the EAR (*see* § 120.42 of this subchapter) exported in furtherance of or produced as a result of a TAA/MLA, retransfer of technical data and defense services, and retransfer of technology subject to the EAR and authorized under a TAA/MLA, to individuals who are dual national or third-country national employees of the foreign signatory or its approved sub-licensees, provided that:

(1) The transfer is to dual nationals or third-country nationals who are bona fide regular employees, directly employed by the foreign signatory or approved sub-licensees;

(2) The individuals are exclusively of countries that are members of NATO, the European Union, Australia, Japan, New Zealand, and Switzerland;

(3) Their employer is a signatory to the agreement or has executed a Non-Disclosure Agreement; and

(4) The retransfer takes place completely within the physical territories of the countries listed in paragraph (a)(2) of this section or the United States.

(b) Permanent retransfer of hardware is not authorized pursuant to paragraph (a) of this section.

PART 125—LICENSES FOR THE EXPORT OF TECHNICAL DATA AND CLASSIFIED DEFENSE ARTICLES

■ 13. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2 and 38, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778); 22 U.S.C. 2651a; E.O. 13637, 78 FR 16129.

■ 14. Section 125.2 is amended by revising paragraph (a) to read as follows:

§ 125.2 Exports of unclassified technical data.

(a) *License.* A license (DSP–5) is required for the export of unclassified technical data unless the export is exempt from the licensing requirements of this subchapter. In the case of a plant visit, details of the proposed discussions must be transmitted to the Directorate of Defense Trade Controls for an appraisal of the technical data.

* * * * *

■ 15. Section 125.7 is amended by revising paragraph (b) to read as follows:

§ 125.7 Procedures for the export of classified technical data and other classified defense articles.

* * * * *

(b) An application for the export of classified technical data or other classified defense articles must be accompanied by a completed Form DSP–83 (see § 123.10 of this subchapter). All classified materials accompanying an application must be transmitted to the Directorate of Defense Trade Controls in accordance with the procedures contained in the Department of Defense National Industrial Security Program Operating Manual (unless such requirements are inconsistent with guidance provided by the Directorate of Defense Trade Controls, in which case the latter guidance must be followed).

PART 126—GENERAL POLICIES AND PROVISIONS

■ 16. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205; 3 CFR, 1994 Comp., p. 899; Sec. 1225, Pub. L. 108–375; Sec. 7089, Pub. L. 111–117; Pub. L. 111–266; Section 7045, Pub. L. 112–74; Section 7046, Pub. L. 112–74; E.O. 13637, 78 FR 16129.

■ 17. Section 126.4 is revised to read as follows:

§ 126.4 Exports and temporary imports made to or on behalf of a department or agency of the U.S. government.

(a) A license is not required for the export or temporary import of a defense article or the performance of a defense service, when made:

(1) To a department or agency of the U.S. government for official use. Defense articles exported or temporarily imported under this provision may only be provided to a regular employee or contractor support personnel of the U.S. government;

Note 1 to paragraph (a): Contractor support personnel means those U.S. persons who provide administrative, managerial, scientific or technical support under contract with a U.S. government department or agency within a U.S. government owned or operated facility or under the direct supervision of a regular U.S. government employee (*e.g.,* Federally Funded Research and Development Center or Systems Engineering and Technical Assistance contractors). For purposes of this section, private security contractors are not considered contractor support personnel, and ''direct supervision'' refers to the control over the manner and means in which contractor support personnel conduct their day-to-day work activities as well as control over the contractor's access to defense articles authorized under this paragraph.

Note 2 to paragraph (a): Any retransfer, reexport, disposal, or change in end-user of a defense article exported pursuant to this section must be performed in accordance with § 123.9 of this subchapter.

(2)(i) By, or on behalf of, a department or agency of the U.S. government for carrying out any foreign assistance, cooperative project, or sales program authorized by law and subject to control by the President by other means, provided:

(A) Items subject to the EAR and controlled for missile technology (MT) reasons (*see* § 742.5 of the EAR (15 CFR 742.5) are not authorized for export under this subsection; and

(B) The United States government performs or directs all aspects of the transaction (export, carriage, and delivery abroad) or the export is covered by a U.S. government Bill of Lading.

(ii) This section does not authorize a U.S. government agency to act as a transmittal agent on behalf of a private individual or firm, either as a convenience or in satisfaction of security requirements.

Note to paragraph (a)(2): Approval of a foreign assistance, cooperative project, or sales program authorizing a U.S. government department and agency to permanently export a defense article described on the Missile Technology Control Regime Annex should be reviewed by the Missile Technology Export Committee, unless

authorized by statutory authority providing export authority notwithstanding the Arms Export Control Act.

(b) This section does not authorize any department or agency of the U.S. government to make any export that is otherwise prohibited by virtue of other administrative provisions or by any statute.

(c) An Electronic Export Information (EEI) filing, required under § 123.22 of this subchapter, and a written statement by the exporter certifying that these requirements have been met must be presented at the time of export to the appropriate Port Directors of U.S. Customs and Border Protection or Department of Defense transmittal authority. For any export made pursuant to paragraph (a)(1) of this section, the shipment documents (bill of lading, airway bill, or other transportation documents) must include the following statement:

''For official use by [insert U.S. government department or agency]. Property will not enter the trade of the country to which it is shipped. No export license required per CFR Title 22, section 126.4. U.S. government point of contact: [insert name and telephone number]''.

■ 18. Section 126.9 is amended by revising paragraph (a) to read as follows:

§ 126.9 Advisory opinions and related authorizations.

(a) *Advisory opinion.* A person may request information from the Directorate of Defense Trade Controls on whether it would likely grant a license or other approval for a particular defense article or defense service to a particular country. Such information from the Directorate of Defense Trade Controls is issued on a case-by-case basis and applies only to the particular matters presented to the Directorate of Defense Trade Controls. These opinions are not binding on the Department of State and may not be used in future matters before the Department. A request for an advisory opinion must be made in writing and must outline in detail the equipment, its usage, the security classification (if any) of the articles or related technical data, and the country or countries involved.

* * * * *

Rose E. Gottemoeller,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2015–12295 Filed 5–21–15; 8:45 am]

BILLING CODE 4710–25–P

COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

28 CFR Part 810

RIN 3225–AA00

Community Supervision: Administrative Sanctions and GPS Monitoring as a Supervision Tool

AGENCY: Court Services and Offender Supervision Agency for the District of Columbia.

ACTION: Proposed rule.

SUMMARY: In this document, the Court Services and Offender Supervision Agency for the District of Columbia (CSOSA) is proposing to amend its current rule regarding the conditions of release requirements for offenders under CSOSA supervision. In addition, CSOSA will expand the language of the regulation to detail and provide notice of when CSOSA Community Supervision Officers will use electronic monitoring as a tool to assist in supervision.

DATES: Comments must be submitted July 21, 2015.

ADDRESSES: Address all comments concerning this proposed rule to the Office of General Counsel, CSOSA, 13th Floor, 633 Indiana Avenue NW., Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Stephanie Carrigg, Assistant General Counsel, at (202) 220–5352 or by email at *stephanie.carrigg@csosa.gov.* Questions about this publication are welcome, but inquiries concerning individual cases cannot be answered over the telephone.

SUPPLEMENTARY INFORMATION: The Court Services and Offender Supervision Agency for the District of Columbia (CSOSA) is proposing to amend its regulations concerning the conditions of release requirements for offenders under CSOSA supervision. Specifically, these regulations pertain to the conditions of release that are imposed on an offender when under CSOSA supervision; specifically, the requirement to maintain a certain frequency of face-to-face contact with one's community supervision officer, and the conditions of release that are articulated in the accountability contract that the offender signs with CSOSA. These regulations also detail the consequences that an offender may face for violating the conditions of his or her supervision.

With this amendment, CSOSA will revise the language to reflect that the regulations apply to probationers as well as parolees, and to offenders who are under supervised release. In addition, CSOSA will expand the language of the regulation to detail and provide notice of when CSOSA Community Supervision Officers will use electronic monitoring as a tool to assist in supervision. Currently, the regulations only reference electronic monitoring as an administrative sanction for an offender who has violated the general or specific conditions of release or who has engaged in criminal activity. The amended language will specify the circumstances under which electronic monitoring is used as a supervision tool, including but not limited to: instances when CSOSA's Community Supervision Services (CSS) Division issues directives to place offenders who fit a certain criminal behavioral pattern on electronic monitoring; and instances when CSS makes an individualized determination to place an offender on electronic monitoring based on an offender's noncompliance with the conditions of his supervised release or for other extenuating circumstances.

Matters of Regulatory Procedure

Administrative Procedure Act

CSOSA is publishing the proposed rule for notice and comment as required by 5 U.S.C. 553(b)(3)(B).

Executive Order 12866

CSOSA has determined that the proposed rule is not a significant rule within the meaning of Executive Order 12866.

Executive Order 13132

The proposed 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. Under Executive Order 13132, this rule does not have sufficient federalism implications requiring a Federalism Assessment.

Regulatory Flexibility Act

The proposed rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act of 1995

The proposed rule will not cause State, local, or tribal governments, or the private sector, to spend $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. No action under the Unfunded Mandates Reform Act of 1995 is necessary.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E—Congressional Review Act)

The proposed rule is not a ''major rule'' as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 Subtitle E—Congressional Review Act), now codified at 5 U.S.C. 804(2). The rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on the ability of United States-based companies to compete with foreign-based companies. Moreover, this is a rule of agency practice or procedure that does not substantially affect the rights or obligations of non-agency parties, and does not come within the meaning of the term ''rule'' as used in Section 804(3)(C), now codified at 5 U.S.C. 804(3)(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Authority: D.C. Code 24–1233(b)(2)(B).

List of Subjects in 28 CFR Part 810

Probation and parole.

For the reasons set forth in the preamble, CSOSA proposes to revise 28 CFR part 810 to read as follows:

Part 810—Community Supervision: Administrative Sanctions and GPS Monitoring as a Supervision Tool

Sec.
810.1 Supervision contact requirements.
810.2 Accountability contract.
810.3 Consequences of violating the conditions of supervision.
810.4 Community supervision: Global Position System monitoring.

Authority: Pub. L. 105–33, 111 Stat. 712 (D.C. Code 24–1233(b)(2)(B)).

§ 810.1 Supervision contact requirements.

If you are an offender under supervision by the Court Services and Offender Supervision Agency for the District of Columbia (''CSOSA''), CSOSA will establish a supervision level for you and your minimum contact requirement (that is, the minimum frequency of face-to-face interactions between you and a Community Supervision Officer (''CSO'')).

§ 810.2 Accountability contract.

(a) Your CSO will instruct you to acknowledge your responsibilities and obligations of being under supervision (whether through probation, parole, or supervised release as granted by the releasing authority) by agreeing to an accountability contract with CSOSA.

(b) The CSO is responsible for monitoring your compliance with the conditions of supervision. The accountability contract identifies the following specific activities constituting substance abuse or non-criminal violations of your conditions of supervision. The activities that constitute violations include, but are not limited to, the activities listed in paragraphs (b)(1) and (2) of this section.

(1) *Substance abuse violations.* (i) Having a positive drug test.

(ii) Failing to report for drug testing.

(iii) Failing to appear for treatment sessions.

(iv) Failing to complete inpatient/outpatient treatment programming.

(2) *Non-criminal violations.* (i) Failing to report to the CSO.

(ii) Leaving the judicial district without the permission of the CSO.

(iii) Failing to work regularly or attend training and/or school.

(iv) Failing to notify the CSO of a change of address and/or employment.

(v) Frequenting places where controlled substances are illegally sold, used, distributed, or administered.

(vi) Associating with persons engaged in criminal activity.

(vii) Associating with a person convicted of a felony without the permission of the CSO.

(viii) Failing to notify the CSO within 48 hours of being arrested or questioned by a law enforcement officer.

(ix) Entering into an agreement to act as an informer or act in a confidential relationship with a law enforcement agency without the permission of the releasing authority.

(x) Failing to adhere to any general or special condition of release.

(c) The accountability contract will identify a schedule of administrative sanctions (see § 810.3(b)) that may be imposed for your first violation and for subsequent violations.

(d) The accountability contract will provide for positive reinforcements for compliant behavior.

§ 810.3 Consequences of violating the conditions of supervision.

(a) If your CSO has reason to believe that you are failing to abide by the general or specific conditions of release or you are engaging in criminal activity, you will be in violation of the conditions of your supervision. Your CSO may then impose administrative sanctions (see paragraph (b) of this section) and/or request a hearing by the releasing authority. This hearing may result in the revocation of your release or changes to the conditions of your release.

(b) Administrative sanctions available to the CSO include, but are not limited to:

(1) Agency or releasing authority reprimand (oral or written)

(2) Daily check-in with Agency supervision for a specified period of time;

(3) Increased group activities for a specified period of time;

(4) Increased drug testing;

(5) Increased supervision contact requirements;

(6) Referral for substance abuse addiction or other specialized assessments;

(7) Global Position System (GPS) monitoring for a specified period of time;

(8) Community service for a specified number of hours;

(8) Placement in a residential sanctions facility or residential treatment facility for a specified period of time; and

(9) Travel restrictions.

(c) You remain subject to further action by the releasing authority. For example, the releasing authority may override the imposition of any of the sanctions in paragraph (b) of this section and issue a warrant or summons if it finds that you are a risk to the public safety or that you are not complying in good faith with the sanctions (see 28 CFR 2.85(a)(15)).

§ 810.4 Community supervision: Global Position System monitoring.

(a) In addition to being placed on Global Position System (GPS) monitoring as a condition of release (see 28 CFR 2.85(b); DC Code section 24–131(a)(3)), or as an administrative sanction, (see § 810.3(b)), CSOSA may place you on GPS monitoring as a tool to assist with your supervision. Circumstances under which a CSO may place you on GPS monitoring include, but are not limited to, the following events:

(1) *CSS-issued directives to place offenders who fit a certain profile on GPS monitoring.* Pursuant to intelligence received or deterrence efforts initiated by law enforcement, CSOSA may elect to place a group of offenders that fit a certain criminal behavioral pattern on GPS monitoring. Separately, and as a result of information that is already in the Agency's possession, CSOSA may issue directives to supervision staff to place offenders who meet certain characteristics on GPS monitoring. In all of the aforementioned instances, the decision to place a group of offenders on GPS monitoring ultimately rests with CSOSA.

(2) *Individualized determinations to place offenders on GPS monitoring.* CSOs make individualized

determinations as to whether to place offenders on GPS monitoring. If an offender is engaged in behavior that puts the offender at a high risk for reoffending or for harm to the offender or others, the offender's CSO may elect to place that offender on GPS monitoring. In all of the aforementioned instances, the decision to place an offender on GPS monitoring ultimately lies with the CSO, although it is subject to review and approval by the CSO's supervisory chain of command.

(b) Unless the releasing authority specifies a different timeframe, CSOSA will place an offender on GPS monitoring for an initial period of thirty (30) days. An offender's CSO may extend the monitoring period for up to ninety (90) days. Extensions past ninety (90) days may be done in thirty (30) day increments and must be reviewed and approved by a Supervisory CSO (SCSO).

Dated: May 15, 2015.

Diane Bradley,

Assistant General Counsel.

[FR Doc. 2015–12204 Filed 5–21–15; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 114

[Docket ID: DOD–2014–OS–0131]

RIN 0790–AJ31

Victim and Witness Assistance

AGENCY: Under Secretary of Defense for Personnel and Readiness (USD(P&R)), DoD.

ACTION: Proposed rule.

SUMMARY: This regulatory action updates established policy, assigned responsibilities, and prescribed procedures for the rights of crime victims under the Uniform Code of Military Justice (UCMJ). The rule discusses notification requirements and assistance available to victims and witnesses of crime, as well as annual reporting requirements on assistance provided across the DoD to victims and witnesses of crime.

DATES: Written comments must be received on or before July 21, 2015.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

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://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Lt. Col. Ryan Oakley, Office of Legal Policy, 703–571–9301.

SUPPLEMENTARY INFORMATION: The Department of Defense is determined to assist victims and witnesses of violent crimes committed in violation of the Uniform Code of Military Justice (UCMJ).

I. Purpose of the Regulatory Action

a. This rule establishes policy, assigns responsibilities, and prescribes procedures to assist victims and witnesses of crimes committed in violation the Uniform Code of Military Justice (UCMJ), and updates established policy, assigns responsibilities, and prescribes procedures for the rights of crime victims under the UCMJ and required mechanisms for enforcement. The rule also provides timely notification of information and assistance available to victims and witnesses of crime from initial contact through investigation, prosecution, confinement, and release, annual reporting requirements on assistance provided across the DoD to victims and witnesses of crime, and legal assistance for crime victims entitled to such services. The Military Services are required to provide legal counsel, known as Special Victims' Counsel/Victims' Legal Counsel (SVC/VLC), to assist victims of alleged sex-related offenses under Articles 120, 120a, 120b, 120c, and 125 of the UCMJ, who are eligible for legal assistance. The Military Services are also required to establish a special victim capability comprised of specially trained criminal investigators, judge advocates, paralegals, and victim/witness assistance personnel to support victims of covered special victim offenses. To de-conflict with ''Special Victims' Counsel'' programs, this distinct group of recognizable professionals will be referred to, at the DoD level, as the ''Special Victim Investigation and Prosecution (SVIP)'' capability.

b. Authority: 10 U.S.C. chapter 47, the UCMJ; 10 U.S.C. 113, 1034, 1044, 1044e 1058, 1059, and 1408; 18 U.S.C. 1512 through 1514; sections 1701 and 1716 of Public Law 113–66, which strengthened the rights of victims of crimes committed under the UCMJ, and designated SVC/VLC for victims of covered offenses; section 573 of Public Law 112–239, which required the Military Services to establish a special victim capability comprised of specially trained investigators, judge advocates, paralegals, and victim witness assistance personnel to support victims of covered offenses; and section 533 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015, which extended eligibility for SVC/VLC services to members of a reserve component of the armed forces.

II. Summary of the Major Provisions of the Regulatory Action in Question

This rule describes the responsibilities that the USD(P&R), Inspector General of the Department of Defense, and DoD component heads have when dealing with the procedures described in the regulatory text. The rule also discusses procedures involving local responsible officials, comprehensive information and services to be provided to victims and witnesses, special victim investigation and prosecution (SVIP) capability, legal assistance for crime victims, and special victims' counsel programs.

III. Costs and Benefits

The combined cost of annual reporting requirements to the DoD and Military Services related to DoD victim and witness assistance programs (VWAP) is approximately $12,317. DoD VWAP programs are administered directly by the DoD Components, including the Military Services, at local installations and regional commands worldwide.

(1) A complete victim and witness assistance policy, to ensure the consistent and effective management of DoD victim and witness assistance programs operated by DoD Components. The proposed rule updates and replaces DoD Directive 1030.01, ''Victim and Witness Assistance'' (April 13, 2004) (available at *http://www.dtic.mil/whs/directives/corres/pdf/103001p.pdf*), and DoD Instruction 1030.2 ''Victim and Witness Procedures'' (June 4, 2004) (available at *http://www.dtic.mil/whs/directives/corres/pdf/103002p.pdf*), to implement statutory requirements for the DoD victim assistance programs

under the a single DoD instruction., which revises the rights for crime victims of offenses committed under the UCMJ, requires the Military Services to create enforcement mechanisms, provides for legal assistance for crime victims entitled to legal services, requires that Military Services to provide SVC/VLC to assist victims of covered offenses, and further implements the SVIP capability, which provides enhanced support to victims of sexual assault, serious domestic violence, and child abuse offenses. requiring each Military Service to establish a special victim capability comprised of specially trained criminal investigators, judge advocates, paralegals, and victim witness personnel to enhance support to victims of sexual assault, serious domestic violence, and child abuse offenses.

VWAP provides guidance for assisting victims and witnesses of crime from initial contact through investigation, prosecution, confinement, and release, until the victim specifies to the local responsible official that he or she no longer requires or desires services. Particular attention is paid to victims of serious and violent crime, including child abuse, domestic violence, and sexual assault.

(2) Strengthens the rights of crime victims in the military justice system and requires the establishment mechanisms for enforcement of these rights in each Military Department, in accordance with section 1701 of Public Law 113–66. These provisions ensure victims have a right to be reasonably heard at public hearings concerning the continuation of confinement before the trial of the accused, preliminary hearings under section 832 (Article 32) of the UCMJ, and court-martial proceedings relating to the Military Rules of Evidence (M.R.E.) 412, 513, and 514 of the Manual for Courts-Martial (MCM) (available at *http://www.apd.army.mil/pdffiles/mcm.pdf*) and that all victims are treated with fairness and respect for their dignity and privacy.

(3) Orients victims and witnesses to the military justice system, about the military criminal justice process, on the role of the victim or witness in the process, and how the victim or witness can obtain additional information concerning the process and the case.

(4) Provides timely notification of information and assistance available to victims and witnesses of crime from initial contact through investigation, prosecution, and confinement.

(5) Enables victims to confer with the attorney for the U.S. Government in the case before preliminary and trial proceedings, and to express their views to the commander or convening authority as to disposition of the case.

(6) Assists victims with prompt return of personal property held as evidence during a military criminal investigation and court-martial.

(7) Provides eligible victims and military families with access to transitional compensation in accordance with Federal law and DoD Instruction 1342.24, ''Transitional Compensation for Abused Dependents,'' May 23, 1995 (available at *http://www.dtic.mil/whs/directives/corres/pdf/134224p.pdf*).

(8) Ensures victims are aware of procedures to receive restitution as provided in accordance with State, local, and federal crime victims' funds, and the procedures for applying for such funds. Restitution may also be available from, or offered by, an accused as a condition in the terms of a pretrial agreement, during the sentencing process, as a part of post-trial mitigation under Rule of Court-Martial 1105, of the MCM. Under Article 139, UCMJ, victims may also be provided with relief if the property loss or damage resulted from wrongful taking or willful damage by a member of the Armed Forces due to riotous, violent, or disorderly conduct.

(9) Mandates compliance with DoD standards for victim assistance services in the military community established in DoD Instruction 6400.07 ''Standards for Victim Assistance Services in the Military Community,'' November 25, 2013 (available at *http://www.dtic.mil/whs/directives/corres/pdf/640007p.pdf*).

(10) Provides that crime victims who are entitled to military legal assistance under sections 1044 and 1044e of title 10, U.S.C., and as further prescribed by the Military Departments and National Guard Bureau policies, may consult with a military legal assistance attorney.

(11) Provides legal counsel, known as Special Victims' Counsel or Victims' Legal Counsel (SVC/VLC), to assist victims of alleged sex-related offenses in accordance with Articles 120, 120a, 120b, 120c, and 125 of the UCMJ, and attempts to commit any of these offenses under Article 80 of the UCMJ, regardless of whether the report of the offense is restricted or unrestricted. Individuals entitled to SVC/VLC representation include any of the following:

(a) Individuals eligible for military legal assistance under sections 1044 and 1044e of title 10, U.S.C., and as further prescribed by the Military Departments' and National Guard Bureau policies.

(b) Members of a reserve component of the armed forces, in accordance with section 533 of the National Defense Authorization Act for Fiscal Year 2015, and as further prescribed by the Military Departments and National Guard Bureau policies.

(12) Establishes a Special Victim Investigation and Prosecution (SVIP) capability in each Military Service comprised of specially trained criminal investigators, judge advocates, paralegals, and victim and witness assistance personnel to work with specially trained military criminal investigators to support victims of adult sexual assault, domestic violence, and child abuse. To de-conflict with the names of SVC/VCL programs, this distinct group of recognizable professionals will be referred to as SVIP at the DoD level. Ensures SVIP training programs meet established DoD and Military Service standards for special prosecutors, paralegal, VWAP coordinators and providers, and legal support personnel.

(13) Establishes local Victim and Witness Assistance Councils, when practicable, at each military installation, to ensure victim and witness service providers follow an interdisciplinary approach. This will ensure effective coordination between VWAP coordinators and DoD personnel providing related services, including sexual assault prevention and response coordinators, family advocacy personnel, military treatment facility health care providers and emergency room personnel, family service center personnel, chaplains, military equal opportunity personnel, judge advocates, SVC/VLCs, unit commanding officers, corrections personnel, and other persons designated by the Secretaries of the Military Departments.

(14) Maintains annual reporting requirements on assistance provided across the DoD to victims and witnesses of crime, which will be provided to the Department of Justice Office of Victims of Crime and the Bureau of Justice Statistics.

IV. Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

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

flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Section 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires 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 2014, that threshold is approximately $141 million. This document will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

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

The Department of Defense certifies that this proposed rule 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. Therefore, the Regulatory Flexibility Act, as amended, does not require DoD to prepare a regulatory flexibility analysis.

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

This proposed rule does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 114

Child welfare, Military law, Uniform Code of Military Justice.

Accordingly, 32 CFR part 114 is proposed to be added to read as follows:

PART 114—VICTIM AND WITNESS ASSISTANCE

Sec.
114.1 Purpose.
114.2 Applicability.
114.3 Definitions.
114.4 Policy.
114.5 Responsibilities.
114.6 Procedures.

Authority: 10 U.S.C. chapter 47, 10 U.S.C. 113, 1034, 1044, 10443, 1058, 1059, and 1408, 18 U.S.C. 1512 through 1514, sections 1701 and 1706 of Pub. L. 113–66, 127 Stat. 672, section 573 of Pub. L. 112–239, 126 Stat. 1632, and section 533 of Pub. L. 113–291, 128 Stat. 3292.

§ 114.1 Purpose.

This part:

(a) Establishes policy, assigns responsibilities, and prescribes procedures to assist victims and witnesses of crimes committed in violation of 10 U.S.C. chapter 47, also known and referred to in this part as the Uniform Code of Military Justice (UCMJ).

(b) Establishes policy, assigns responsibilities, and prescribes procedures for:

(1) The rights of crime victims under the UCMJ and required mechanisms for enforcement, in accordance with section 1701 of Public Law 113–66, ''National Defense Authorization Act for Fiscal Year 2014,'' and in accordance with DoD standards for victim witness assistance services in the military community established in DoD Instruction 6400.07, ''Standards for Victim Assistance Services in the Military Community,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/640007p.pdf*).

(2) Providing timely notification of information and assistance available to victims and witnesses of crime from initial contact through investigation, prosecution, confinement, and release, in accordance with 18 U.S.C. 1512 through 1514, 32 CFR part 286, DoD Instruction 1325.07, ''Administration of Military Correctional Facilities and Clemency and Parole Authority,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/132507p.pdf*), DoD Instruction 1342.24, ''Transitional Compensation for Abused Dependents,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/134224p.pdf*), DoD Directive 7050.06, ''Military Whistleblower Protection,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/705006p.pdf*), and 10 U.S.C. 113, 1034, 1059, and 1408; and section 1706 of Public Law 113–66.

(3) Annual reporting requirements on assistance provided across the DoD to victims and witnesses of crime.

(c) Provides for legal assistance for crime victims entitled to such services pursuant to 10 U.S.C. 1044, and 10 U.S.C. 1565b, and as further prescribed by the Military Departments and National Guard Bureau policies.

(d) Incorporates section 573 of Public Law 112–239, ''The National Defense Authorization Act for Fiscal Year 2013,'' January 2, 2013, requiring each Military Service to establish a special victim capability comprised of specially trained criminal investigators, judge advocates, paralegals, and victim and witness assistance personnel to support victims of covered special victim offenses. To de-conflict with SVC/VCL programs, this distinct group of recognizable professionals will be referred to, at the DoD level, as the Special Victim Investigation and Prosecution (SVIP) capability.

(e) Incorporates the victim and witness portion of the special victim capability in accordance with) DoDI 5509.19, ''Establishment of Special Victim Investigation and Prosecution (SVIP) Capability within the Military Criminal Investigative Organizations (MCIOs),'' February 3, 2015 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550519p.pdf*), and Directive-type Memorandum (DTM) 14–003, ''DoD Implementation of Special Victim Capability (SVC) Prosecution and Legal Support,'' February 12, 2014, Incorporating Change 1, February 5, 2015

(f) Incorporates section 1716 of Public Law 113–66, and section 533 of the National Defense Authorization Act for 2005 (NDAA 2005), requiring the Military Services to provide legal counsel, known as Special Victims' Counsel or Victims' Legal Counsel, (SVC/VLC) to assist victims of alleged sex-related offenses in accordance with Articles 120, 120a, 120b, 120c, 125 of the UCMJ, and attempts to commit any of these offenses under Article 80 of the UCMJ, who are eligible for legal assistance in accordance with 10 U.S.C. 1044 and 1044e, and as further prescribed by the Military Departments and National Guard Bureau policies.

§ 114.2 Applicability.

This part applies to OSD, 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 DoD (referred to collectively in this part as the ''DoD Components'').

§ 114.3 Definitions.

Unless otherwise noted, these terms and their definitions are for the purpose of this part:

Central repository. A headquarters office, designated by Service regulation, to serve as a clearinghouse of

information on a confinee's status and to collect and report data on the delivery of victim and witness assistance, including notification of confinee status changes.

Confinement facility victim/witness assistance coordinator. A staff member at a military confinement facility who is responsible for notifying victims and witnesses of changes in a confinee's status and reporting those notifications to the central repository.

Court proceeding. A preliminary hearing held pursuant to Article 32 of the UCMJ; a hearing under Article 39a of the UCMJ; a court-martial; a military presentencing hearing; or a military appellate hearing. The providence (guilty plea) inquiry between the military judge and the accused when a pretrial agreement has been entered into between the accused and the convening authority, and conferences, such as those under Military Rule of Evidence 802, which occur between attorneys and the military judge, or between attorneys and Article 32 of the UCMJ preliminary hearing officers, or other official, are not court proceedings for purposes of this part. If all or part of a court proceeding has been closed to the public by the military judge, preliminary hearing officer, or other official, the victims and witnesses will still be notified of the closed hearing as provided in this part, and of the reasons for the closure. In such a case, the military judge, preliminary hearing officer, or other official may place reasonable limits on the reasons disclosed, if such limits are necessary to protect the safety of any person, the fairness of the proceeding, or are otherwise in the interests of national security.

DoD Component responsible official. Person designated by each DoD Component head to be primarily responsible in the DoD Component for coordinating, implementing, and managing the victim and witness assistance program established by this part.

Equal opportunity. The right of all persons to participate in, and benefit from, programs and activities for which they are qualified. These programs and activities will be free from social, personal, or institutional barriers that prevent people from rising to the highest level of responsibility possible. Persons will be evaluated on individual merit, fitness, and capability, regardless of race, color, sex, national origin, or religion.

Local responsible official. Person designated by the DoD Component responsible official who has primary responsibility for identifying victims and witnesses of crime and for coordinating the delivery of services described in this part through a multidisciplinary approach. The position or billet of the local responsible official will be designated in writing by Service regulation. The local responsible official may delegate responsibilities in accordance with this part.

Local Victim and Witness Assistance Council. A regular forum held at the DoD installation, or regional command level, that promotes efficiencies, coordinates victim assistance-related programs, and assesses the implementation of victim assistance standards and victim assistance-related programs, in accordance with this part, DoD Instruction 6400.07, and any other applicable Service guidance.

Military Department Clemency and Parole Board. In accordance with DoD Instruction 1325.07, a board which assists the Military Department Secretary as the primary authority for administration and execution of clemency, parole, and mandatory supervised release policy and programs.

Military Services. Refers to the Army, the Navy, the Air Force, and the Marine Corps, the Coast Guard, and the Reserve Components, which include the Army and Air National Guards of the United States.

Protected communication. (1) Any lawful communication to a Member of Congress or an IG.

(2) A communication in which a member of the Armed Forces communicates information that the member reasonably believes evidences a violation of law or regulation, including a law or regulation prohibiting sexual harassment or unlawful discrimination, gross mismanagement, a gross waste of funds or other resources, an abuse of authority, or a substantial and specific danger to public health or safety, when such communication is made to any of the following:

(i) A Member of Congress, an IG, or a member of a DoD audit, inspection, investigation, or law enforcement organization.

(ii) Any person or organization in the chain of command; or any other person designated pursuant to regulations or other established administrative procedures to receive such communications.

Reprisal. Taking or threatening to take an unfavorable personnel action, or withholding or threatening to withhold a favorable personnel action, for making or preparing to make a protected communication.

Restricted reporting. Defined in DoD Directive 6495.01, ''Sexual Assault Prevention and Response (SAPR) Program'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/649501p.pdf*).

Sexual assault forensic examiner. A health care provider who has specialized training through his or her military service, or has a nationally recognized certification to perform medical examinations to evaluate and collect evidence related to a sexual assault.

Special victim investigation and prosecution (SVIP) capability. In accordance with section 573 of Public Law 112–239 and DoDI 5505.09, ''Establishment of Special Victim Investigation and Prosecution (SVIP) Capability within the Military Criminal Investigative Organizations (MCIOs),'' February 3, 2015 (available at *http://www.dtic.mil/whs/directives/corres/pdf/550519p.pdf*), and Directive-type Memorandum (DTM), ''DoD Implementation of Special Victim Capability (SVC) Prosecution and Legal Support,'' February 12, 2014, Incorporating Change 1, February 5, 2015 (available at *http://www.dtic.mil/whs/directives/corres/pdf/DTM-14-003.pdf*), a distinct, recognizable group of appropriately skilled professionals, consisting of specially trained and selected military criminal investigative organization (MCIO) investigators, judge advocates, victim witness assistance personnel, and administrative paralegal support personnel who work collaboratively to:

(1) Investigate allegations of adult sexual assault, domestic violence involving sexual assault and/or aggravated assault with grievous bodily harm, and child abuse involving sexual assault and/or aggravated assault with grievous bodily harm.

(2) Provide support for the victims of such covered offenses.

Special victim offenses. The designated criminal offenses of sexual assault, domestic violence involving sexual assault, and/or aggravated assault with grievous bodily harm, and child abuse involving sexual assault and/or aggravated assault with grievous bodily harm, in accordance with the UCMJ. Sexual assault includes offenses under Articles 120 (rape and sexual assault general), 120b (rape and sexual assault of a child), and 120c (other sexual misconduct), or forcible sodomy under Article 25 of the UCMJ or attempts to commit such offenses under Article 80 of the UCMJ. Aggravated assault with grievous bodily harm, in relation to domestic violence and child abuse cases, includes an offense as specified under Article 128 of the UCMJ (assault). The Military Services and National Guard Bureau may deem other UCMJ

offenses appropriate for SVIP support, based on the facts and circumstances of specific cases, and the needs of victims.

Special Victims' Counsel/Victims' Legal Counsel (SVC/VLC). Legal counsel provided to assist eligible victims of alleged sex-related offenses pursuant to Article 120, 120a, 120b, 120c, and 125 of the UCMJ and attempts to commit any of these offenses under Article 80 of the UCMJ (or other offenses as defined by the Military Services), in accordance with 10 U.S.C. 1044, 1044e, and 1565b; section 1716 of Public Law 113–66; and section 533 of the NDAA 2005.

Specially trained prosecutors. Experienced judge advocates detailed by Military Department Judge Advocate Generals (TJAGs), the Staff Judge Advocate to the Commandant of the Marine Corps, or other appropriate authority to litigate or assist with the prosecution of special victim cases and provide advisory support to MCIO investigators and responsible legal offices. Before specially trained prosecutors are detailed, their Service TJAG, Staff Judge Advocate to the Commandant of the Marine Corps, or other appropriate authority has determined they have the necessary training, maturity, and advocacy and leadership skills to carry out those duties.

Unrestricted reporting. Defined in DoD Directive 6495.01 (available at *http://www.dtic.mil/whs/directives/corres/pdf/649501p.pdf*).

Victim. A person who has suffered direct physical, emotional, or pecuniary harm as a result of the commission of a crime committed in violation of the UCMJ. Such individuals will include, but are not limited to:

(1) Service members and their dependents.

(2) When stationed outside the continental United States (CONUS), DoD civilian employees and contractors and their family members. This designation makes services, such as medical care in military medical facilities, available to them that are not available to DoD civilian employees, contractors, and their family members in stateside locations.

(3) When a victim is under 18 years of age, incompetent, incapacitated, or deceased, the term includes one of the following (in order of precedence): A spouse, legal guardian, parent, child, sibling, another family member, or another person designated by the court or the DoD Component responsible official, or designee. For a victim that is an institutional entity, an authorized representative of the entity. Federal Departments and State and local agencies, as entities, are not eligible for services available to individual victims.

Victim assistance personnel. Personnel who are available to provide support and assistance to victims of crime and harassment consistent with their assigned responsibilities and in accordance with this part. They include part-time, full-time, collateral duty, and other authorized individuals, and may be domestic violence or sexual assault prevention and response coordinators (to include unit and uniformed victim advocates), Sexual Assault Response Coordinators, victim-witness assistance personnel, or military equal opportunity advisors.

Victim assistance-related programs. The SAPR Program; FAP; and the VWAP. A complainant under the DoD MEO Program may be referred by the MEO office to one of the victim assistance-related programs for additional assistance.

Witness. A person who has information or evidence about a criminal offense within the investigative jurisdiction of a DoD Component and who provides that knowledge to a DoD Component. When the witness is a minor, that term includes a parent or legal guardian, or other person responsible for the child. The term does not include a defense witness or an individual involved in the crime as an alleged perpetrator or accomplice.

§ 114.4 Policy.

It is DoD policy that:

(a) The DoD is committed to protecting the rights of victims and witnesses of crime and supporting their needs in the criminal justice process. The DoD Components will comply with all statutory and policy mandates and will take all additional actions within the limits of available resources to assist victims and witnesses of crime without infringing on the constitutional or other legal rights of a suspect or an accused.

(b) DoD victim assistance services will focus on the victim and will respond, protect, and care for the victim from initiation of a report through offense disposition, if applicable, and will continue such support until the victim specifies to the local responsible official that he or she no longer requires or desires services.

(c) Each DoD Component will provide particular attention and support to victims of serious, violent crimes, including child abuse, domestic violence, and sexual assault. In order to ensure the safety of victims, and their families, victim assistance personnel shall respect the dignity and the privacy of persons receiving services, and carefully observe any safety plans and military or civilian protective orders in place.

(d) Victim assistance services must meet DoD competency, ethical, and foundational standards established in DoD Instruction 6400.07, ''Standards for Victim Assistance Services in the Military Community,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/640007p.pdf*).

(e) Making or preparing to make or being perceived as making or preparing to make a protected communication, to include reporting a violation of law or regulation, including a law or regulation prohibiting rape, sexual assault, or other sexual misconduct, in violation of 10 U.S.C. 920 through 920c, sexual harassment, or unlawful discrimination, in accordance with 10 U.S.C. 1034, section 1709 of Public Law 113–66, and DoD Directive 7050.06, ''Military Whistleblower Protection,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/705006p.pdf*), shall not result in reprisal activity from management officials.

(f) This part is not intended to, and does not, create any entitlement, cause of action, or defense at law or in equity, in favor of any person or entity arising out of the failure to accord to a victim or a witness the assistance outlined in this part. No limitations are hereby placed on the lawful prerogatives of the DoD or its officials.

§ 114.5 Responsibilities.

(a) The Under Secretary of Defense for Personnel and Readiness (USD(P&R)):

(1) Establishes overall policy for victim and witness assistance and monitors compliance with this part.

(2) Approves procedures developed by the Secretaries of the Military Departments that implement and are consistent with this part.

(3) Maintains the DoD Victim Assistance Leadership Council, in accordance with DoD Instruction 6400.07, which advises the Secretary of Defense on policies and practices related to the provision of victim assistance and provides a forum that promotes efficiencies, coordinates victim assistance-related policies, and assesses the implementation of victim assistance standards across the DoD's victim assistance-related programs.

(b) The Director, DoD Human Resources Activity, through the Defense Manpower Data Center, and under the authority, direction, and control of the USD(P&R), assists in formulating a data collection mechanism to track and report victim notifications from initial contact through investigation to disposition, to include prosecution, confinement, and release.

(c) The Inspector General of the Department of Defense (IG DoD):

(1) Establishes investigative policy and performs appropriate oversight reviews of the management of the Victim Witness Assistance Program (VWAP) by the DoD military criminal investigative organizations (MCIOs). This is not intended to substitute for the routine managerial oversight of the program provided by the MCIOs, the USD(P&R), the DoD Component heads, the DoD Component responsible officials, or the local responsible officials.

(2) Investigates and oversees DoD Component Inspector General investigations of allegations or reprisal for making or preparing to make or being perceived as making or preparing to make a protected communication, in accordance with 10 U.S.C. 1034, and section 573 of Public Law 112–239.

(c) The DoD Component heads:

(1) Ensure compliance with this part, and establish policies and procedures to implement the VWAP within their DoD Components.

(2) Designate the DoD Component responsible official for the VWAP, who will report annually to the USD(P&R) using DD Form 2706, ''Victim and Witness Assistance Annual Report.''

(3) Provide for the assignment of personnel in sufficient numbers to enable those programs identified in the 10 U.S.C. 113 note to be carried out effectively.

(4) Designate a central repository for confinee information for each Military Service, and establish procedures to ensure victims who so elect are notified of changes in inmate status.

(5) Maintain a Victim and Witness Assistance Council, when practicable, at each military installation, to ensure victim and witness service providers follow an interdisciplinary approach. These providers may include chaplains, sexual assault prevention and response personnel, family advocacy personnel, military treatment facility health care providers and emergency room personnel, family service center personnel, military equal opportunity personnel, judge advocates, SVC/VLCs, unit commanding officers, corrections personnel, and other persons designated by the Secretaries of the Military Departments.

(6) Maintain training programs to ensure Victim Witness Assistance Program (VWAP) providers receive instruction to assist them in complying with this part. Training programs will include specialized training for VWAP personnel assigned to the SVIP capability, in accordance with § 114.6(c).

(7) Designate local responsible officials in writing in accordance with Military Service regulations and § 114.6(a)(1).

(8) Maintain oversight procedures to ensure establishment of an integrated support system capable of providing the services outlined in § 114.6, and meet the competency, ethical, and foundational standards established in DoD Instruction 6400.07. Such oversight may include coverage by DoD Component Inspectors General, staff assistance visits, surveys, and status reports.

(9) Establish mechanisms for ensuring that victims are notified of and afforded the rights specified in the UCMJ, including the rights specified in 10 U.S.C. 806b (Article 6b) and Rule of Court-Martial (R.C.M.) 306 in title 10 of the United States Code.

(10) Establish mechanisms for the enforcement of the rights specified in the UCMJ, including mechanisms for the application for such rights and for consideration and disposition of applications for such rights. At a minimum, such enforcement mechanisms will include the designation of an authority within each Military Service to receive and investigate complaints relating to the provision or violation of such rights and the establishment of disciplinary sanctions for responsible military and civilian personnel who wantonly fail to comply with the requirements relating to such rights.

§ 114.6 Procedures.

(a) *Local responsible officials.* Local responsible officials:

(1) Will coordinate to ensure that systems are in place at the installation level to provide information on available benefits and services, assist in obtaining those benefits and services, and provide other services required by this section.

(2) May delegate their duties as appropriate, but retain responsibility to coordinate the delivery of required services.

(3) May use an interdisciplinary approach involving the various service providers listed in paragraph (b)(7) of this section, to coordinate the delivery of information and services to be provided to victims and witnesses.

(b) *Comprehensive information and services to be provided to victims and witnesses*—(1) *Rights of crime victims.* Personnel directly engaged in the prevention, detection, investigation, and disposition of offenses, to include courts-martial, including law enforcement and legal personnel, commanders, trial counsel, and staff judge advocates, will ensure that victims are accorded their rights in accordance with Article 6b of UCMJ and section 1701 of Public Law 113–66. A crime victim has the right to:

(i) Be reasonably protected from the accused offender.

(ii) Be provided with reasonable, accurate, and timely notice of:

(A) A public hearing concerning the continuation of confinement before the trial of the accused.

(B) A preliminary hearing pursuant to section 832 of the UCMJ (Article 32) relating to the offense.

(C) A court-martial relating to the offense.

(D) A public proceeding of the Military Department Clemency and Parole Board hearing relating to the offense.

(E) The release or escape of the accused, unless such notice may endanger the safety of any person.

(iii) Be present at, and not be excluded from any public hearing or proceeding described in paragraph (b)(1)(ii) of this section, unless the military judge or preliminary hearing officer of a preliminary hearing pursuant to Section 832, UCMJ, (Article 32), after receiving clear and convincing evidence, determines that testimony by the victim would be materially affected if the victim heard that hearing or proceeding.

(iv) Be reasonably heard personally or through counsel at:

(A) A public hearing concerning the continuation of confinement before the court-martial of the accused.

(B) A preliminary hearing pursuant to section 832 (Article 32) of the UCMJ and court-martial proceedings relating to the Military Rules of Evidence (M.R.E.) 412, 513, and 514 of the Manual for Courts-Martial (MCM) in title 10 of the United States Code, also referred to in this part as the MCM, and regarding other rights provided by statute, regulation, or case law.

(C) A public sentencing hearing relating to the offense.

(D) A public Military Department Clemency and Parole Board hearing relating to the offense. A victim may make a personal appearance before the Military Department Clemency and Parole Board or submit an audio, video, or written statement.

(v) Confer with the attorney for the U.S. Government in the case. This will include the reasonable right to confer with the attorney for U.S. Government at any proceeding described in paragraph (b)(1)(ii) of this section.

(A) Crime victims who are entitled to legal assistance may consult with a military legal assistance attorney in

accordance with paragraph (c)(1) of this section.

(B) Victims of an offense under Articles 120, 120a, 120b, or 120c or forcible sodomy under the UCMJ or attempts to commit such offenses under Article 80 of the UCMJ, who are entitled to legal assistance in accordance with 10 U.S.C. 1044, may consult with a SVC/VLC in accordance with paragraph (d)(1) of this section. Victims of these covered offenses shall be informed by a sexual assault response coordinator (SARC), victim advocate, victim witness liaison, military criminal investigator, trial counsel, or other local responsible official that they have the right to consult with a SVC/VLC as soon as they seek assistance from the individual in accordance with 10 U.S.C. 1565b, and as otherwise authorized by Military Department and National Guard Bureau policy.

(C) All victims may also elect to seek the advice of a private attorney, at their own expense.

(vi) Receive restitution as provided in accordance with State and Federal law.

(vii) Proceedings free from unreasonable delay.

(viii) Be treated with fairness and respect for his or her dignity and privacy.

(ix) Express his or her views to the commander or convening authority as to disposition of the case.

(2) *Initial information and services.* (i) Immediately after identification of a crime victim or witness, the local responsible official, law enforcement officer, or criminal investigation officer will explain and provide information to each victim and witness, as appropriate, including:

(A) The DD Form 2701, ''Initial Information for Victims and Witnesses of Crime,'' or computer-generated equivalent will be used as a handout to convey basic information. Specific points of contact will be recorded on the appropriate form authorized for use by the particular Military Service.

(B) Proper completion of this form serves as evidence that the local responsible official or designee, law enforcement officer, or criminal investigative officer notified the victim or witness of his or her rights, as described in paragraph (b)(1) of this section. The date the form is given to the victim or witness shall be recorded by the delivering official. This serves as evidence the victim or witness was timely notified of his or her statutory rights.

(ii) The local responsible official will explain the form to victims and witnesses at the earliest opportunity. This will include:

(A) Information about available military and civilian emergency medical and social services, victim advocacy services for victims of domestic violence or sexual assault, and, when necessary, assistance in securing such services.

(B) Information about restitution or other relief a victim may be entitled to, and the manner in which such relief may be obtained.

(C) Information to victims of intra-familial abuse offenses on the availability of limited transitional compensation benefits and possible entitlement to some of the active duty Service member's retirement benefits pursuant to 10 U.S.C. 1059 and 1408 and DoD Instruction 1342.24 ''Transitional Compensation for Abused Dependents,'' May 23, 1995 (available at *http://www.dtic.mil/whs/directives/corres/pdf/134224p.pdf*).

(D) Information about public and private programs available to provide counseling, treatment, and other support, including available compensation through federal, State, and local agencies.

(E) Information about the prohibition against intimidation and harassment of victims and witnesses, and arrangements for the victim or witness to receive reasonable protection from threat, harm, or intimidation from an accused offender and from people acting in concert with or under the control of the accused offender.

(F) Information concerning military and civilian protective orders, as appropriate.

(G) Information about the military criminal justice process, the role of the victim or witness in the process, and how the victim or witness can obtain additional information concerning the process and the case in accordance with section 1704 of Public Law 113–66. This includes an explanation of:

(*1*) Victim's roles and rights during the defense counsel interviews, preliminary hearings pursuant to section 832, UCMJ (Article 32) and section 1702 of Public Law 113–66.

(*2*) Victim's rights when action is taken by the convening authority pursuant to Article 60 of the UCMJ process, and during the post-trial/clemency phase of the process in accordance with section 1706 of Public Law 113–66.

(H) If necessary, assistance in contacting the people responsible for providing victim and witness services and relief.

(I) If necessary, how to file a military whistleblower complaint with an Inspector General regarding suspected reprisal for making, preparing to make, or being perceived as making or preparing to make a protected communication in accordance with 10 U.S.C. 1034 and DoD Directive 7050.06,.

(J) Information about the victim's right to seek the advice of an attorney with respect to his or her rights as a crime victim pursuant to federal law and DoD policy. This includes the right of Service members and their dependents to consult a military legal assistance attorney in accordance with paragraph (c)(1) of this section, or a SVC/VLC in accordance with paragraph (d)(1) of this section.

(3) *Information to be provided during investigation of a crime.* (i) If a victim or witness has not already received the DD Form 2701 from the local responsible official or designee, it will be provided by law enforcement officer or investigator.

(ii) Local responsible officials or law enforcement investigators and criminal investigators will inform victims and witnesses, as appropriate, of the status of the investigation of the crime, to the extent providing such information does not interfere with the investigation.

(4) *Information and services to be provided concerning the prosecution of a crime.* (i) The DD Form 2702, ''Court-Martial Information for Victims and Witnesses of Crime,'' will be used as a handout to convey basic information about the court-martial process. The date it is given to the victim or witness shall be recorded by the delivering official. If applicable, the following will be explained and provided by the U.S. Government attorney, or designee, to victims and witnesses:

(A) Notification of crime victims' rights, to include victim's right to express views as to disposition of case to the responsible commander and convening authority, in accordance with Rule for Court-Martial 306 of the MCM.

(B) Notification of the victim's right to seek the advice of an attorney with respect to his or her rights as a crime victim pursuant to federal law and DoD policy. This includes the right of service members and their dependents to consult a military legal assistance attorney in accordance with paragraph (c)(1) of this section or a SVC/VLC in accordance with paragraph (d)(1) of this section.

(C) Consultation concerning the decisions to prefer or not prefer charges against the accused offender and the disposition of the offense if other than a trial by court-martial.

(D) Consultation concerning the decision to refer or not to refer the charges against the accused offender to trial by court-martial and notification of the decision to pursue or not pursue

court-martial charges against the accused offender.

(E) Notification of the initial appearance of the accused offender before a reviewing officer or military judge at a public pretrial confinement hearing or at a preliminary hearing in accordance with section 832 (Article 32) of the UCMJ.

(F) Notification of the release of the suspected offender from pretrial confinement.

(G) Explanation of the court-martial process on referral to trial.

(H) Before any court proceedings (as defined to include preliminary hearings pursuant to section 832 (Article 32) of the UCMJ, pretrial hearings pursuant to Article 39(a) of the UCMJ, trial, and presentencing hearings), assistance in obtaining available services such as transportation, parking, child care, lodging, and courtroom translators or interpreters that may be necessary to allow the victim or witness to participate in court proceedings.

(I) During the court proceedings, a private waiting area out of the sight and hearing of the accused and defense witnesses. In the case of proceedings conducted aboard ship or in a deployed environment, provide a private waiting area to the greatest extent practicable.

(J) Notification of the scheduling, including changes and delays, of a preliminary hearing pursuant to section 832 (Article 32) of the UCMJ, and each court proceeding the victim is entitled to or required to attend will be made without delay. On request of a victim or witness whose absence from work or inability to pay an account is caused by the crime or cooperation in the investigation or prosecution, the employer or creditor of the victim or witness will be informed of the reasons for the absence from work or inability to make timely payments on an account. This requirement does not create an independent entitlement to legal assistance or a legal defense against claims of indebtedness.

(K) Notification of the recommendation of a preliminary hearing officer when an Article 32 of the UCMJ preliminary hearing is held.

(L) Consultation concerning any decision to dismiss charges or to enter into a pretrial agreement.

(M) Notification of the disposition of the case, to include the acceptance of a plea of ''guilty,'' the rendering of a verdict, the withdrawal or dismissal of charges, or disposition other than court-martial, to specifically include nonjudicial punishment under Article 15 of the UCMJ, administrative processing or separation, or other administrative actions.

(N) Notification to victims of the opportunity to present to the court at sentencing, in compliance with applicable law and regulations, a statement of the impact of the crime on the victim, including financial, social, psychological, and physical harm suffered by the victim. The right to submit a victim impact statement is limited to the sentencing phase and does not extend to the providence (guilty plea) inquiry before sentencing.

(O) Notification of the offender's sentence and general information regarding minimum release date, parole, clemency, and mandatory supervised release.

(P) Notification of the opportunity to receive a copy of proceedings. The convening authority or subsequent responsible official must authorize release of a copy of the record of trial without cost to a victim of sexual assault as defined in Rule of Court-Martial (R.C.M.) 1104 of the MCM and Article 54(e) of the UCMJ. Victims of offenses other than sexual assault may also receive a copy of the record of trial, without cost, when necessary to lessen the physical, psychological, or financial hardships suffered as a result of a criminal act.

(ii) After court proceedings, the local responsible official will take appropriate action to ensure that property of a victim or witness held as evidence is safeguarded and returned as expeditiously as possible.

(iii) Except for information that is provided by law enforcement officials and U.S. Government trial counsel in accordance with paragraphs (b)(3) and (4) of this section, requests for information relating to the investigation and prosecution of a crime (*e.g.,* investigative reports and related documents) from a victim or witness will be processed in accordance with DoD Instruction 1342.24.

(iv) Any consultation or notification required by paragraph (b)(5)(i) of this section may be limited to avoid endangering the safety of a victim or witness, jeopardizing an ongoing investigation, disclosing classified or privileged information, or unduly delaying the disposition of an offense. Although the victim's views should be considered, this part is not intended to limit the responsibility or authority of the Military Service or the Defense Agency officials to act in the interest of good order and discipline.

(5) *Information and services to be provided on conviction.* (i) The Military Department trial counsel will explain and provide services to victims and witnesses on the conviction of an offender in a court-martial. The DD Form 2703, ''Post-Trial Information for Victims and Witnesses of Crime,'' will be used as a handout to convey basic information about the post-trial process.

(ii) When appropriate, the following will be provided to victims and witnesses:

(A) General information regarding convening authority action, the appellate process, the corrections process, information about work release, furlough, probation, parole, mandatory supervised release, or other forms of release from custody, and eligibility for each.

(B) Specific information regarding the election to be notified of further actions in the case, to include the convening authority's action, hearings and decisions on appeal, changes in inmate status, and consideration for parole. The DD Form 2704, ''Victim/Witness Certification and Election Concerning Prisoner Status,'' will be explained and used for victims and appropriate witnesses (*e.g.,* those who fear harm by the offender) to elect to be notified of these actions, hearings, decisions, and changes in the offender's status in confinement.

(*1*) For all cases resulting in a sentence to confinement, the DD Form 2704 will be completed and forwarded to the Service central repository, the gaining confinement facility, the local responsible official, and the victim or witness, if any, with appropriate redactions made by the delivering official.

(*i*) Incomplete DD Forms 2704 received by the Service central repository must be accompanied by a signed memorandum detailing the reasons for the incomplete information, or they will be sent back to the responsible legal office for correction.

(*ii*) Do not allow an inmate access to DD Form 2704 or attach a copy of the forms to any record to which the confinee has access. Doing so could endanger the victim or witness.

(*2*) For all cases resulting in conviction but no sentence to confinement, the DD Form 2704 will be completed and forwarded to the Service central repository, the local responsible official, and the victim or witness, if any.

(*3*) The DD Forms 2704 and 2705, ''Notification to Victim/Witness of Prisoner Status,'' are exempt from release in accordance with 32 CFR part 286.

(C) Specific information regarding the deadline and method for submitting a written statement to the convening authority for consideration when taking action on the case in accordance with

Article 60 of the UCMJ and R.C.M. 1105A of the MCM.

(6) *Information and services to be provided on entry into confinement facilities.* (i) The victim and witness assistance coordinator at the military confinement facility will:

(A) On entry of an offender into post-trial confinement, obtain the DD Form 2704 to determine victim or witness notification requirements. If the form is unavailable, ask the Service central repository whether any victim or witness has requested notification of changes in inmate status in the case.

(B) When a victim or witness has requested notification of changes in inmate status on the DD Form 2704, and that status changes as listed in paragraph (b)(6)(ii) of this section, use the DD Form 2705, ''Victim and Witness Notification of Changes in Inmate Status,'' to notify the victim or witness.

(*1*) The date the DD Form 2705 is given to the victim or witness shall be recorded by the delivering official. This serves as evidence that the officer notified the victim or witness of his or her statutory rights.

(*2*) Do not allow the inmate access to DD Form 2705 or attach a copy of the forms to any record to which the inmate has access. Doing so could endanger the victim or witness.

(C) Provide the earliest possible notice of:

(*1*) The scheduling of a clemency or parole hearing for the inmate.

(*2*) The results of the Service Clemency and Parole Board.

(*3*) The transfer of the inmate from one facility to another.

(*4*) The escape, immediately on escape, and subsequent return to custody, work release, furlough, or any other form of release from custody of the inmate.

(*5*) The release of the inmate to supervision.

(*6*) The death of the inmate, if the inmate dies while in custody or under supervision.

(*7*) A change in the scheduled release date of more than 30 days from the last notification due to a disposition or disciplinary and adjustment board.

(D) Make reasonable efforts to notify all victims and witnesses who have requested notification of changes in inmate status of any emergency or special temporary home release granted an inmate.

(E) On transfer of an inmate to another military confinement facility, forward the DD Form 2704 to the gaining facility, with an information copy to the Service central repository.

(ii) The status of victim and witness notification requests will be reported annually to the Service central repository.

(7) *Information and services to be provided on appeal.* (i) When an offender's case is docketed for review by a Court of Criminal Appeals, or is granted review by the Court of Appeals for the Armed Forces (C.A.A.F.) or by the U.S. Supreme Court, the U.S. Government appellate counsel for the Government or appropriate Military Service designee will ensure that all victims who have indicated a desire to be notified receive this information, if applicable:

(A) Notification of the scheduling, including changes and delays, of each public court proceeding that the victim is entitled to attend.

(B) Notification of the decision of the court.

(ii) When an offender's case is reviewed by the Office of The Judge Advocate General (TJAG) of the Military Department concerned, pursuant to Article 69 and Article 73 of the UCMJ, TJAG will ensure that all victims who have indicated a desire to be notified on DD Form 2704 receive notification of the outcome of the review.

(iii) The Military Services may use the sample appellate notification letter found at Figure 1 of this section, or develop their own templates to keep victims informed of appellate court proceedings.

(8) *Information and services to be provided on consideration for parole or supervised release.* (i) Before the parole or supervised release of a prisoner, the military confinement facility staff will review the DD Form 2704 to ensure it has been properly completed. If there is a question concerning named persons or contact information, it will be immediately referred to the appropriate staff judge advocate for correction.

(ii) When considering a prisoner for release on supervision, the military confinement facility commander will ensure that all victims on the DD Form 2704 indicating a desire to be notified were provided an opportunity to provide information to the Military Department Clemency and Parole Board in advance of its determination, as documented in the confinement file.

(9) *Reporting procedures.* (i) To comply with the requirements of 10 U.S.C., Public Law 113–66, and title 18 of the United States Code, the DoD Component responsible official will submit an annual report using the DD Form 2706 to: Office of the Under Secretary of Defense for Personnel and Readiness, Attention: Legal Policy Office, 4000 Defense Pentagon, Washington, DC 20301–4000.

(ii) The report will be submitted by March 15 for the preceding calendar year and will address the assistance provided victims and witnesses of crime.

(iii) The report will include:

(A) The number of victims and witnesses who received a DD Form 2701 from law enforcement or criminal investigations personnel.

(B) The number of victims who received a DD Form 2702 from U.S. Government trial counsel, or designee.

(C) The number of victims and witnesses who received a DD Form 2703 from U.S. Government trial counsel or designee.

(D) The number of victims and witnesses who elected via the DD Form 2704 to be notified of changes in inmate status.

(E) The number of victims and witnesses who were notified of changes in inmate status by the confinement facility victim witness assistance coordinators via the DD Form 2705 or a computer-generated equivalent.

(F) The cumulative number of inmates in each Military Service for whom victim witness notifications must be made by each Service's confinement facilities. These numbers are derived by totaling the number of inmates with victim or witness notification requirements at the beginning of the year, adding new inmates with the requirement, and then subtracting those confinees who were released, deceased, or transferred to another facility (*e.g.,* federal, State, or sister Military Service) during the year.

(iv) The Office of the USD(P&R) will consolidate all reports submitted by each Military Service, and submit an annual report to the, and Bureau of Justice Statistics, and the Office for Victims of Crime, Department of Justice.

(c) *Special victim investigation and prosecution (SVIP) capability.* (1) In accordance with DTM 14–003, section 573 of Public Law 112–239, and, the Military Services will maintain a distinct, recognizable group of professionals to provide effective, timely, and responsive worldwide victim support, and a capability to support the investigation and prosecution of special victim offenses within the respective Military Departments.

(2) Covered special victim offenses include:

(i) Unrestricted reports of adult sexual assault.

(ii) Unrestricted reports of domestic violence involving sexual assault and/or aggravated assault with grievous bodily harm.

(iii) Child abuse involving child sexual abuse and/or aggravated assault with grievous bodily harm.

(3) Military Service SVIP programs will include, at a minimum, specially trained and selected:

(i) Investigators from within MCIOs of the Military Departments.

(ii) Judge advocates to serve as prosecutors.

(iii) VWAP personnel.

(iv) Paralegal or administrative legal support personnel.

(4) Each Military Service will maintain standards for the selection, training, and certification of personnel assigned to provide this capability. At a minimum, SVIP training must:

(i) Focus on the unique dynamics of sexual assault, aggravated domestic violence, and child abuse cases.

(ii) Promote methods of interacting with and supporting special victims to ensure their rights are understood and respected.

(iii) Focus on building advanced litigation, case management, and technical skills.

(iv) Ensure that all SVIP legal personnel understand the impact of trauma and how this affects an individual's behavior and the memory of a traumatic incident when interacting with a victim.

(v) Train SVIP personnel to identify any safety concerns and specific needs of victims.

(vi) Ensure SVIP personnel understand when specially trained pediatric forensic interviewers are required to support the investigation and prosecution of complex child abuse and child sexual abuse cases.

(5) Each Military Service will maintain and periodically review measures of performance and effectiveness to objectively assess Service programs, policies, training, and services. At a minimum, these Service-level review measures will include:

(i) Percentage of all preferred court-martial cases that involve special victim offenses in each fiscal year.

(ii) Percentage of special victim offense courts-martial tried by, or with the direct advice and assistance of, a specially trained prosecutor.

(iii) Compliance with DoD VWAP informational, notification, and reporting requirements specified in paragraphs (b)(1) through (9) of this section, to ensure victims are consulted with and regularly updated by special victim capability legal personnel.

(iv) Percentage of specially trained prosecutors and other legal support personnel having received additional and advanced training in topical areas.

(6) The Military Services will also consider victim feedback on effectiveness of special victim prosecution and legal support services and recommendations for possible improvements, as provided in DoD survivor experience surveys or other available feedback mechanisms. This information will be used by the Military Services to gain a greater understanding of the reasons why a victim elected to participate or declined to participate at trial in accordance with Enclosure 12 of DoD Instruction 6495.02, and whether SVIP, VWAP, and other legal support services had any positive impact on this decision.

(7) Designated SVIP capability personnel will collaborate with local DoD SARCs, sexual assault prevention and response victim advocates, Family Advocacy Program (FAP) managers, and domestic abuse victim advocates during all stages of the military justice process to ensure an integrated capability.

(8) To support this capability, active liaisons shall be established at the installation level with these organizations and key individuals:

(i) Local military and civilian law enforcement agencies.

(ii) SARCs.

(iii) Victim advocates.

(iv) FAP managers.

(v) Chaplains.

(vi) Sexual assault forensic examiners and other medical and mental health care providers.

(vii) Unit commanding officers.

(viii) Other persons designated by the Secretaries of the Military Departments necessary to support special victims.

(9) In cases of adult sexual assault the staff judge advocate or designated representative of the responsible legal office will participate in case management group meetings, in accordance with DoD Instruction 6495.02, on a monthly basis to review individual cases. Cases involving victims who are assaulted by a spouse or intimate partner will be reviewed by FAP.

(10) The staff judge advocate of the responsible legal office will participate in FAP case review or incident determination meetings of domestic violence, spouse or intimate partner sexual assault, and child abuse cases in accordance with DoD Instruction 6400.06.

(11) In the case of a victim who is under 18 years of age and not a member of the Military Services, or who is incompetent, incapacitated, or deceased, the military judge will designate in writing a representative of the estate of the victim, a family member, or another suitable individual to assume the victim's rights under the UCMJ. The victim's representative is designated for the sole purpose of assuming the legal rights of the victim as they pertain to the victim's status as a victim of any offense(s) properly before the court. Under no circumstances will the individual designated as representative have been accused of any crime against the victim.

(i) The Secretaries of the Military Departments may publish additional guidance or regulation regarding, who, before referral, may designate an appropriate representative, such as the convening authority or other qualified local responsible official.

(ii) In making a decision to appoint a representative, the designating authority should consider:

(A) The age and maturity, relationship to the victim.

(B) The physical proximity to the victim.

(C) The costs incurred in effecting the appointment.

(D) The willingness of the proposed designee to serve in such a role.

(E) The previous appointment of a guardian by a court of competent jurisdiction.

(F) The preference of the victim, if known.

(G) Any potential delay in any proceeding that may be caused by a specific appointment.

(H) Any other relevant information.

(iii) The representative, legal guardian, or equivalent of a victim of who is eligible, or in the case of a deceased victim, was eligible at the time of death for legal assistance provided by SVC/VLC, may elect legal representation for a SVC/VLC on behalf of the victim.

(c) *Legal assistance for crime victims*—(1) *Eligibility.* Active and retired Service members and their dependents are entitled to receive legal assistance pursuant to 10 U.S.C. 1044 and 1565 and Under Secretary for Defense for Personnel and Readiness Memorandum, ''Legal Assistance for Sexual Assault Victims,'' October 17, 2011.

(2) *Information and Services.* Legal assistance services for crime victims will include confidential advice and assistance for crime victims to address:

(i) Rights and benefits afforded to the victim under law and DoD policy.

(ii) Role of the VWAP coordinator or liaison.

(iii) Role of the victim advocate.

(iv) Privileges existing between the victim and victim advocate.

(v) Differences between restricted and unrestricted reporting.

(vi) Overview of the military justice system.

(vii) Services available from appropriate agencies for emotional and

mental health counseling and other medical services.

(viii) Advising of rights to expedited transfer.

(ix) Availability of and protections offered by civilian and military protective orders.

(d) *Special Victims' Counsel/Victims' Legal Counsel programs*—(1) *Eligibility.* In accordance with 10 U.S.C. 1044, 1044e, and 1565b, section 1716 of Public Law 113–66, and section 533 of the NDAA 2005, the Military Services provide legal counsel, known as SVC/VLC, to assist victims of alleged sex-related offenses including Articles 120, 120a, 120b, and 120c, forcible sodomy under Article 125 of the UCMJ, attempts to commit such offenses under Article 80 of the UCMJ, or other crimes under the UCMJ as authorized by the Service, who are eligible for legal assistance pursuant to 10 U.S.C. 1044e and as further prescribed by the Military Departments and National Guard Bureau policies. Individuals eligible for SVC/VLC representation include any of the following:

(i) Individuals entitled to military legal assistance under 10 U.S.C. 1044 and 1044e, and as further prescribed by the Military Departments and National Guard Bureau policies. (ii) Members of a reserve component of the armed forces, in accordance with section 533 of NDAA 2005, and as further prescribed by the Military Departments and National Guard Bureau policies.

(2) *Attorney-client information and services.* The types of legal services provided by SVC/VLC programs in each Military Service will include:

(i) Legal consultation regarding the VWAP, including:

(A) The rights and benefits afforded the victim.

(B) The role of the VWAP liaison.

(C) The nature of communication made to the VWAP liaison in comparison to communication made to a SVC/VLC or a legal assistance attorney pursuant to 10 U.S.C. 1044.

(ii) Legal consultation regarding the responsibilities and support provided to the victim by the SARC, a unit or installation sexual assault victim advocate, or domestic abuse advocate, to include any privileges that may exist regarding communications between those persons and the victim.

(iii) Legal consultation regarding the potential for civil litigation against other parties (other than the DoD).

(iv) Legal consultation regarding the military justice system, including, but not limited to:

(A) The roles and responsibilities of the military judge, trial counsel, the defense counsel, and military criminal investigators.

(B) Any proceedings of the military justice process in which the victim may observe or participate in person or through his or her SVC/VLC.

(v) Accompanying or representing the victim at any proceedings when necessary and appropriate, including interviews, in connection with the reporting, investigation, and prosecution of the alleged sex-related offense.

(vi) Legal consultation regarding eligibility and requirements for services available from appropriate agencies or offices for emotional and mental health counseling and other medical services.

(vii) Legal representation or consultation and assistance:

(A) In personal civil legal matters in accordance with 10 U.S.C. 1044.

(B) In any proceedings of the military justice process in which a victim can participate as a witness or other party.

(C) In understanding the availability of, and obtaining any protections offered by, civilian and military protecting or restraining orders.

(D) In understanding the eligibility and requirements for, and obtaining, any available military and veteran benefits, such as transitional compensation benefits found in 10 U.S.C. 1059, DoD Instruction 1342.24, ''Transitional Compensation for Abused Dependents,'' (available at *http://www.dtic.mil/whs/directives/corres/pdf/134224p.pdf*), and other State and federal victims' compensation programs.

(E) The victim's rights and options at trial, to include the option to state a preference to decline participation or withdraw cooperation as a witness and the potential consequences of doing so.

(viii) Legal representation or consultation regarding the potential criminal liability of the victim stemming from or in relation to the circumstances surrounding the alleged sex-related offense (collateral misconduct), regardless of whether the report of that offense is restricted or unrestricted in accordance with DoD Instruction 6495.02. Victims may also be referred to the appropriate defense services organization for consultation on the potential criminal implications of collateral misconduct.

(ix) Other legal assistance as the Secretary of Defense or the Secretary of the Military Department concerned may authorize.

Figure 1. Sample Appellate Notification Letter

[Victim Name]

[Address]

Dear [Mr.][Mrs.][Ms.] [Victim Name]:

The United States [Military Service] believes it is important to keep victims of crimes under the Uniform Code of Military Justice informed of court proceedings. Based on your request, we are providing you with information about the military appellate process and upcoming events in your case, in accordance with Department of Defense Instruction 1030.02, ''Victim Witness Assistance.''

[Name of Accused] (Appellant) filed an appeal of [his][her] criminal conviction on [Date] at the [Service] Court of Criminal Appeals. The process may take time before a decision is reached by the Court of Criminal Appeals. An appeal is a legal proceeding by which a case is brought before a higher court for review of the decision made by the lower, or trial, court. The Court of Criminal Appeals may decide this appeal solely on the basis of the brief submitted by the Appellant and the response which will be submitted by the U.S. Government, or the Court may decide to hold a public courtroom proceeding and hear the arguments made by the attorneys for both sides. If the Court does determine a courtroom proceeding is warranted, you will be notified of the date and location so that you may attend. If the Court declines to hold a courtroom proceeding and decides the issue on the basis of the Appellant's brief and the U.S. Government's response, you will be notified of the ultimate decision.

The ruling of the [Service] Court of Criminal Appeals is not necessarily the final resolution of this case. There are two courts superior to the Court of Criminal Appeals from which the Appellant could also seek review. If the Court of Criminal Appeals rules against the Appellant, [he][she] can seek review of that ruling at the Court of Appeals for the Armed Forces (C.A.A.F). If the Appellant is denied review by the C.A.A.F. [his][her] case becomes final and you will be informed. If review is granted by the C.A.A.F., you will be informed of the review taking place, of any courtroom proceedings, and of the final ruling. If C.A.A.F. grants review of the Appellant's case and rules against [him][her], [he][she] could potentially appeal that decision to the Supreme Court of the United States. If this were to occur, you will be notified. Cases are also sometimes returned to the [Service] Court of Criminal Appeals for further proceedings. In addition, the Appellants may also petition the respective Military Department Judge Advocate General for a new trial based on newly discovered evidence or fraud upon the court. If that were to occur, you will be notified.

For now, the Appellant has sought review of [his][her] conviction at the [Service] Court of Criminal Appeals. Nothing is required of you, but should you so desire, have any questions, or require further information, please contact [DESIGNATED REPRESENTATIVE AND CONTACT INFORMATION].

Sincerely,

(Service designee)

Dated: May 15, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–12256 Filed 5–21–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 155

[Docket No. USCG–2011–0576]

RIN 1625–AB75

Higher Volume Port Area—State of Washington

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes redefining the boundaries of the existing higher volume port area in the Strait of Juan de Fuca and Puget Sound, in Washington. This rulemaking is required by statute, and is related to the Coast Guard's maritime safety and stewardship missions.

DATES: Comments and related material must either be submitted to our online docket via *http://www.regulations.gov* on or before August 20, 2015 or reach the Docket Management Facility by that date.

ADDRESSES: You may submit comments identified by docket number USCG–2011–0576 using any one of the following methods:

(1) Federal eRulemaking Portal: *http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email LCDR John G. Peterson, CG–CVC–1, Coast Guard; telephone 202–372–1226, email *John.G.Peterson@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

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I. Public Participation and Request for Comments

We encourage you to submit comments (or related material) on this rulemaking. We will consider all submissions and may adjust our final action based on your comments. Comments should be marked with docket number USCG–2011–0576 and should provide a reason for each suggestion or recommendation. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008).

Mailed or hand-delivered comments should be in an unbound 8½ × 11 inch format suitable for reproduction. The Docket Management Facility will acknowledge receipt of mailed comments if you enclose a stamped, self-addressed postcard or envelope with your submission.

Documents mentioned in this notice of proposed rulemaking and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following the Web site's instructions. You can also view the docket at the Docket Management Facility (see the mailing address under **ADDRESSES**) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

We are not planning to hold a public meeting but will consider doing so if public comments indicate a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

BLS Bureau of Labor Statistics
CFR Code of Federal Regulations
E.O. Executive Order
FR Federal Register

GSA General Services Administration
HVPA Higher volume port area
MISLE Marine Information for Safety and Law Enforcement
NAICS North American Industry Classification System
OMB Office of Management and Budget
OSRO Oil spill removal organization
Pub. L. Public Law
SBA Small Business Administration
§ Section symbol
U.S.C. United States Code
VRP Vessel response plan

III. Background

The legal basis of this proposed rule is 33 U.S.C. 1231 and 1321(j), which require the Secretary of the department in which the Coast Guard is operating to issue regulations necessary for implementing the Ports and Waterways Safety Act, and to require the President to issue regulations requiring response plans and other measures to protect against oil and hazardous substance spills. The President's authority under 33 U.S.C. 1321(j) is delegated to the Secretary by Executive Order (E.O.) 12777, and the Secretary's authority is delegated to the Coast Guard by DHS Delegation No. 0170.1(II)(70), (73), and (80).

The purpose of this proposed rule is to implement section 710 of the Coast Guard Authorization Act of 2010 (''the Act''),[1] which requires the Coast Guard to initiate by October 15, 2011, a rulemaking to modify the 33 CFR 155.1020 definition of the State of Washington's higher volume port area (the Washington HVPA) by replacing a reference to Port Angeles, WA, with a reference to Cape Flattery, WA, and by reviewing any modifications to vessel response plans (VRPs), made in response to the definitional change, not later than October 15, 2015. The Coast Guard initiated this project by the October 15, 2011 deadline.

Oil or hazardous material pollution prevention regulations for a U.S. vessel, and for a foreign vessel operating in U.S. waters, appear in Coast Guard regulations at 33 CFR part 155. Many of those regulations require a vessel response plan (VRP) describing measures that the vessel owner or operator has taken or will take to mitigate or respond to an oil spill from the vessel. The VRP must demonstrate the vessel's ability, following a spill, to secure response resources within given time periods. These measures typically include the services of nearby response resources under a contract between the vessel's owner or operator and an oil spill removal organization (OSRO) that owns the response resources. The regulations provide for three different timeframes within which a combination of required response resources must arrive on the scene, which are described as Tiers 1, 2, and 3.

In 33 CFR part 155, subparts D (petroleum oil as cargo), F (animal fat or vegetable oil as cargo), G (non-petroleum oil as cargo), and J (petroleum oil as fuel or secondary cargo) all share the same definition of ''Higher volume port areas.'' Required response times are significantly reduced in HVPAs. For example, Tier 1 response times for an oil tanker within an HVPA are half that required of the same vessel operating in open ocean. As defined in 33 CFR 155.1020, the Strait of Juan de Fuca and Puget Sound, Washington constitute one of 14 HVPAs designated around the country.

Since 1996, 33 CFR 155.1020 has defined the seaward boundary of the Washington HVPA as an arc 50 nautical miles seaward of the entrance to Port Angeles, Washington. Port Angeles is approximately 62 miles inland from the Pacific Ocean entrance to the Strait of Juan de Fuca, at Cape Flattery, WA, and therefore, the Washington HVPA does not currently include any Pacific Ocean waters. Section 710 of the Act requires the Coast Guard to initiate a rulemaking to relocate the HVPA's arc so that it extends seaward from Cape Flattery, not Port Angeles. This would add 50 nautical miles of Pacific Ocean water and an additional 12 nautical miles in the western portion of the Strait of Juan de Fuca. Waters affected by sec. 710 and by this rulemaking are shown on National Oceanic and Atmospheric Administration charts.[2]

Section 710 requires us to initiate a rulemaking not later than October 15, 2011, to modify the definition of the Washington HVPA to relocate the arc. Section 710 also requires us to approve VRPs that require modification as a result of the rulemaking not later than October 15, 2015. We have determined that, with respect to existing VRPs, no modifications or new Coast Guard VRP approvals will be needed.

To maximize the affected public's ability to plan for the change in the Washington HVPA's boundaries, we published a 2011 **Federal Register** notice of our intent to comply with sec. 710.[3] This advised the public that regulatory implementation of sec. 710 was forthcoming. The notice did not request public comments and no public comments were received.

IV. Discussion of Proposed Rule

The current definition of the Washington HVPA's boundaries[4] reads: ''*Higher volume port area* means the following areas, including any water area within 50 nautical miles seaward of the entrance(s) to the specified port: . . . (13) Strait of Juan De Fuca at Port Angeles, WA to and including Puget Sound, WA.'' In strict compliance with the express wording of sec. 710(a), we propose amending that definition by striking ''Port Angeles, WA'' and inserting ''Cape Flattery, WA'' in its place. As amended, the definition would then read: ''*Higher volume port area* means the following areas, including any water area within 50 nautical miles seaward of the entrance(s) to the specified port: . . . (13) Strait of Juan de Fuca at Cape Flattery, WA to and including Puget Sound, WA.''

Port Angeles lies about 62 miles east of the entrance to the Strait of Juan de Fuca. By moving the arc so that it centers on Cape Flattery, which lies at the entrance to the Strait, the proposed redefined Washington HVPA would cover an additional 50 nautical miles of Pacific Ocean water, while continuing to cover all the waters now included within the current HVPA. The larger Washington HVPA may affect the time and resources needed to respond to an oil spill from a vessel, because it is harder and more time-consuming to transit rough Pacific Ocean waters than it is to transit the sheltered waters of the Strait and the Sound. (We discuss these possibilities in more detail in the Regulatory Analysis section that follows.)

V. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and E.O.s related to rulemaking. Below we summarize our analyses based on these statutes or E.O.s.

A. Regulatory Planning and Review

Executive Orders 12866 (''Regulatory Planning and Review'') and 13563 (''Improving Regulation and Regulatory Review'') direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

[1] Pub. L. 111–281, 124 Stat. 2905.

[2] Waters affected by sec. 710 and this rulemaking are shown on National Oceanic and Atmospheric Administration charts 18460 (Cape Flattery, WA) and 18465 (Port Angeles, WA).

[3] 76 FR 76299 (Dec. 7, 2011).

[4] 33 CFR 155.1020(13).

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866 as supplemented by E.O. 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866. The Office of Management and Budget (OMB) has not reviewed it under E.O. 12866. We developed an analysis of the costs and benefits of the proposed rule to ascertain its probable impacts on industry. A draft preliminary Regulatory Assessment follows.

This proposed rule would expand the existing Washington HVPA for Puget Sound and the Strait of Juan de Fuca. Currently, the Washington HVPA boundary is measured from Port Angeles in a 50-mile seaward arc westward to the Pacific Ocean. As mandated by sec. 710 of the Act, this proposed rule would amend the definition of the term ''Higher volume port area'' and relocate the point at which the seaward arc is measured from Port Angeles to Cape Flattery, WA, an approximately 62-mile westward shift. As a result, the Washington HVPA would cover an additional 50 miles of open ocean and an additional 12 nautical miles in the western portion of the Strait of Juan de Fuca. A VRP must list the OSRO provider that the vessel owner or operator has contracted with and stipulate the vessel's ability to secure response resources within specific regulatory timeframes (Tiers 1, 2, and 3) in the event of an oil spill. This proposed rule would codify the changes delineated in the Act and it would not require changes to VRPs.

Affected Population

Part 155 in 33 CFR directly applies to and regulates vessel owners and operators. Specified vessels prepare vessel response plans that must list the OSRO provider that the vessel owner or operator has contracted with and stipulate the vessel's ability to secure response resources within specific regulatory timeframes (Tiers 1, 2, and 3) in the event of an oil spill. The proposed rule has the potential to impact vessel response planholders covering vessels that transit the Washington HVPA and OSROs that provide response resources in the event of an oil spill. Based on Coast Guard review of vessel response plans, 2 OSROs may be impacted by the proposed rule. One OSRO has about 500 response resource contracts and the other OSRO has about 650 contracts with planholders that own vessels that call on the Cape Flattery higher volume port area. For the OSRO that has 500 contracts, about 3 percent or 15 are with U.S. planholders; the OSRO that has 650 contracts, about 2 percent or 13 are with U.S. planholders.

Costs

Vessel owners and operators would not need to revise or modify a current VRP to take into account expansion of the HVPA. Current VRPs already specify one or both of the OSROs that provide response resources to vessel owners and operators in the affected waters. Vessel owners and operators must only list the OSRO by name and include the contact information for each OSRO in the VRP; no other information or details are required in the VRP that are dependent upon the geographic location of response equipment.

In addition to identifying the OSRO in the vessel response plan, vessel owners and operators must ensure the availability of response resources from the OSRO through a contract or other approved means. Depending on how the contract language is formulated, a contract may need to be modified to reflect the change in the HVPA geographical definition. One OSRO provided information which stated that contracts would need to be modified slightly to incorporate the geographic change of the expanded higher volume port while the other OSRO provided information which stated that no changes or modifications to existing contracts would be necessary on the part of either the OSROs or the planholders. For the purpose of this analysis, we estimate costs to modify a contract for the planholders of the OSRO that stated that changes would be necessary. This OSRO has about 500 planholders with written contractual agreements to secure response resource services in the event of an oil spill; of this amount, only about 3 percent or 15, are with U.S. planholders. Based on information we obtained from industry in formulating the Nontank Vessel Response Final Rule [78 *FR* 60100], it would take a General and Operations Manager approximately 2 hours of planholder time to amend the contract and send the contract to the OSRO for approval. If a plan preparer amends the contract on behalf of the planholder, we estimate it would take the same amount of time. We found that 36 percent of planholders perform this work internally and 64 percent hire a plan preparer to perform this work on their behalf. The amendment of a contract is a one-time cost; we estimate little or no submission cost for planholders because nearly 100 percent of contracts are submitted by email to the responsible OSRO.

For planholders who perform the work internally and using the Bureau of Labor Statistics (BLS) May 2013 National Industry-Specific Occupational Employment and Wage Estimates for General and Operations Manager (Occupation Code 11–1021), we obtain a mean hourly wage rate of $62.68. We then use BLS' 2014 Employer Cost for Employee Compensation databases to calculate and apply a load factor of 1.52 to obtain a loaded hourly labor rate of about $95.30 for this occupation.[5] For plan preparers, we obtained publicly available fully loaded billing rates for Senior Regulatory and Environmental Consultants and Environmental Program Managers from three environmental service companies using the General Services Administration's (GSA) Federal Acquisition eLibrary for service contracts.[6] We took the average of these three rates to obtain a fully loaded hourly wage rate of $151.00 (rounded). Of about 500 planholders who have contracts with this OSRO, only about 15 are U.S. planholders. Of the 15 U.S. planholders, about 36 percent would amend the contract internally. We estimate the one-time cost to these planholders to be about $1,030 ($95.30 × 2 hours × 500 planholders × 0.03 × 0.36, rounded). For the remaining 64 percent of U.S. planholders who have a plan preparer amend the contracts on their behalf, we estimate the one-time cost to be about $2,899 ($151.00 × 2 hours × 500 planholders × .03 × 0.64, rounded); combined the total estimated one-time cost to U.S. planholders to amend the contracts would be about $3,930, rounded and undiscounted. We estimate the average one-time or initial cost for each U.S. planholder to amend a contract to be about $262 ($3,930/15

[5] Information can be viewed at, *http://www.bls.gov/oes/current/naics3_483000.htm.* A loaded labor rate is what a company pays per hour to employ a person, not the hourly wage. The loaded labor rate includes the cost of benefits (health insurance, vacation, etc.). The load factor for wages is calculated by dividing total compensation by wages and salaries. For this analysis, we used BLS' Employer Cost for Employee Compensation/Transportation and Materials Moving Occupations, Private Industry report (Series IDs, CMU2010000520000D and CMU2020000520000D for all workers using the multi-screen data search). Using 2014 Q2 data, we divide the total compensation amount of $25.85 by the wage and salary amount of $17.04 to get the load factor of 1.517 or 1.52. *See* the following Web site, *http://www.bls.gov/ncs/ect/data.htm.* We then rounded $62.68 to $62.70 and multiplied by 1.52 to obtain a loaded hourly wage rate of about $95.00.

[6] GSA Contract GS–10F–0263U Accessed 11/26/2014; GSA Contract GS–10F–0104T Accessed 11/26/2014; *https://www.gsaadvantage.gov/ref_text/GS10F0335R/0N9LCV.2VV7AR_GS-10F-0335R_GS10F0335R.PDF.*

U.S. planholders). We estimate the 10-year discounted cost to be about $3,673 using a 7 percent discount rate and the annualized cost to be about $523. Taking into consideration the uncertainty of this analysis, we request public comment on the cost impacts of this rule on OSROs and VRP planholders.

The remaining 485 planholders are foreign. For 36 percent of them who would amend the contracts internally, we estimate the one-time cost to be about $33,300 ($95.30 × 2 hours × 485 planholders × 0.36, rounded). For the remaining 64 percent of foreign planholders who have a plan preparer amend the contracts on their behalf, we estimate the one-time cost to be about $93,740 ($151.00 × 2 hours × 485 planholders × 0.64, rounded); combined the total estimated one-time cost to foreign planholders to amend the contracts would be about $127,040, rounded, or about $262 per planholder ($127,040/485 foreign planholders).

The final category of potential costs relates to the OSRO's ability to meet the specified response times in the new geographic area of the HVPA. Based on information provided to Coast Guard, one OSRO stated that additional response equipment would not be required and capital expenditures would not be necessary as result of the expanded higher volume port area under current Coast Guard OSRO classification guidelines. Based on data from the other OSRO, we estimate that total initial capital costs could be as high as $5.5 million for temporary storage equipment and warehousing with annual capital recurring costs of approximately $250,000 for equipment maintenance, and up to $1 million for barge recertification (included in the $5.5 million estimate), warehousing, and other necessary resource equipment. However, we lack independent methods to verify these estimates. Moreover, the actual costs the OSRO may incur depend considerably on how they choose to comply with our regulations, which give OSROs substantial flexibility with respect to pre-positioning response resources.

To the extent one OSRO would incur additional costs due to this proposed rule (such as increased capitalization costs), we expect that these costs would be generally passed onto their VRP planholders equally although the OSRO who provided this information conceded that this was speculative at this point due to the uncertainty of expenditures that may be needed as described below. Using the highest value of capital costs provided to us of $5.5 million, we use the capital recovery cost factor to determine the amount needed annually to recovery this payout since we assume the OSRO would finance the expenditures and attempt to recapture them equally over the life of the equipment. The capital recovery factor or ratio as it is often referred to, is the ratio of a constant annuity to the present value of the annuity over a given period of time using an acceptable discount rate, as in this case, 7 percent. The ratio also includes the general life expectancy of the investment and can be simply described as the ''share of the net cost that must be recovered each year to 'repay the cost of the fixed input at the end of its useful life.' '' If we use a standard life expectancy of 20 years, we calculate the net amount that must be recovered by the OSRO annually to be about $519,161, undiscounted.[7] If we assume this cost is distributed equally over the 650 planholders (U.S. and foreign planholders who own vessels that transit the higher volume port area) under contract with this OSRO, the amount needed to be recovered by the OSRO to recapture this initial investment is estimated to be about $800 (rounded) from each planholder annually, most likely in the form of higher retainer fees. However, only about 2 percent, or 13 of the 650 planholders are U.S. planholders. Therefore, for the 13 U.S. planholders, we estimate the total capital cost of this proposed rule to be about $10,400 (650 planholders × 0.02 × $800) annually, undiscounted, in addition to annual maintenance costs of about $385 per planholder ($250,000/650 planholders), undiscounted, in years 2 through 10 of the analysis period. We estimate the total 10-year discounted cost to the 13 U.S. planholders to be about $75,400 using a 7 percent discount rate (the 10-year discounted cost is estimated to be about $91,600 using a 3 percent discount rate) and the annualized cost to be about $10,734. *See* Table 1.

It follows that the remaining 637 planholders are foreign. Again, if we assume this OSRO passes along its capital cost in the form of higher retainer fees to foreign planholders, we estimate the total capital cost of this proposed rule to foreign planholders to be about $509,600 (637 × $800) annually, undiscounted, in addition to annual maintenance costs of about $245,000 (637 × $385), undiscounted, in years 2 through 10 of the analysis period. We estimate the total 10-year discounted cost to foreign planholders to be about $3.6 million using a 7 percent discount rate (the 10-year discounted cost is estimated to be about $4.3 million using a 3 percent discount rate). As stated earlier, we neither have knowledge of the OSROs billing structure nor how costs would be distributed among planholders, although in our discussion with one OSRO, we learned that the composition of a planholder's vessel fleet affects the amount of the retainer fee since vessels such as nontank ships requires different response resources as opposed to towing vessels, for example.

Table 1 summarizes the total estimated cost of the proposed rule to 28 U.S. planholders over a 10-year period of analysis.

TABLE 1—SUMMARY OF ESTIMATED COSTS OF THE PROPOSED RULE TO U.S. PLANHOLDERS

[7 percent discount rate, 10-year period of analysis, 2015 dollars]

Year	Update contracts for 15 U.S. planholders		OSRO equipment and other capital costs		Total costs	
	Undiscounted	Discounted	Undiscounted	Discounted	Undiscounted	Discounted
1	$3,930	$3,673	$10,400	$9,720	$14,330	$13,393
2	0	0	10,785	9,420	10,785	9,420
3	0	0	10,785	8,804	10,785	8,804
4	0	0	10,785	8,228	10,785	8,228
5	0	0	10,785	7,690	10,785	7,690
6	0	0	10,785	7,187	10,785	7,187
7	0	0	10,785	6,716	10,785	6,716

[7] Calculated using a capital recovery factor of 0.0944.

TABLE 1—SUMMARY OF ESTIMATED COSTS OF THE PROPOSED RULE TO U.S. PLANHOLDERS—Continued

[7 percent discount rate, 10-year period of analysis, 2015 dollars]

Year	Update contracts for 15 U.S. planholders		OSRO equipment and other capital costs		Total costs	
	Undiscounted	Discounted	Undiscounted	Discounted	Undiscounted	Discounted
8	0	0	10,785	6,277	10,785	6,277
9	0	0	10,785	5,866	10,785	5,866
10	0	0	10,785	5,483	10,785	5,483
Total		3,673		75,390		79,062
Annualized		523		10,734		11,257

Totals may not sum due to independent rounding.

As Table 1 shows, for 15 U.S. planholders who may need to revise their contracts, we estimate the 10-year discounted cost of the proposed rule to be about $3,673 at a 7 percent discount rate (using a 3 percent discount rate, we estimate the 10-year discounted cost to be about $3,816). We estimate the annualized cost to be about $523 for these 15 planholders.

For the OSRO who may incur capital costs as a result of this proposed rule and pass these costs along to its 13 U.S. planholders, we estimate the 10-year discounted cost to be about $75,400 at a 7 percent discount rate (using a 3 percent discount rate, we estimate the 10-year discounted cost to be about $91,624). We estimate the annualized cost to be about $10,734 at a 7 percent discount rate for these 13 planholders.

We estimate the total present discounted cost of the proposed rule to all 28 U.S. planholders to be about $79,062 at a 7 percent discount rate (using a 3 percent discount rate, we estimate the total 10-year discounted cost to be about $95,440). We estimate the annualized cost to be about $11,257 at a 7 percent discount rate.

We do not anticipate that this proposed rule would impose new costs on the Coast Guard or require the Coast Guard to expend additional resources because we do not expect any changes would be required to their VRPs.

Alternatives

Due to the specific nature of sec. 710(a), we are limited in the alternative approaches we can use to comply with Congress' intent. We considered three alternatives (including the preferred alternative) in the development of the proposed rule: (1) Revise 33 CFR 155.1020 by striking ''Port Angeles, WA'' in the definition of ''Higher volume port area'' of that section and inserting ''Cape Flattery, WA''; (2) Revise 33 CFR 155.1020 by striking ''50 nautical miles'' in the definition of ''Higher volume port area'' and inserting ''110 nautical miles''; and (3) Take no action. The Regulatory Analysis section further discusses the analysis of the preferred alternative (*i.e.,* express adoption of the wording from sec. 710(a)) in comparison with other regulatory approaches considered.

Analysis of Alternatives

We considered three alternatives (including the preferred alternative) in the development of this proposed rule. The key factors that we evaluated in considering each alternative included: (1) The degree to which the alternative comported with the congressional mandate in sec. 710 of the Act; (2) What benefits, if any, would be derived, such as enhancement of personal and environmental safety and security; and (3) Cost effectiveness. The alternatives considered are as follows:

Alternative 1: Revise 33 CFR 155.1020 by striking ''Port Angeles, WA'' in the definition of ''Higher volume port area'' of that section and inserting ''Cape Flattery, WA.'' Since 1996, 33 CFR 155.1020 has defined the seaward boundary of the Washington HVPA as an arc 50 nautical miles seaward of the entrance to Port Angeles, WA. The proposed change would relocate the arc's center to Cape Flattery, covering approximately 50 additional nautical miles of open ocean.

Alternative 2: Revise 33 CFR 155.1020 by striking ''50 nautical miles'' in the definition of ''Higher volume port area'' and inserting ''110 nautical miles.'' This change would affect the other 13 HVPAs throughout the United States because of the level of response resources required with the significantly reduced response times that would be associated with a 110-mile outward shift of the existing HVPAs from their entrances. A shift of this distance would require the purchasing and positioning of heavier and more expensive equipment such as oceangoing tugs and barges. In addition, OSROs would incur considerable costs of potentially retrofitting existing HVPAs with shoreside docks. Since this would include all HVPAs, the economic impact on the response resource industry, as a whole, would be greater as opposed to a single HVPA. Furthermore, this option goes beyond the requirements of sec. 710 of the Act, which specifically requires the Coast Guard to initiate a rulemaking proceeding to modify the definition of the term ''Higher volume port area'' by striking ''Port Angeles, WA'' and inserting ''Cape Flattery, WA.''

Alternative 3: Take no action. This option was not selected as it would not implement the intent of sec. 710 of the Act, which specifically requires the Coast Guard to initiate a rulemaking to modify the definition of the term ''Higher volume port area'' by striking ''Port Angeles, WA'' and inserting ''Cape Flattery, WA.'' It also precludes the protection intended by Congress for the waters at the entrance to and in the Strait of Juan de Fuca.

We chose Alternative 1, which codifies the regulation directly and specifically implements sec. 710 of the Act as described earlier. We rejected Alternative 2, because it went beyond the direction provided by Congress in sec. 710 and adds burden, both in the Puget Sound region and in the other HVPAs throughout the United States. We rejected Alternative 3, the ''no action'' alternative, because it would not implement sec. 710.

Benefits

We do not identify any historic cases that could support the development of quantifiable benefits associated with this proposed rule. Using the Coast Guard's Marine Information for Safety and Law Enforcement (MISLE) database with casualty cases transferred from MISLE's predecessor, the Marine Safety Management System database, we examined 283 spill cases from 1995 to 2013, beginning with the first spills that appeared in our database for this geographic region. Based on information from Coast Guard personnel who have experience in casualty case investigations and analysis, we found

no cases or spills that would have benefitted from the expanded HVPA.

Qualitatively, oil spills are likely to result in a negative impact to the ecosystem and the economy of the surrounding area. These represent social welfare effects that are not accounted for solely by the amount of oil spilled into the water. In many cases, the scope of the impact is contingent on the vulnerability and resiliency of the affected area. A barrel of spilled oil may not have the same impact in one area as it would in another. Some locations are more sensitive or vulnerable than others. Depending on the ecosystem, VRPs could mitigate impacts to habitats that house multiple species. An area with an ecosystem that is damaged as a result of previous environmental incidents or damaged due to the cumulative effects of environmental injuries over time can be expected to have higher benefits from oil spill mitigation.

The primary benefit of this proposed rule is to ensure that in the event of a spill, adequate response resources are available and can be mobilized within the expanded HVPA. This will ensure a timely response by vessel owners and operators and the OSROs in an effort to reduce the likelihood, and mitigate the impact of an oil spill on the marine environment that might occur in the expanded HVPA.

B. Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

Regarding vessel owners and operators, as previously discussed, this proposed rule would codify the requirements in the Act of an expanded HVPA, and it would not require vessel owners and operators to make changes to VRPs. Therefore, owners and operators of vessels that transit the HVPA would not incur additional VRP modification costs as a result of this proposed rule. However, as assumed earlier for the purpose of this analysis, if contracts would need to be modified, as stated by one OSRO on the part of the planholders, U.S. planholders would bear some costs of this proposed rule as shown earlier in this preamble. We estimate that each of the 15 U.S. planholders would incur an average one-time cost of about $262 to amend its contract with the OSRO.

Also, regarding capital costs, it is unclear whether or how these costs impact vessel owners and operators without knowledge of the OSROs' billing structures. Additionally, proprietary information is not available that would allow us to determine the distribution of costs among many vessel owners and operators contracting with each OSRO. Nevertheless, in our earlier analysis, if we assume capital costs are incurred by one of the OSROs and we assume this cost would be passed along equally to U.S. planholders in the form of higher retainer fees, we estimate each of the 13 U.S. planholders would incur an annual cost of about $800 from one particular OSRO in addition to $385 in maintenance costs in years 2 through 10 of the analysis period for a total planholder cost of about $1,185 in years 2 through 10 of the analysis period.

We assume for the purpose of this analysis that the two OSROs that provide response resource capabilities to the HVPA in Puget Sound may incur costs from this proposed rule and may likely pass along these costs to planholders in the form of higher retainer fees or planholders may incur one-time costs to amend their contracts with one of the OSROs. Using the North American Industry Classification System (NAICS) codes for businesses and the Small Business Administration's (SBA) size standards for small businesses, we determined the size of each OSRO. One OSRO has a primary NAICS code of 541618 with an SBA size standard of $15 million, which is under the subsector group 541 of the NAICS code with the description of ''Professional, Scientific, and Technical Services.'' The other OSRO has a primary NAICS code of 562998 with an SBA size standard of $7.5 million, which is under the subsector group 562 of the NAICS code with the description of ''Waste Management and Remediation Services.'' Based on the information above and annual revenue data from publicly available and proprietary sources, Manta and ReferenceUSA, neither OSRO is considered to be small.

There are about 1,400 U.S. planholders that have either tank vessel, nontank vessel, or combined vessel response plans. Based on the affected population of this proposed rule relative to the size of the industry as a whole, in this case U.S. vessel response plan owners (planholders), this proposed rule would potentially affect 28 or about 2 percent of the total population of U.S. planholders in the United States. As described earlier and dependent upon the OSRO considered, we estimate a U.S. planholder may incur an annual cost between $262 and $1,185 in years 2 through 10 of the analysis period (and between $262 and $800 in the initial year since we assume maintenance costs are not incurred in the initial year of the analysis period) as a result of this proposed rule. Given the cost analysis and pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Coast Guard certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why you think it qualifies and how and to what degree this rule would economically affect it.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996,[8] we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult LCDR John G. Peterson (see **FOR FURTHER INFORMATION CONTACT**). 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 proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995.[9]

[8] Pub. L. 104–121.

[9] 44 U.S.C. 3501–3520.

E. Federalism

A rule has implications for federalism under E.O. 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132. Our analysis follows.

As noted earlier in the preamble, this rule implements sec. 710 of the Act, which specifically directs the Coast Guard to amend 33 CFR 155.1020 by removing ''Port Angeles, WA'' and replacing it with ''Cape Flattery, WA.'' This rule carries out the Congressional mandate by amending the regulations to reflect this required change. Furthermore, this rule does not have a substantial direct effect upon the laws or regulations of the State of Washington. Therefore, this rule is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

While it is well settled that States may not regulate in categories in which Congress intended the Coast Guard to be the sole source of a vessel's obligations, the Coast Guard recognizes the key role that State and local governments may have in making regulatory determinations. Additionally, for rules with federalism implications and preemptive effect, E.O. 13132 specifically directs agencies to consult with State and local governments during the rulemaking process. If you believe this rule has implications for federalism under E.O. 13132, please contact the person listed in the **FOR FURTHER INFORMATION** section of this preamble.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 [10] requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed 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 proposed rule would not cause a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

H. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Protection of Children

We have analyzed this proposed rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

J. Indian Tribal Governments

A rule has implications for Indian Tribal Governments under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental principles and requirements described in E.O. 13175.

As noted above, this rulemaking implements the Congressional mandate by implementing sec. 710 of the Act. It will improve marine safety by increasing response times to mitigate or respond to an oil spill from vessels and does not have tribal implications that would require consultation under the E.O.

The Coast Guard, however, recognizes the key role that Indian Tribal Governments have in making regulatory determinations. Additionally, for rules with tribal implications, E.O. 13175 specifically directs agencies to consult with Indian Tribal Governments during the rulemaking process. If you believe this rule has implications for Indian Tribal Governments under E.O. 13175, please contact the person listed in the **FOR FURTHER INFORMATION** section of this preamble.

K. Energy Effects

We have analyzed this proposed rule under E.O. 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 because it is not a ''significant regulatory action'' under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. We have determined that it is not a ''significant energy action'' under E.O. 13211, because although it is a ''significant regulatory action'' under E.O. 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy, and the Administrator of OMB's Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under E.O. 13211.

L. Technical Standards

The National Technology Transfer and Advancement Act [11] directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

M. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969,[12] and have made a preliminary determination that this is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under the ''Public Participation and Request for Comments'' section of this preamble. This rule is categorically excluded under section 6(b) of the ''Appendix to National Environmental Policy Act: Coast Guard Procedures for Categorical Exclusions, Notice of Final Agency Policy.'' [13] This rule involves

[10] 2 U.S.C. 1531–1538.

[11] 15 U.S.C. 272 note.

[12] 42 U.S.C. 4321–4370f.

[13] 67 FR 48244 (July 23, 2002).

Congressionally-mandated regulations designed to protect the environment, specifically, regulations implementing the requirements of the Act (redefining and enlarging the boundaries of the existing higher volume port area in the Strait of Juan de Fuca and Puget Sound, in Washington). An environmental analysis checklist is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 155

Alaska, Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

■ 1. The authority citation for part 155 is revised to read as follows:

Authority: 3 U.S.C. 301 through 303; 33 U.S.C. 1225, 1231, 1321(j), 1903(b), 2735; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 155.1020 also issued under section 710 of Pub. L. 111–281. Section 155.480 also issued under section 4110(b) of Pub. L. 101.380.

§ 155.1020 [Amended]

■ 2. In § 155.1020, amend paragraph (13) of the definition of ''Higher volume port area'' by removing the words ''Port Angeles'' and adding, in their place, the words ''Cape Flattery''.

Dated: May 7, 2015.

J.C. Burton,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2015–11760 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0084]

RIN 1625–AA00, AA11

Great Lakes—Regulated Navigation Areas and Safety Zones

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its Great Lakes Regulated Navigation Areas regulations to include two safety zones to close designated waters for recreational ice users and three Regulated Navigation Areas to manage vessel traffic in ice-prone waterways. Further, the Coast Guard proposes to redefine (without changing) the three existing regulated navigation areas in the rule as safety zones. These proposed amendments provide needed updates to the regulations and align the rule with existing waterway regulations. The proposed amendments are necessary to protect waterway users, vessels, and mariners from hazards associated with winter conditions and navigation.

DATES: Comments and related material must be received by the Coast Guard on or before July 6, 2015.

ADDRESSES: You may submit comments identified by docket number USCG–2015–0084 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these four methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LTJG Matthew Stroebel, Ninth Coast Guard District Prevention; telephone 216–902–6060, email *matthew.k.stroebel@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
RNA Regulated Navigation Area

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2015–0084), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov,* or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number [USCG–2015–0084] in the ''Search'' box and click ''Search.'' Click the ''Comment'' box on the line associated with this supplemental notice of proposed rulemaking. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, type the docket number USCG–2015–0084 in the ''SEARCH'' box and click ''Search.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with

the Department of Transportation to use the Docket Management Facility.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. You may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

There is no recent regulatory history related to 33 CFR 165.901. The Coast Guard made a substantive amendment to the rule on August 4, 1983 (48 FR 35402) to adjust the position of the second RNA on Lake Huron under § 165.901(a)(2).

C. Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish RNAs and limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

33 CFR 165.901 lists three Great Lakes RNAs—(1) the waters of Lake Huron known as South Channel; (2) the waters of Lake Huron between Mackinac Island and St. Ignace, Michigan; and (3) the waters of Lake Michigan known as Gray's Reefs passage. Although termed RNAs, these three areas are actually closure zones. Title 33 CFR 165.901(c) of the rule authorizes the Captain of the Port (COTP) Sault Sainte Marie to close and open the RNAs as ice conditions dictate. Normally, closures take place once in the winter with openings occurring in the spring. When closed, vessels are prohibited from navigating the RNAs without COTP authorization.

The Coast Guard has identified the need for two additional closure areas on the Great Lakes, specifically, (1) designated waters of Lake Huron on Saginaw Bay, Michigan; and (2) U.S. waters of Lake Erie in the vicinity of the South Passage and the Erie Islands, Ohio. The specific coordinates for these closures areas are set forth in the proposed regulatory text under § 165.901(a)(1)–(2). These areas attract recreational ice users during winter months. Vessel traffic would disrupt ice integrity in these areas and pose risks to these recreational waterway users, which may include people and vehicles falling through the ice. To mitigate these risks, the Coast Guard proposes to establish safety zones to close these areas to vessel traffic during the winter.

The Coast Guard also identified the need for three vessel traffic management areas or RNAs on the Great Lakes. These areas generally include (1) the waters of Lake Erie known as the Maumee Bay Entrance Channel; (2) the waters connecting Lake Huron to Lake Michigan known as the Straits of Mackinac; and (3) the waters of Lake Michigan known as Green Bay. Specific coordinates for these RNAs are set forth in the proposed regulatory text under § 165.901(c)(1)–(3). Vessel traffic ply the waters in these areas during winter months; however, seasonal ice conditions, which can worsen on short notice, pose risks to vessel traffic in these areas. To manage these risks, the Coast Guard proposes to establish RNAs in these areas to regulate vessel movement and safeguard vessel traffic. During periods of ice-cover, the Coast Guard anticipates issuing temporary vessel operating requirements, as provided for under 33 CFR 165.11, to promote the safe passage of vessels through the RNAs. Bases for these temporary traffic rules include winter navigation, channel obstructions, unusual weather conditions, or unusual water levels. Such temporary operating requirements may include transiting the RNA with an assist tug or standing fast until conditions permit safe passage.

D. Discussion of Proposed Rule

In light of the foregoing discussion, the Coast Guard proposes to amend 33 CFR 165.901 to add two safety zones to protect recreational ice users and three RNAs to safeguard vessel traffic. In addition, the three closure areas in the rule, presently termed RNAs, will be redefined as safety zones. This redefinition will not affect the position or seasonal implementation of these closure areas. These proposed amendments will provide regulatory authority for the Coast Guard (1) to close designated waters on the Great Lakes to vessel traffic to protect recreational ice users during the winter season; (2) to manage vessel traffic in designated areas to protect vessels and mariners from dangers of ice conditions; and (3) to redefine the existing RNAs in the rule to safety zones. Since the existing closure areas do not involve vessel traffic management, they are more appropriately defined as safety zones, which generally provide for the closure of a waterway in the interest of safety.

E. Regulatory Analyses

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

1. Regulatory Planning and Review

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We conclude that this proposed rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The proposed amendments involve closure areas and vessel management areas, designed to be implemented only during winter months, as ice conditions dictate. As to the impact of the closure area on Lake Erie near the South Channel and the Erie Islands, OH, the Coast notes that industry vessels have taken alternative routes bypassing the Erie Islands when recreational ice users are present. The Coast Guard anticipates the same practice when this area is closed. Further, regarding the closure area on the waters of Lake Huron in Saginaw Bay, Michigan, the Coast Guard anticipates closing the bay after giving due consideration to industry's need to traverse the area. Moreover, under certain circumstances, the Coast Guard may permit vessel traffic to transit the closure areas. Regarding the three proposed vessel management areas, they are designed to regulate the conditions of vessel transit for safety. Overall, we expect the economic impact of this proposed rule to be minimal and that a full Regulatory Evaluation is unnecessary.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit

organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule may affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit the proposed safety zones and RNAs during the winter months.

These proposed amendments will not have a significant economic impact on a substantial number of small entities for the reasons cited in the *Regulatory Planning and Review* section.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. 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 proposed 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 contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. 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 proposed rule under that Order and have determined that it does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This proposed rule would 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.

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

We have analyzed this proposed 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 because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

13. Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272) 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 proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. Because this proposed rule involves amendments to navigation regulations and establishment of a safety zones, it is categorically excluded under paragraph 34(g) of the Commandant Instruction. A Categorical Exclusion Determination (CED) and an environmental analysis checklist are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a

significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.901 to read as follows:

§ 165.901 Great Lakes—regulated navigation areas and safety zones.

(a) The following are safety zones:

(1) *Lake Erie.* The U.S. waters of Lake Erie at the intersection of the International Border at 082°55′00″ W., following the International Border eastward to the intersection of the International Border at 082°35′00″ W., moving straight south to position 41°25′00″ N., 082°35′00″ W., continuing west to position 41°25′00″ N., 082°55′00″ W., and ending north at the International Border and 082°55′00″ W.

(2) *Lake Huron.* (i) The waters of Lake Huron known as South Channel between Bois Blanc Island and Cheboygan, Michigan; bounded by a line north from the mainland at 45°39′48″ N., 84°27′36″ W.; to Bois Blanc Island at 45°43′42″ N., 84°27′36″ W.; and a line north from the mainland at 45°43′00″ N., 84°35′30″ W.; to the western tangent of Bois Blanc Island at 45°48′42″ N., 84°35′30″ W.

(ii) The waters of Lake Huron between Mackinac Island and St. Ignace, Michigan, bounded by a line east from position 45°52′12″ N., 84°43′00″ W.; to Mackinac Island at 45°52′12″ N., 84°39′00″ W.; and a line east from the mainland at 45°53′12″ N., 84°43′30″ W.; to the northern tangent of Mackinac Island at 45°53′12″ N., 84°38′48″ W.

(iii) The waters of Lake Huron known as Saginaw Bay, Michigan; bounded by a line from Port Austin Reef Light (LL–10275) at 44°04′55″ N., 082°58′57″ W.; to Tawas Light (LL–11240) at 44°15′13″ N., 083°26′58″ W.; to Saginaw Bay Range Front Light (LL–10550) at 43°38′54″ N., 083°51′06″ W.; then to the point of beginning.

(3) *Lake Michigan.* The waters of Lake Michigan known as Gray's Reef Passage bounded by a line from Gray's Reef Light (LL–2006) at 45°46′00″ N., 85°09′12″ W.; to White Shoals Light (LL–2003) at 45°50′30″ N., 85°08′06″ W.; to a point at 45°49′12″ N., 85°04′48″ W.; then to a point at 45°45′42″ N., 85°08′42″ W.; then to the point of beginning.

(b) *Regulations.* The District Commander or respective Captain of the Port (COTP) will enforce these safety zones as ice conditions dictate. Under normal seasonal conditions, only one closing each winter and one opening each spring are anticipated. Prior to closing or opening these safety zones, the District Commander or respective COTP will give the public advance notice, not less than 72 hours prior to the closure. The general regulations in 33 CFR 165.23 apply. The District Commander or respective COTP retains the discretion to permit vessels to enter/transit a closed safety zone under certain circumstances.

(c) The following are regulated navigation areas (RNAs):

(1) *Lake Erie.* The waters of Lake Erie known as the Maumee Bay Entrance Channel between Maumee Bay Entrance Channel Light at 41°49′32″ N., 083°11′37″ W.; and Grassy Island at 41°42′23″ N., 083°26′49″ W.

(2) *Straits of Mackinac.* The waters connecting Lake Huron to Lake Michigan known as the Straits of Mackinac from Lansing Shoal Light at 45°54′8″ N., 085°33′25″ W. southwest to 45°50′7″ N., 085°34′3″ W. to Old Mackinac Point Lighthouse at 45°47′36″ N., 084°44′23″ W. eastward to Bois Blanc Island at 45°49′7″ N., 084°34′28″ W. then northwest to Mackinaw Island at 45°51′5″ N., 084°36′19″ W., encompassing Round Island, westward to the northern point of the Mackinaw Bridge at 45°50′57″ N., 084°43′47″ W. and returning to the beginning at Lansing Shoal Light.

(3) *Green Bay.* The waters of Lake Michigan known as Green Bay from Rock Island Passage or Porte Des Morts Passage north to Escanaba Light at 45°44′48″ N., 087°02′14″ W.; south to the Fox River Entrance at 44°32′22″ N., 088°00′19″ W., to the Sturgeon Bay Ship Canal from Sherwood Point Light at 44°53′34″ N., 087°26′00″ W.; to Sturgeon Bay Ship Canal Light at 44°47′42″ N., 087°18′48″ W.; and then to the point of beginning.

(d) *Regulations.* In the RNAs under paragraph (c) of this section, the District Commander or respective COTP may issue orders to control vessel traffic for reasons which include but are not limited to: channel obstructions, winter navigation, unusual weather conditions, or unusual water levels. Prior to issuing these orders, the District Commander or respective COTP will provide advance notice as reasonably practicable under the circumstances. The general regulations in 33 CFR 165.13 apply. The District Commander or respective COTP retains the discretion to authorize vessels to operate outside of issued orders.

Dated: May 4, 2015.

F. M. Midgette,

Rear Admiral, U.S. Coast Guard, Commander, Ninth Coast Guard District.

[FR Doc. 2015–11804 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2013–0040; FRL– 9928–05-Region-4]

Approval and Promulgation of Implementation Plans; Florida Infrastructure Requirements for the 2008 Lead National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of the October 14, 2011, State Implementation Plan (SIP) submission, provided by the State of Florida, through the Department of Environmental Protection (FL DEP) for inclusion into the Florida SIP. This proposal pertains to the Clean Air Act (CAA or the Act) infrastructure requirements for the 2008 Lead national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure'' SIP. FL DEP certified that the Florida SIP contains provisions that ensure the 2008 Lead NAAQS is implemented, enforced, and maintained in Florida. With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting, EPA is proposing to approve Florida's infrastructure submission, provided to EPA on October 14, 2011, as satisfying the required infrastructure elements for the 2008 Lead NAAQS.

DATES: Written comments must be received on or before June 22, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–

OAR–2013–0040, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: R4–ARMS@epa.gov.*
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5. *Hand Delivery or Courier:* Lynorae Benjamin, Chief, *Air Regulatory Management Section,* Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

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FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9152. Mr. Farngalo can be reached via electronic mail at *farngalo.zuri@epa.gov.*

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I. Background

On October 5, 1978, EPA promulgated primary and secondary NAAQS for Lead under section 109 of the Act. *See* 43 FR 46246. Both primary and secondary standards were set at a level of 1.5 micrograms per cubic meter (μg/m ^{3}), measured as Lead in total suspended particulate matter (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 Air Quality Criteria for Lead (USEPA, August 7, 1977). On November 12, 2008 (75 FR 81126), EPA issued a final rule to revise the primary and secondary Lead NAAQS. The primary and secondary Lead NAAQS were revised to 0.15 μg/m ^{3}. By statute, SIPs meeting the requirements of sections 110(a)(1) and (2) are to be submitted by states within three years after promulgation of a new or revised NAAQS. Sections 110(a)(1) and (2) require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs to EPA no later than October 15, 2011, for the 2008 Lead NAAQS.[1]

Today's action is proposing to approve Florida's infrastructure SIP submission for the applicable requirements of the 2008 Lead NAAQS, with the exception of the preconstruction PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J). With respect to Florida's infrastructure SIP submission related to the provisions pertaining to the PSD permitting requirements for major sources of section 110(a)(2)(C), prong 3 of D(i), and (J), EPA's approval of these elements was published on March 18, 2015 (80 FR 14019). For the aspects of Florida's submittal proposed for approval today, EPA notes that the Agency is not approving any specific rule, but rather proposing that Florida's already approved SIP meets certain CAA requirements.

II. What elements are required under sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the

[1] In these infrastructure SIP submissions states generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federally-approved SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Throughout this rulemaking, unless otherwise indicated, regulations referenced herein as the ''Florida Administrative Code (F.A.C.)'' have been approved into Florida's federally-approved SIP. Florida state statutes, referenced as ''Florida Statue (F.S.)'' herein are not a part of the SIP unless otherwise indicated.

obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2008 Lead NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with the 1978 Lead NAAQS.

Section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for ''infrastructure'' SIP requirements related to a newly established or revised NAAQS. As mentioned above, these requirements include SIP infrastructure elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAQS. The requirements that are the subject of this proposed rulemaking are listed below [2] and in EPA's October 14, 2011, memorandum entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)'' (2011 Lead Infrastructure SIP Guidance).

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement, prevention of significant deterioration (PSD) and new source review (NSR).[3]
- 110(a)(2)(D): Interstate and international transport provisions.
- 110(a)(2)(E): Adequate personnel, funding, and authority.
- 110(a)(2)(F): Stationary source monitoring and reporting.
- 110(a)(2)(G): Emergency Powers.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(I): Nonattainment area plan or plan revision under part D.[4]
- 110(a)(2)(J): Consultation with government officials, public notification, and PSD and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Florida that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 Lead NAAQS. Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''each such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA, ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[5] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that ''each'' SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.[6] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be

[2] Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA, and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. Today's proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

[3] This rulemaking only addresses requirements for this element as they relate to attainment areas.

[4] As mentioned above, this element is not relevant to today's proposed rulemaking.

[5] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

[6] *See, e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

promulgated.[7] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit ''a plan'' to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[8] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[9]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[10]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the ''applicable requirements'' of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[11] EPA issued the 2011 Lead Infrastructure SIP Guidance[12] to provide states with up-to-date guidance for Lead infrastructure SIPs. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions. The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.[13]

[7] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, e.g., that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

[8] *See, e.g.,* ''Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,'' 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and ''Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS,'' (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[9] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

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

[11] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[12] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Required under Clean Air Act Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS),'' Memorandum from Stephen D. Page, October 14, 2011.

[13] Although not intended to provide guidance for purposes of infrastructure SIP submissions for the 2008 Lead NAAQS, EPA notes, that following the 2011 Lead Infrastructure SIP Guidance, EPA issued the ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2).'' Memorandum from Stephen D. Page, September 13, 2013. This 2013 guidance provides recommendations for air agencies' development and the EPA's review of infrastructure SIPs for the 2008

Continued

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[14] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[15] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[16]

IV. What is EPA's analysis of how Florida addressed the elements of sections 110(a)(1) and (2) ''infrastructure'' provisions?

The Florida infrastructure submission addresses the provisions of sections 110(a)(1) and (2) as described below.

1. 110(a)(2)(A)—Emission limits and other control measures: Florida's infrastructure submission cites provisions of the Florida Administrative Code (F.A.C.) that provide FL DEP with the necessary authority to adopt and enforce air quality controls, which include enforceable emission limitations and other control measures. Chapters 62–204, F.A.C., *Air Pollution Control Provisions;* 62–210, F.A.C., *Stationary Sources—General Requirements;* 62–212,F.A.C. *Stationary Source-Preconstruction Review;* 62–296, F.A.C., *Stationary Sources—Emissions Standards;* and 62–297, F.A.C., *Stationary Sources—Emissions Monitoring,* establish emission limits for Lead and address the required control measures, means and techniques for compliance with the 2008 Lead NAAQS respectively. EPA has made the preliminary determination that the above provisions and Florida's practices are adequate to protect the 2008 Lead NAAQS in the State. Accordingly, EPA is proposing to approve Florida's infrastructure SIP submission with respect to section 110(a)(2)(A).

In this action, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during startup, shutdown, and malfunction (SSM) of operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, ''State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown'' (September 20, 1999), and the Agency plans to address such state regulations in the future.[17] In the meantime, EPA encourages any state having a deficient SSM provision to take steps to correct it as soon as possible.

Additionally, in this action, EPA is not proposing to approve or disapprove any existing State rules with regard to director's discretion or variance provisions. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B)—Ambient air quality monitoring/data system: SIPs are required to provide for the establishment and operation of ambient air quality monitors; the compilation and analysis of ambient air quality data; and the submission of these data to EPA upon request. Chapters 62–204, F.A.C., *Air Pollution Control Provisions,* 62–210, F.A.C., *Stationary Sources—General Requirements,* and 62–212, F.A.C., *Stationary Sources—Preconstruction Review* of the Florida SIP, along with the Florida Network Description and Ambient Air Monitoring Network Plan, provide for an ambient air quality monitoring system in the State. Annually, States develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, and includes

ozone primary and secondary NAAQS, the 2010 primary nitrogen dioxide (NO_2) NAAQS, the 2010 primary sulfur dioxide (SO_2) NAAQS, and the 2012 primary fine particulate matter ($PM_{2.5}$) NAAQS, as well as infrastructure SIPs for new or revised NAAQS promulgated in the future.

[14] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,'' 74 FR 21639 (April 18, 2011).

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

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

[17] On February 22, 2013, EPA published a proposed action in the **Federal Register** entitled, ''State Implementation Plans: Response to Petition for Rulemaking; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction; Proposed Rule.'' 78 FR 12459.

the annual ambient monitoring network design plan and a certified evaluation of the agency's ambient monitors and auxiliary support equipment.[18] The latest monitoring network plan for Florida was submitted to EPA in May 2014 and on November 7, 2014, EPA approved this plan. Florida's approved monitoring network plan can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2013–0040. EPA has made the preliminary determination that Florida's SIP and practices are adequate for the ambient air quality monitoring and data system requirements related to the 2008 Lead NAAQS.

3. 110(a)(2)(C)—Program for enforcement, Prevention of Significant Deterioration (PSD) and new source review (NSR): This element consists of three sub-elements; enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and preconstruction permitting of major sources and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (*i.e.,* the major source PSD program). In this action EPA is proposing to approve Florida's infrastructure SIP submission for the 2008 Lead NAAQS with respect to the general requirement of 110(a)(2)(C) to include a program in the SIP that provides for enforcement of emission limits and control measures and regulation of minor sources and minor modifications as well as the enforcement of lead emission limits to assist in the protection of air quality in nonattainment, attainment or unclassifiable areas. This is established in Chapters 62–210, F.A.C., *Stationary Sources—General Requirements, Section 200—Definitions;* and 62–212, F.A.C., *Stationary Sources—Preconstruction Review, Section 400—Prevention of Significant Deterioration..*

Enforcement: FL DEP's SIP approved regulations provide for enforcement of lead emission limits and control measures and construction permitting for new or modified stationary lead sources.

Preconstruction PSD Permitting for Major Sources: With respect to Florida's infrastructure SIP submission related to the preconstruction PSD permitting requirements for major sources of section 110(a)(2)(C), EPA approved this element at 80 FR 14019, published on March 18, 2015, and thus is not proposing any action today regarding these requirements.

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the regulation of new and modified minor sources and minor modifications. FL DEP's SIP-approved rule chapters 62–204, 62–210, and 62–212, F.A.C., collectively establish a preconstruction, new source permitting program that meets the NNSR requirements under parts C and D of the CAA for pollutant-emitting activities that contribute to lead concentrations in the ambient air and also provide for the enforcement of lead emission limits and control measures. FL DEP's SIP-approved preconstruction review program applies to minor sources and modifications as well as major stationary sources and modifications (as discussed above).

EPA has made the preliminary determination that Florida's SIP and practices are adequate for enforcement of control measures and regulation of minor sources and modifications related to the 2008 Lead NAAQS.

4. 110(a)(2)(D)(i)(I) and (II), and 110(a)(2)(D)(ii)—Interstate and International transport provisions: Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components have two subparts resulting in four distinct components, commonly referred to as ''prongs,'' that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (''prong 1''), and interfering with maintenance of the NAAQS in another state (''prong 2''). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state from interfering with measures required to prevent significant deterioration of air quality in another state (''prong 3''), or to protect visibility in another state (''prong 4''). Section 110(a)(2)(D)(ii) Intestate and International transport provisions requires SIPs to include provisions insuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement.

110(a)(2)(D)(i)(I)—prongs 1 and 2: Section 110(a)(2)(D)(i) requires infrastructure SIP submissions to include provisions prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment, or interfering with maintenance, of the NAAQS in another state.

The physical properties of lead prevent lead emissions from experiencing that same travel or formation phenomena as $PM_{2.5}$ and ozone for interstate transport as outlined in prongs 1 and 2. More specifically, there is a sharp decrease in the lead concentrations, at least in the coarse fraction, as the distance from a lead source increases. EPA believes that the requirements of prongs 1 and 2 can be satisfied through a state's assessment as to whether a lead source located within its State in close proximity to a state border has emissions that contribute significantly to the nonattainment or interfere with maintenance of the NAAQS in the neighboring state. For example, EPA's experience with the initial lead designations suggests that sources that emit less than 0.5 tpy generally appear unlikely to contribute significantly to the nonattainment in another state. EPA's experience also suggest that sources located more than two miles from the state border generally appear unlikely to contribute significantly to the nonattainment in another state. Florida has two lead sources that have emissions of lead over 0.5 tons per year (tpy) but these sources are located well beyond two miles from the State border.[19] Thus, EPA believes there are no sources in Florida that are likely to contribute significantly to the nonattainment or interfere with maintenance of the NAAQS in another state. Therefore, EPA has made the preliminary determination that Florida's SIP meets the requirements of section 110(a)(2)(D)(i)(I).

110(a)(2)(D)(i)(II)—prong 3: With respect to Florida's infrastructure SIP submission related to the interstate transport requirements of section 110(a)(2)(D)(i)(II) (prong 3), EPA approved this element at 80 FR 14019, published on March 18, 2015, and thus is not proposing any action today regarding these requirements.

110(a)(2)(D)(i)(II)—prong 4: With regard to section 110(a)(2)(D)(i)(II), the visibility sub-element, referred to as prong 4, significant impacts from lead emissions from stationary sources are expected to be limited to short distances from the source. The 2011 Lead Infrastructure SIP Guidance notes that

[18] On occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

[19] There are two facilities in Florida that have Lead emissions greater than 0.5 tpy. The facilities are EnviroFocus Technologies and GulfPower Company Crist power plant. EnviroFocus Technologies is located at 1901 N 66th St, Tampa, FL 33619, which about 150 miles from the border of Georgia. GulfPower Company Crist power plant is located in Escambia County 11999 Pate Street, Pensacola, FL, approximately 10 miles from Alabama.

the lead constituent of PM would likely not travel far enough to affect Class I areas and that the visibility provisions of the CAA do not directly regulate lead. Lead stationary sources in Florida are located distances from Class I areas such that visibility impacts are negligible. In addition, Florida's Regional Haze SIP, which addresses visibility protection, was approved on August 29, 2013 (78 FR 53250). Accordingly, EPA has preliminarily determined that the Florida SIP meets the relevant visibility requirements.

110(a)(2)(D)(ii)—Interstate and International transport provisions: Chapters 62–204, 62–210, and 62–212, F.A.C. require that any new major source or major modification undergo PSD or NNSR permitting and thereby provide notification to other potentially affected federal, state, and local government agencies. EPA is unaware of any pending obligations for the State of Florida pursuant to sections 115 and 126. EPA has made the preliminary determination that Florida's SIP and practices are adequate for insuring compliance with the applicable requirements relating to interstate and international pollution abatement for the 2008 Lead NAAQS.

5. 110(a)(2)(E)—Adequate personnel, funding, and authority. Section 110(a)(2)(E) requires that each implementation plan provide (i) necessary assurances that the State will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the State comply with the requirements respecting State Boards pursuant to section 128 of the Act, and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Florida's SIP as meeting the requirements of sub-elements 110(a)(2)(E)(i) through (iii). EPA's rationale for today's proposal respecting sub-element (i) through (iii) is described in turn below.

To satisfy the requirements of sections 110(a)(2)(E)(i) and (iii), Florida's infrastructure SIP submission describes that rules regarding emissions standards general policies, a system of permits, and fee schedules for the review of plans, and other planning needs. 403.601 (2),F.S., 403.601(4), F.S., section 403 .182, F.S., are the statutes that Florida relies on to meet this element. As evidence of the adequacy of FL DEP's resources, EPA submitted a letter to Florida on March 6, 2015, outlining 105 grant commitments and the current status of these commitments for fiscal year 2014. The letter EPA submitted to Florida can be accessed at *www.regulations.gov* using Docket ID No. EPA–R04–OAR–2013–0040. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Florida satisfactorily met all commitments agreed to in the Air Planning Agreement for fiscal year 2014, therefore Florida's grants were finalized and closed out. EPA has made the preliminary determination that Florida has adequate resources for implementation of the 2008 Lead NAAQS.

The section 128(a)(1) State Board requirements—as applicable to the infrastructure SIP pursuant to section 110(a)(2)(E)(ii)—provide that each SIP shall require that any board or body which approves permits or enforcement orders shall be subject to the described public interest and income restrictions therein. Subsection 128(a)(2), also pursuant to section 110(a)(2)(E)(ii), requires that any board or body, or the head of an executive agency with similar power to approve permits or enforcement orders under the CAA, shall also be subject to conflict of interest disclosure requirements.

For purposes of section 128(a)(1), Florida has no boards or bodies with authority over air pollution permits or enforcement actions. Such matters are instead handled by an appointed Secretary. Appeals of final administrative orders and permits are available only through the judicial appellate process described at Florida Statute 120.68. As such, a ''board or body'' is not responsible for approving permits or enforcement orders in Florida, and the requirements of section 128(a)(1) are not applicable.

With respect to section 128(a)(2), FL DEP previously submitted the relevant provisions of Florida Statutes, specifically subsections 112.3143(4) and 112.3144, F.S., for incorporation into the Florida SIP in its infrastructure submittal for the 1997 ozone NAAQS. EPA approved these conflict of interest provisions for inclusion in the Florida SIP on July 30, 2012. *See* 77 FR 44485. These provisions of the Florida SIP are sufficient to satisfy the conflict of interest provisions applicable to the head of FL DEP and all public officers within the Department. Thus, EPA has made the preliminary determination that Florida's SIP and practices are adequate for insuring compliance with the applicable requirements relating to state boards for the 2008 Lead NAAQS.

6. 110(a)(2)(F)—Stationary source monitoring system: Florida's infrastructure SIP submission describes how the State establishes requirements for emissions compliance testing and utilizes emissions sampling and analysis. It further describes how the State ensures the quality of its data through observing emissions and monitoring operations. FL DEP uses these data to track progress towards maintaining the NAAQS, develop control and maintenance strategies, identify sources and general emission levels, and determine compliance with emission regulations and additional EPA requirements. These requirements are provided in Chapters 62–204, *Air Pollution Control Provisions;* 62–210, F.A.C., *Stationary Sources—General Requirements;* 62–212, F.A.C., *Stationary Sources—Preconstruction Review;* 62–296, F.A.C., *Stationary Sources—Emissions Standards:* and 62–297, F.A.C., *Stationary Sources—Emissions Monitoring.*

Additionally, Florida is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and the precursors that form them—NO_X, sulfur dioxide, ammonia, Lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Florida made its latest update to the 2013 NEI on December 24, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html.* EPA has made the preliminary determination that Florida's SIP and practices are adequate for the stationary source monitoring systems related to the 2008 Lead NAAQS.

7. 110(a)(2)(G)—Emergency Powers: This section of the CAA requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to

implement such authority. This section of Florida's infrastructure SIP submission identifies Florida Statutes subsections 403.131 and 120.569(2)(n), F.S which authorize DEP to ''[s]eek injunctive relief to prevent irreparable injury to the air, waters, and property, including animal, plant, and aquatic life, of the state and to protect human health, safety, and welfare caused or threatened by any violation''; and to issue emergency orders to address immediate dangers to the public health, safety, or welfare. These statutes were incorporated into the SIP to address the requirements of section 110(a)(2)(G) of the CAA in an EPA action approving certain portions of Florida's infrastructure SIP for the 1997 ozone NAAQS on July 30, 2012. *See* 77 FR 44485. EPA has made the preliminary determination that Florida's SIP and practices are adequate for emergency powers related to the 2008 Lead NAAQS.

8. 110(a)(2)(H)—Future SIP revisions: FL DEP is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS in Florida. Florida Statutes Subsection 403.061(35) grants FL DEP the broad authority to implement the CAA; also, subsection 403.061(9), F.S., which authorizes FL DEP to adopt a comprehensive program for the prevention, control, and abatement of pollution of the air of the state, and from time to time review and modify such programs as necessary. FL DEP has the ability and authority to respond to calls for SIP revisions, and has provided a number of SIP revisions over the years for implementation of the NAAQS. Florida has one nonattainment area for the 2008 Lead NAAQS in Hillsborough County related to the EnviroFocus Technologies, LLC facility. On June 29, 2012, FL DEP submitted the required attainment demonstration for this Area. EPA approved this SIP revision on April 16, 2015. *See* 80 FR 6485. EPA has made the preliminary determination that Florida's SIP and practices adequately demonstrate a commitment to provide future SIP revisions related to the 2008 Lead NAAQS, when necessary.

9. 110(a)(2)(J): EPA is proposing to approve Florida's infrastructure SIP for the 2008 Lead NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that provides for meeting the applicable consultation requirements of section 121, the public notification requirements of section 127; and visibility protection requirements of part C of the Act. With respect to Florida's infrastructure SIP submission related to the preconstruction PSD permitting, EPA approved this sub-element of 110(a)(2)(J) on March 18, 2015, and thus is not proposing any action today regarding these requirements. *See* 80 FR 14019. EPA's rationale for its proposed action regarding applicable consultation requirements of section 121, the public notification requirements of section 127, and visibility protection requirements is described below.

110(a)(2)(J) (121 consultation) Consultation with government officials: Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and federal land managers (FLMs) carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. Chapters 62–204, F.A.C., *Air Pollution Control Provisions;* 62–210, F.A.C., Stationary Sources—General Requirements, and 62–212, F.A.C., *Stationary Sources—Preconstruction Review,* as well as Florida's Regional Haze Implementation Plan (which allows for consultation between appropriate state, local, and tribal air pollution control agencies as well as the corresponding Federal Land Managers), provide for consultation with government officials whose jurisdictions might be affected by SIP development activities. Florida adopted state-wide consultation procedures for the implementation of transportation conformity. These consultation procedures include considerations associated with the development of mobile inventories for SIPs. Implementation of transportation conformity as outlined in the consultation procedures requires FL DEP to consult with federal, state and local transportation and air quality agency officials on the development of motor vehicle emissions budgets. EPA approved Florida's consultation procedures on August 11, 2003. *See* 68 FR 47468. EPA has made the preliminary determination that Florida's SIP and practices adequately demonstrate that the State meets applicable requirements related to consultation with government officials related to the 2008 Lead NAAQS, when necessary.

110(a)(2)(J) (127 public notification) Public notification: To meet the public notification requirements of section 110(a)(2)(J), Florida has state statutes, subsections 403.061(20) *Department; powers and duties* which provides FL DEP with the authority ''to control and prohibit pollution of air and water in accordance with the law and rules adopted and promulgated by it and, for this purpose, to: collect and disseminate information and conduct educational and training programs relating to pollution.'' Along with 403.061 (21), F.S. which states that the FL DEP also can advise, consult, cooperate, and enter into agreements with other agencies of the state, the Federal Government, other states, interstate agencies, groups, political subdivisions, and industries affected by the provisions of this act, rules, or policies of the department. Chapters 62–204, F.A.C., *Air Pollution Control Provisions;* 62–210, F.A.C., *Stationary Sources—General Requirements,* and 62–212, F.A.C., *Stationary Sources—Preconstruction Review* also include public notice requirements for the State's permitting program. Additionally, Notification to the public of instances or areas exceeding the NAAQS and associated health effects is provided through implementation of the Air Quality Index reporting system in all required areas. EPA has made the preliminary determination that Florida's SIP and practices adequately demonstrate the State's ability to provide public notification related to the 2008 Lead NAAQS when necessary. Accordingly, EPA is proposing to approve Florida's infrastructure SIP submission with respect to section 110(a)(2)(J) public notification.

110(a)(2)(J) Visibility Protection: The 2011 Lead Infrastructure SIP Guidance notes that EPA does not generally treat the visibility protection aspects of section 110(a)(2)(J) as applicable for purposes of the infrastructure SIP approval process. EPA recognizes that states are subject to visibility protection and regional haze program requirements under Part C of the Act (which includes sections 169A and 169B). However, in the event of the establishment of a new primary NAAQS, the visibility protection and regional haze program requirements under part C do not change. Thus, EPA concludes there are no new applicable visibility protection obligations under section 110(a)(2)(J) as a result of the 2008 Lead NAAQS, and as such, EPA is proposing to approve section 110(a)(2)(J) of FL DEP's infrastructure SIP submission as it relates to visibility protection.

10. 110(a)(2)(K)—Air quality and modeling/data: Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and submission of such data to the USEPA can be made. Chapter 62–204.800, F.A.C., *Air Pollution Control Provisions;* 62–210, F.A.C., *Stationary Sources—General Requirements,* and 62–212, F.A.C., *Stationary Sources—*

Preconstruction Review, incorporates by reference 40 CFR 52.21(l), which specifies that air modeling be conducted in accordance with 40 CFR part 51, Appendix W ''Guideline on Air Quality Models.'' These regulations demonstrate that Florida has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2008 Lead NAAQS. Additionally, Florida supports a regional effort to coordinate the development of emissions inventories and conduct regional modeling for several NAAQS, including the 2008 Lead NAAQS, for the Southeastern states. Taken as a whole, Florida's air quality regulations demonstrate that FL DEP has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2008 Lead NAAQS. EPA has made the preliminary determination that Florida's SIP and practices adequately demonstrate the State's ability to provide for air quality and modeling, along with analysis of the associated data, related to the 2008 Lead NAAQS when necessary.

11. 110(a)(2)(L)—Permitting fees: This element necessitates that the SIP require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover (i) the reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V. Florida statute subsection 403.087(6)(a), F.S., *Permit Fees* directs FL DEP to require a processing fee in an amount sufficient for the reasonable cost of reviewing and acting upon PSD and NNSR permits. The local air program costs are covered by the Air Pollution Control Trust Fund which is comprised of various funding sources. Additionally, Florida has a fully approved title V operating permit program at subsection 403.0872, F.S., Annual *Emissions Fee.* and Chapter 62.213, F.A.C. *Operation Permits For Major Sources of Air Pollution* that covers the cost of implementation and enforcement of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Florida's statues and practices adequately provide for permitting fees related to the 2008 Lead NAAQS, when necessary.

12. 110(a)(2)(M)—Consultation/participation by affected local entities: This element requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. Chapter 62–204, *Air Pollution Control Provisions,* requires that SIPs be submitted in accordance with 40 CFR part 51, subpart F. Florida statute subsection 403.061(21), F.S. authorizes FDEP to ''advise, consult, cooperate and enter into agreements with other agencies of the state, the Federal Government, other states, interstate agencies, groups, political subdivisions, and industries affected by the provisions of this act, rules, or policies of the department.'' EPA has made the preliminary determination that Florida's SIP and practices adequately demonstrate consultation with affected local entities related to the 2008 Lead NAAQS, when necessary.

V. Proposed Action

With the exception of the PSD permitting requirements for major sources contained in sections 110(a)(2)(C), prong 3 of D(i) and (J), EPA is proposing to approve Florida's October 14, 2011, SIP submission to incorporate provisions into the Florida SIP to address infrastructure requirements for the 2008 Lead NAAQS. EPA is proposing to approve these portions of Florida's infrastructure submission for the 2008 Lead NAAQS because this submission is consistent with section 110 of the CAA.

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The Florida SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: May 12, 2015.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2015–12350 Filed 5–21–15; 8:45 am]

BILLING CODE 6560–50–P

LEGAL SERVICES CORPORATION

45 CFR Parts 1610, 1627, and 1630

Use of Non-LSC Funds, Transfer of LSC Funds, Program Integrity; Subgrants and Membership Fees or Dues; Cost Standards and Procedures—Extension of Comment Period

AGENCY: Legal Services Corporation.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Legal Services Corporation (''LSC'') issued a proposed rule in the **Federal Register** of April 20, 2015, concerning proposed amendments to its regulations governing transfers of LSC funds, subgrants to third parties, and cost standards and procedures. This notice extends the comment period for 21 days, to June 10, 2015.

DATES: The comment period for the proposed rule published April 20, 2015, at 80 FR 21692, is reopened. Comments must be submitted by June 10, 2015.

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

Email: SubgrantRulemaking@lsc.gov. Include ''Subgrant Rulemaking'' in the subject line of the message.

Fax: (202) 337–6519, ATTN: Subgrant Rulemaking.

Mail: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007, ATTN: Subgrant Rulemaking.

Hand Delivery/Courier: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007, ATTN: Subgrant Rulemaking.

Instructions: Electronic submissions are preferred via email with attachments in Acrobat PDF format. LSC may not consider written comments sent via any other method or received after the end of the comment period.

FOR FURTHER INFORMATION CONTACT: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K Street NW., Washington, DC 20007, (202) 295–1563 (phone), (202) 337–6519 (fax), *sdavis@lsc.gov.*

SUPPLEMENTARY INFORMATION: LSC is extending the public comment period stated in the **Federal Register** notice for this rulemaking. 80 FR 21692, Apr. 20, 2015 [FR Doc. No. 2015–8951]. In that notice, LSC proposed amendments to its regulations governing transfers of LSC funds (45 CFR part 1610), subgrants to third parties (45 CFR part 1627), and cost standards and procedures (45 CFR part 1630). LSC has received requests for an extension of the comment period to allow interested parties and stakeholders additional time to develop their comments on the proposed rulemaking, including obtaining data about the potential effects of proposed changes. LSC is therefore extending the comment period for 21 days, from May 20, 2015, to June 10, 2015.

Dated: May 18, 2015.

Stefanie K. Davis,

Assistant General Counsel.

[FR Doc. 2015–12371 Filed 5–21–15; 8:45 am]

BILLING CODE 7050–01–P

Notices

Federal Register

Vol. 80, No. 99

Friday, May 22, 2015

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

Forest Service

Information Collection; Community Forest and Open Space Program

AGENCY: Forest Service, USDA.

ACTION: Correction Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service (FS) is seeking comments from all interested individuals and organizations on the extension with no revision of a currently approved information collection; Community Forest and Open Space Program (Community Forest Program).

The Agency is in the process of a proposed rule revision that will include a new information collection request; when the revised rule is final, the Agency will merge the new information collection with this information collection.

This notice replaces **Federal Register** document #2015–07996 that was published in the **Federal Register** on April 7, 2015.

DATES: Comments must be received in writing on or before July 21, 2015 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Maya Solomon, USDA Forest Service, Cooperative Forestry Staff, 1400 Independence Avenue SW., Mailstop 1123, Washington, DC 20250. Comments may also be submitted electronically via email to *communityforest@fs.fed.us.* If comments are sent electronically, do not duplicate via regular mail.

The public may inspect comments received at the USDA Forest Service, Yates Building, 1400 Independence Avenue, Washington, DC during normal business hours. Visitors are encouraged to call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Maya Solomon, Forest Legacy Program Specialist, by phone at 202–206–1376. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title: Community Forest and Open Space Program.

OMB Number: 0596–0227.

Expiration Date of Approval: August 31, 2015.

Type of Request: Extension with no change.

Abstract: The purpose of the Community Forest Program is to achieve community benefits through grants to local governments, Tribal Governments, and qualified nonprofit organizations to establish community forests by acquiring and protecting private forestlands. This rule includes information requirements necessary to implement the Community Forest Program and comply with grants regulations and OMB Circulars. The information requirements are used to help the Forest Service in the following areas: (1) To determine that the applicant is eligible to receive funds under the program; (2) to determine if the proposal meets the qualifications in the law and regulations; (3) to evaluate and rank the proposals based on a standard, consistent information process; and (4) to determine if the project costs are allowable and that sufficient cost share is provided.

Local governmental entities, Tribal Governments, and qualified nonprofit organizations are the only entities eligible for the program, and therefore are the only organizations from which information is collected.

The information collection currently required for a request for proposals and grant application is approved and has been assigned the OMB Control No. 0596–0227.

Estimated Annual Number of Respondents: 150.

Estimated Burden per Response: 22.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 150.

Estimated Total Annual Burden on Respondents: 4,778 hours.

Comment Is Invited

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: May 19, 2015.

Patti Hirami,

Associate Deputy Chief, State and Private Forestry.

[FR Doc. 2015–12515 Filed 5–21–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Announcement of Grant Application Deadlines

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice of Solicitation of Applications (NOSA).

SUMMARY: The Rural Utilities Service (RUS), an agency of the United States Department of Agriculture (USDA), announces its Distance Learning and Telemedicine (DLT) Grant Program application window for Fiscal Year (FY) 2015. RUS has published on its Web site *http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas* the amount of funding received through the final appropriations act. Expenses incurred in developing applications will be at the applicant's risk.

In addition to announcing the application window, RUS announces the minimum and maximum amounts

for DLT grants applicable for the fiscal year. The DLT Grant Program regulations can be found at 7 CFR part 1703, subparts D through G.

DATES: You may submit completed applications for grants on paper or electronically by the following deadline:

- *Paper submissions:* Paper submissions must be postmarked and mailed, shipped, or sent overnight *no later* than July 6, 2015 to be eligible for FY 2015 grant funding. Late or incomplete applications will not be eligible for FY 2015 grant funding.
- *Electronic submissions:* Electronic submissions must be received by July 6, 2015 to be eligible for FY 2015 grant funding. Late or incomplete applications will not be eligible for FY 2015 grant funding.
- If the submission deadline falls on Saturday, Sunday, or a Federal holiday, the application is due the next business day.

ADDRESSES: Copies of the FY 2015 Application Guide and materials for the DLT grant program may be obtained by the following:

(1) The DLT Web site: *http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants* and

(2) Contacting the RUS Loan Origination and Approval Division at 202–720–0800.

Completed applications may be submitted in the following ways:

(1) *Paper:* Paper applications are to be submitted to the Rural Utilities Service, Telecommunications Program, 1400 Independence Ave. SW., Room 2808, STOP 1597, Washington, DC 20250–1597. Applications should be marked ''Attention: Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service.''

(2) *Electronic:* Electronic applications must be submitted through Grants.gov. Information on how to submit applications electronically is available on the Grants.gov Web site (*http://www.grants.gov*). Applicants must successfully pre-register with Grants.gov to use the electronic applications option. Application information may be downloaded from Grants.gov without preregistration.

FOR FURTHER INFORMATION CONTACT: Shawn Arner, Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service, U.S. Department of Agriculture, Telephone: (202) 720–0800, fax: (202) 205–2921.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency: Rural Utilities Service (RUS).

Funding Opportunity Title: Distance Learning and Telemedicine Grants.

Announcement Type: Initial announcement.

Funding Opportunity Number: RUS–15–01–DLT.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.855.

Dates: You may submit completed applications for grants on paper or electronically according to the deadlines indicated in section D(4).

A. Program Description

DLT grants are specifically designed to provide access to education, training and health care resources for rural Americans. The DLT Program is authorized by 7 U.S.C. 950aaa and provides financial assistance to encourage and improve telemedicine services and distance learning services in rural areas through the use of telecommunications, computer networks, and related advanced technologies to be used by students, teachers, medical professionals, and rural residents. Regulations for the DLT Program can be found at 7 CFR part 1703 (Subparts D through G).

The grants, which are awarded through a competitive process, may be used to fund telecommunications-enabled information, audio and video equipment, and related advanced technologies which extend educational and medical applications into rural areas. Grants are intended to benefit end users in rural areas, who are often not in the same location as the source of the educational or health care service.

As in years past, the FY 2015 DLT Grant Application Guide has been updated based on program experience. All applicants should carefully review and prepare their applications according to instructions in the FY 2015 Application Guide and sample materials when completing a DLT grant application.

Expenses incurred in developing applications will be at the applicant's own risk.

B. Federal Award Information

Under 7 CFR 1703.124, the Administrator has established a minimum grant amount of $50,000 and a maximum grant amount of $500,000 for FY 2015.

Award documents specify the term of each award. The Agency will make awards and successful applicants will be required to execute documents appropriate to the project prior to any advance of funds to successful applicants. Prior DLT grants cannot be renewed; however, applications from existing DLT awardees for new projects are acceptable (grant applications must be submitted during the application window) and will be evaluated as new applications.

C. Eligibility Information

1. Eligible Applicants (See 7 CFR 1703.103)

a. Only entities legally organized as one of the following are eligible for DLT grants:

i. An incorporated organization or a partnership,

ii. An Indian tribe or tribal organization, as defined in 25 U.S.C. 450b,

iii. A state or local unit of government,

iv. A consortium, as defined in 7 CFR 1703.102,

v. A library, or

vi. Other legal entity, including a private corporation organized on a for-profit or not-for-profit basis.

b. Individuals are not eligible for DLT program financial assistance directly.

c. Electric and telecommunications borrowers under the Rural Electrification Act of 1936 (7 U.S.C. 901 *et seq.*) are not eligible for grants.

d. Corporations that have been convicted of a Federal felony within the past 24 months are not eligible. Any corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance.

e. Applicants must have an active registration with current information in the System for Award Management (SAM) (previously the Central Contractor Registry (CCR)) at *https:\\www.sam.gov* and have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number.

2. Cost Sharing or Matching

The DLT Program requires matching contributions for grants. See 7 CFR 1703.125(g) for information on required matching contributions.

a. Grant applicants must demonstrate matching contributions, in cash or in kind (new, non-depreciated items), of at least fifteen (15) percent of the total amount of financial assistance requested. Matching contributions must be used for eligible purposes of DLT grant assistance (see 7 CFR 1703.121 and section D(6)(a)(ii) of this Notice).

b. Greater amounts of eligible matching contributions may increase an applicant's score (see 7 CFR 1703.126(b)(4)).

c. Applications that do not provide evidence of the required fifteen percent match will be declared ineligible. See the FY 2015 Application Guide for more information on matching contributions.

d. Matching contributions which are not sufficiently documented are subject to disallowance and may result in an ineligible application.

e. Discounts. The DLT Program regulation provides that manufacturers' and service providers' discounts are not eligible matches. In the past, the Agency did not consider as eligible any proposed match from a vendor, manufacturer, or service provider whose products or services would also be purchased for the DLT project. However, the agency has now determined that if a vendor can demonstrate that the donated product is normally sold at the in-kind matching price, then it will accept such products for in-kind matches, and not at a discount. Similarly, if a vendor, manufacturer, or other service provider proposes a cash match (or any in-kind match) when their products or services will be purchased with grant or match funds, such products or services must be shown to be normally offered at, or higher than, the contract price of the products or services to be provided on the project.

f. Eligible Equipment & Facilities. Please see 7 CFR 1703.102 and the FY 2015 Application Guide for more information regarding eligible and ineligible items.

g. Apportioning budget items. Many DLT applications propose to use items for a blend of specific DLT eligible project purposes and other purposes. RUS will consider funding such items in the overall context of the project, but such items will affect the competitive value of the project compared with other projects. The proposed project could receive a lower score in the subjective areas of the grant to the extent that its budget requests items that have limited or questionable value to the purposes of distance learning or telemedicine. See the FY 2015 Application Guide for detailed information on how to apportion use and apportioning illustrations.

3. Other

a. Minimum Rurality Requirements. The DLT grant program is designed to bring the benefits of distance learning and telemedicine to residents of rural America. Therefore, to be eligible, applicants must deliver distance learning or telemedicine services to entities that operate a rural community facility or to residents of rural areas, at rates calculated to ensure that the benefit of the financial assistance is passed through to such entities or to residents of rural areas. All projects proposed for DLT grant assistance must meet a minimum rurality threshold, to ensure that benefits from the projects flow to rural residents.

b. Ineligibility of Projects in Coastal Barrier Resources Act Areas. Projects located in areas covered by the Coastal Barrier Resources Act (16 U.S.C. 3501 *et seq.*) are not eligible for financial assistance from the DLT Program. Please see 7 CFR 1703.123(a)(11).

D. Application and Submission Information

See the FY 2015 Application Guide for more information on the items that comprise a complete application. For requirements of completed grant applications you may also refer to 7 CFR 1703.125. The FY 2015 Application Guide provides specific, detailed instructions for each item that constitutes a complete application. The Agency strongly emphasizes the importance of including every required item and strongly encourages applicants to follow the instructions carefully, using the examples and illustrations in the FY 2015 Application Guide. Applications that do not include all items that determine project eligibility and applicant eligibility by the application deadline will be returned as ineligible. Scoring and eligibility information not provided by the application deadline will not be solicited or considered by the Agency. Applications that do not include all items necessary for scoring, depending on the specific scoring criteria, may still be eligible applications, but may not receive full or any credit if the information cannot be verified. Please see the FY 2015 Application Guide for a full discussion of each required item and for samples and illustrations.

1. *Address to Request Application Package.* The FY 2015 Application Guide, copies of necessary forms and samples, and the DLT Program regulation are available from these sources:

a. The Internet: *http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants.*

b. The Rural Utilities Service, Loan Origination and Approval Division, for paper copies of these materials: 202–720–0800.

2. *Content and Form of Application Submission.*

Applicants are reminded that the DLT Grant Program is intended to meet the educational and health care needs of rural America. Hub sites may be located in rural or non-rural areas, but end-user sites need to be located in rural areas. Non-fixed sites serving a geographical service area may include non-rural areas.

If a grant application includes a site that is included in any other DLT grant application for FY 2015, or a site that has been included in any DLT grant funded in FY 2014 or FY 2013, the application should contain a detailed explanation of the related applications or grants. The Agency must make a nonduplication finding for each grant approved; however, an apparent but unexplained duplication of funding for a site can prevent such a finding.

a. Detailed information on each item included in the *Table of Required Elements of a Completed Grant Application* found in section D(2)(g) of this Notice can be found in the sections of the DLT Program regulation listed in the table, and the DLT grant Application Guide. Applicants are strongly encouraged to read and apply both the regulation and the Applications Guide, which describes the regulation.

i. When the table refers to a narrative, it means a written statement, description or other written material prepared by the applicant, for which no form exists. The Agency recognizes that each project is unique and requests narratives to allow applicants to explain their request for financial assistance.

ii. When documentation is requested, it means letters, certifications, legal documents, or other third-party documentation that provides evidence that the applicant meets the listed requirement. For example, to confirm rurality scores, applicants can use printouts from the Web site *http://factfinder2.census.gov/faces/nav/jsf/pages/index.xhtml.* Leveraging documentation generally will be letters of commitment from other funding sources. In-kind matches must be items purchased or donated after the application deadline date that are essential to the project and documentation from the vendor or donor must demonstrate the relationship of each item to the project's function. Evidence of legal existence is sometimes proven by submitting articles of incorporation. The examples here are not intended to limit the types of documentation that must be submitted to fulfill a requirement. DLT Program regulations and the Application Guide provide specific guidance on each of the items in the table.

b. The DLT Application Guide and ancillary materials provide all necessary sample forms and worksheets.The FY 2015 Application Guide also specifies the format and order of all required items.

c. Most DLT grant projects contain numerous project sites. The Agency requires that site information be consistent throughout an application. Sites must be referred to by the same designation throughout all parts of an application. The Agency has provided a site worksheet that requests the necessary information, and can be used as a guide by applicants. RUS strongly recommends that applicants complete the site worksheet, listing all requested information for each site. Applications without consistent site information will be returned as ineligible.

d. While the table in section D(2)(g) of this Notice includes all items of a completed application, the Agency may ask for additional or clarifying information for applications submitted by the deadline which appear to demonstrate that they meet eligibility requirements, but which may require follow up by the Agency.

e. Given the high volume of program interest, to expedite processing applicants are asked to submit the required application items in the order depicted in the FY 2015 Application Guide. The FY 2015 Application Guide specifies the format and order of all required items. Applications that are not assembled and tabbed in the order specified prevent timely determination of eligibility. For applications with inconsistency among submitted copies, the Agency will base its evaluation on the original signed application received by the Agency.

f. Compliance with other federal statutes.

The applicant must provide evidence of compliance with other federal statutes and regulations as provided in the FY 2015 Application Guide, including, but not limited to the following:

i. 7 CFR part 15, subpart A—Nondiscrimination in Federally-Assisted Programs of the Department of Agriculture—Effectuation of Title VI of the Civil Rights Act of 1964.

ii. 2 CFR part 417—Nonprocurement Debarment and Suspension.

iii. 2 CFR parts 200 and 400 (Uniform Assistance Requirements, Cost Principles and Audit Requirements For Federal Awards).

iv. 2 CFR part 182 (Governmentwide Requirements For Drug-Free Workplace (Financial Assistance)) and 2 CFR part 421 (Requirements For Drug Free Workplace (Financial Assistance)).

v. Executive Order 13166, ''Improving Access to Services for Persons with Limited English Proficiency.'' For information on limited English proficiency and agency-specific guidance, go to *http://www.LEP.gov.*

vi. Federal Obligation Certification on Delinquent Debt.

g. Table of Required Elements of a Completed Grant Application

Application item	REQUIRED items, unless otherwise noted	
	Grants (7 CFR 1703.125 and 7 CFR 1703.126)	Comment
SF–424 (Application for Federal Assistance form)	Yes	*Completely* filled out.
Site Worksheet	Yes	Agency worksheet.
Survey on Ensuring Equal Opportunity for Applicants	Optional	OMB Form.
Evidence of Legal Authority to Contract with the Government.	Yes	Documentation.
Evidence of Legal Existence	Yes	Documentation.
Executive Summary	Yes	Narrative.
Telecommunications System Plan and Scope of Work	Yes	Narrative & documentation such as maps and diagrams.
Budget	Yes	Agency Worksheets with documentation.
Financial Information/Sustainability	Yes	Narrative.
Statement of Experience	Yes	Narrative 3-page, single-spaced limit.
Rurality Worksheet	Yes	Agency worksheet with documentation.
National School Lunch Program (NSLP) Worksheet	Yes	Agency worksheet with documentation.
Leveraging Evidence and Funding Commitments from all Sources.	Yes	Agency worksheet and source documentation.
Request for Additional NSLP	Optional	Agency Worksheet and narrative.
Need for and Benefits derived from Project	Yes	Narrative & documentation.
Innovativeness of the Project	Yes	Narrative & documentation.
Cost Effectiveness of Project	Yes	Narrative & documentation.
Consultation with the USDA State Director, Rural Development, and evidence that application conforms to State Strategic Plan, if any.	Yes	Documentation.
Special Consideration	Optional	Documentation supporting end user site is in a Trust Area or Tribal Jurisdiction Area.
Certifications		
Equal Opportunity and Nondiscrimination	Yes	Form provided in FY 2015 Application Tool Kit.
Architectural Barriers	Yes	Form provided in FY 2015 Application Tool Kit.
Flood Hazard Area Precautions	Yes	Form provided in FY 2015 Application Tool Kit.
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970.	Yes	Form provided in FY 2015 Application Tool Kit.
Drug-Free Workplace	Yes	Form provided in FY 2015 Application Tool Kit.
Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions.	Yes	Form provided in FY 2015 Application Tool Kit.
Lobbying for Contracts, Grants, Loans, and Cooperative Agreements.	Yes	Form provided in FY 2015 Application Tool Kit.
Non-Duplication of Services	Yes	Form provided in FY 2015 Application Tool Kit.
Environmental Impact/Historic Preservation Certification	Yes	Form provided in FY 2015 Application Tool Kit.

Application item	REQUIRED items, unless otherwise noted	
	Grants (7 CFR 1703.125 and 7 CFR 1703.126)	Comment
Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.	Yes	Form provided in the FY 2015 Application Tool Kit.

h. Number of copies of submitted applications.

i. Applications submitted on paper.

A. Submit the original application and two (2) copies to RUS; and

B. Submit one (1) additional copy to the state government single point of contact (if one has been designated) at the same time as you submit the application to the Agency for the State where the project is located. If the project is located in more than one State, submit a copy to each state government single point of contact. See *http://www.whitehouse.gov/omb/grants_spoc* for an updated listing of State government single points of contact.

ii. Electronically submitted applications. Grant applications may be submitted electronically. Please carefully read the FY 2015 Application Guide for guidance on submitting an electronic application. In particular, we ask that you identify and number each page in the same way you would a paper application so that we can assemble them as you intended.

iii. The additional paper copy is not necessary if you submit the application electronically through Grants.gov.

iv. Submit one (1) copy to the state government single point of contact (if one has been designated) at the same time as you submit the application to the Agency. If the project is located in more than one State, submit a copy to each state government single point of contact. See *http://www.whitehouse.gov/omb/grants_spoc* for an updated listing of State government single points of contact.

3. *Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM).* The applicant for a grant must supply a Dun and Bradstreet Data Universal Numbering System (DUNS) number as part of an application. The Standard Form 424 (SF–424) contains a field for the DUNS number. The applicant can obtain the DUNS number free of charge by calling Dun and Bradstreet. Please see *http://fedgov.dnb.com/webform* for more information on how to obtain a DUNS number or how to verify your organization's number.

Prior to submitting an application, the applicant must register in the System for Award Management (SAM) (formerly Central Contractor Registry, (CCR)). Applicants must register for the SAM at *https://www.sam.gov/portal/public/SAM/.* SAM registration must remain active with current information at all times while RUS is considering an application or while a Federal grant award is active. To maintain SAM registration the applicant must review and update the information in the SAM database annually from the date of initial registration or from the date of the last update. The applicant must ensure that the information in the database is current, accurate, and complete.

4. *Submission Dates and Times.*

a. Paper grant applications must be postmarked and mailed, shipped, or sent overnight no later than July 6, 2015 to be eligible for FY 2015 grant funding. Late applications, applications which do not include proof of mailing or shipping as described in section D(7)(a)(ii), and incomplete applications are not eligible for FY 2015 grant funding.

b. Electronic grant applications must be received by July 6, 2015 to be eligible for FY 2015 funding. Late or incomplete applications will not be eligible for FY 2015 grant funding.

c. If the submission deadline falls on Saturday, Sunday, or a Federal holiday, the application is due the next business day.

5. *Intergovernmental Review.* The DLT grant program is subject to Executive Order 12372, ''Intergovernmental Review of Federal Programs.'' As stated in section D(2)(h)(i)(B) of this Notice, a copy of a DLT grant application must be submitted to the state single point of contact if one has been designated. Please see *http://www.whitehouse.gov/omb/grants_spoc* to determine whether your state has a single point of contact.

6. *Funding Restrictions.*

a. Ineligible purposes.

i. Hub sites that are not located in rural areas are not eligible for grant assistance unless they are necessary to provide DLT services to end-users in rural areas. Please see 7 CFR 1703.101(h).

ii. To fulfill the policy goals laid out for the DLT Program in 7 CFR 1703.101, the following table lists purposes for financial assistance and whether each purpose is generally considered to be eligible for the form of financial assistance. Please consult the FY 2015 Application Guide and the program regulations (7 CFR 1703.102) for definitions, in combination with the portions of the regulation cited in the table, for detailed requirements for the items in the table. RUS strongly recommends that applicants exclude ineligible items from the grant and match portions of grant application budgets and reiterates that reimbursement of pre-award costs is not allowed. However, some items ineligible for funding or matching contributions may be vital to the project. RUS encourages applicants to document those costs in the application's budget. Please see the FY 2015 Application Guide for a recommended budget format, and detailed budget compilation instructions.

	Grants
Lease or purchase of new eligible DLT equipment and facilities	Yes, equipment only.
Acquire new instructional programming that is capital asset	Yes.
Technical assistance, develop instructional material for the operation of the equipment, and engineering or environmental studies in the implementation of the project.	Yes, up to 10% of the grant.
Telemedicine or distance learning equipment or facilities necessary to the project	Yes.
Vehicles using distance learning or telemedicine technology to deliver services	No.
Teacher-student links located at the same facility	No.
Links between medical professionals located at the same facility	No.
Site development or building alteration, except for equipment installation and associated inside wiring	No.

	Grants
Land or building purchase	No.
Building Construction	No.
Acquiring telecommunications transmission facilities	No (such facilities are only eligible for DLT loans).
Internet services, telecommunications services or other forms of connectivity	No.
Salaries, wages, benefits for medical or educational personnel	No.
Salaries or administrative expenses of applicant or project	No.
Recurring project costs or operating expenses	No (equipment & facility leases are not recurring project costs).
Equipment to be owned by the LEC or other telecommunications service provider, if the provider is the applicant.	No.
Duplicative distance learning or telemedicine services	No.
Any project that for its success depends on additional DLT financial assistance or other financial assistance that is not assured.	No.
Application Preparation Costs	No.
Other project costs not in regulation	No.
Cost (amount) of facilities providing distance learning broadcasting	No.
Reimburse applicants or others for costs incurred prior to RUS receipt of completed application	No.

7. *Other Submission Requirements.*

Grant applications may be submitted on paper or electronically.

a. Submitting applications on paper.

i. Address paper applications to the Telecommunications Program, RUS, U.S. Department of Agriculture, 1400 Independence Ave. SW., Room 2808, STOP 1597, Washington, DC 20250–1550. Applications should be marked ''Attention: Deputy Assistant Administrator, Loan Origination and Approval Division.''

ii. Paper grant applications must show proof of mailing or shipping by the deadline consisting of one of the following:

A. A legibly dated U.S. Postal Service (USPS) postmark;

B. A legible mail receipt with the date of mailing stamped by the USPS; or

C. A dated shipping label, invoice, or receipt from a commercial carrier.

iii. Due to screening procedures at the U.S. Department of Agriculture, packages arriving via regular mail through the USPS are irradiated, which can damage the contents and delay delivery to the DLT Program. RUS encourages applicants to consider the impact of this procedure in selecting their application delivery method.

b. *Electronically submitted applications.*

i. Applications will not be accepted via fax or electronic mail.

ii. Electronic applications for grants must be submitted through the Federal government's Grants.gov initiative at *http://www.grants.gov/.*

iii. How to use Grants.gov.

A. Grants.gov contains full instructions on all required passwords, credentialing and software.

B. System for Award Management. Submitting an application through Grants.gov requires that your organization list in the System for Award Management (SAM) (formerly Central Contractor Registry, CCR). The Agency strongly recommends that you obtain your organization's DUNS number and SAM listing well in advance of the deadline specified in this notice. See section C(1)(e) for more information on SAM.

C. Credentialing and authorization of applicants. Grants.gov will also require some credentialing and online authentication procedures. These procedures may take several business days to complete, further emphasizing the need for early action by applicants to complete the sign-up, credentialing and authorization procedures at Grants.gov before you submit an application at that Web site.

D. Some or all of the SAM and Grants.gov registration, credentialing and authorizations require updates. If you have previously registered at Grants.gov to submit applications electronically, please ensure that your registration, credentialing and authorizations are up to date well in advance of the grant application deadline.

iv. RUS encourages applicants who wish to apply through Grants.gov to submit their applications in advance of the deadlines.

v. If a system problem occurs or you have technical difficulties with an electronic application, please use the customer support resources available at the Grants.gov Web site.

E. Application Review Information

1. *Criteria.*

a. Grant application scoring criteria (total possible points: 235). See 7 CFR 1703.125 for the items that will be reviewed during scoring, and 7 CFR 1703.126 and section E.3 of this NOSA for scoring criteria.

b. Grant applications are scored competitively subject to the criteria listed below.

i. *Rurality* category—Rurality of the proposed service area (up to 45 points).

ii. *NSLP* category—percentage of students eligible for the NSLP in the proposed service area (up to 35 points).

iii. *Leveraging* category—matching funds above the required matching level (up to 35 points).

iv. Need for services proposed in the application and the benefits that will be derived if the application receives a grant (up to 55 points).

A. *Additional NSLP* category—up to 10 of the possible 55 possible points are to recognize economic need not reflected in the project's National School Lunch Program (NSLP) score, and can be earned only by applications whose overall NSLP eligibility is less than 50%. To be eligible to receive points under this category, the application must include an affirmative request for consideration of the possible 10 points, and compelling documentation of reasons why the NSLP eligibility percentage does not represent the economic need of the proposed project beneficiaries.

B. *Needs and Benefits* category—up to 45 of the 55 possible points under this criterion are available to all applicants. Points are awarded based on the required narrative crafted by the applicant that documents the need for services and the benefits derived from such services. RUS encourages applicants to carefully read the cited portions of the Program regulation and the FY 2015 Application Guide for full discussions of this criterion.

v. Innovativeness category—level of innovation demonstrated by the project (up to 15 points).

vi. Cost Effectiveness category—system cost-effectiveness (up to 35 points).

vii. Special Consideration Areas—Application must contain at least one end-user site within a trust area or a tribal jurisdictional area (15 points).

2. *Review and Selection Process.*

Grant applications are ranked by final score. RUS selects applications based on those rankings, subject to the availability of funds. In addition, the Agency has the authority to limit the number of applications selected in any one state, or for one project, during a fiscal year. See 7 CFR 1703.127 for a description of the grant application selection process. In addition, it should be noted that an application receiving fewer points can be selected over a higher scoring application in the event that there are insufficient funds available to cover the costs of the higher scoring application, as stated in 7 CFR 1703.172(b)(3).

a. In addition to the scoring criteria that rank applications against each other, the Agency evaluates grant applications for possible awards on the following items, in accordance with 7 CFR 1703.127:

i. Financial feasibility. A proposal that does not indicate financial feasibility or that is not sustainable will not be approved for an award.

ii. Technical considerations. If the application contains flaws that would prevent the successful implementation, operation or sustainability of a project, the Agency will not award a grant.

iii. Other aspects of proposals that contain inadequacies that would undermine the ability of the project to comply with the policies of the DLT Program.

b. *Special considerations or preferences.*

i. American Samoa, Guam, Virgin Islands, and Northern Mariana Islands applications are exempt from the matching requirement for awards having a match amount of up to $200,000 (see 48 U.S.C. 1469a; 91 Stat. 1164).

ii. Special Consideration Areas. RUS will offer special consideration to applications that contain at least one end-user site within a trust area or a tribal jurisdictional area. Such applications will be awarded 15 points. The application must include a map showing the end-user site(s) located in the trust area or tribal jurisdictional area, as well as the geographical coordinate(s), and physical address(es) of the end-user site(s). The applicant will also need to submit evidence indicating that the area where the end-user site is located is a trust area or a tribal jurisdictional area.

RUS will use one or more of the following resources in determining whether a particular end-user site is located in a trust area or a tribal jurisdictional area:

A. Official maps of Federal Indian Reservations based on information compiled by the U.S. Department of the Interior, Bureau of Indian Affairs, and made available to the public;

B. Title Status Reports issued by the U.S. Department of the Interior, Bureau of Indian Affairs showing that title to such land is held in trust or is subject to restrictions imposed by the United States;

C. Trust Asset and Accounting Management System data, maintained by the Department of the Interior, Bureau of Indian Affairs;

D. Official maps of the Department of Hawaiian Homelands of the State of Hawaii identifying land that has been given the status of Hawaiian home lands under the provisions of section 204 of the Hawaiian Homes Commission Act, 1920;

E. Official records of the U.S. Department of the Interior, the State of Alaska, or such other documentation of ownership as RUS may determine to be satisfactory, showing that title is owned by a Regional Corporation or a Village Corporation as such terms are defined in the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*);

F. Evidence that the land is located on Guam, American Samoa or the Commonwealth of the Northern Mariana Islands, and is eligible for use in the U.S. Department of Veterans Affairs' direct loan program for veterans purchasing or constructing homes on communally owned land; and

G. Any other evidence submitted by the applicant that is satisfactory to RUS to establish that area where the end-user site is located is a trust area or a tribal jurisdictional area within the meaning of 38 U.S.C. 3765(1).

b. Clarification: DLT grant applications which have non-fixed end-user sites, such as ambulance and home health care services, are scored according to the location of the hub or hubs used for the project. For Hybrid Projects which combine a non-fixed portion of a project to a fixed portion of a project, the Rurality Score and NSLP score will be based on the score of the end sites of the fixed portion plus the score of the hub that serves the non-fixed portion. See the FY 2015 Application Guide for specific guidance on preparing an application with non-fixed end users.

F. Federal Award Administration Information

1. Federal Award Notices

RUS generally notifies by mail applicants whose projects are selected for awards. The mere receipt of an award letter does not serve to authorize the applicant to commence performance under the award. The Agency follows the award letter with an agreement that contains all the terms and conditions for the grant. A copy of the standard agreement is posted on the RUS Web site at *http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants.* An applicant must execute and return the agreement, accompanied by any additional items required by the agreement, within the number of days shown in the selection notice letter.

2. Administrative and National Policy Requirements

The items listed in Section E of this notice, the DLT Program regulation, FY 2015 Application Guide and accompanying materials implement the appropriate administrative and national policy requirements, which includes but is not limited to:

a. Execute a Distance Learning and Telemedicine Grant Agreement;

b. Use Form SF 270, ''Request for Advance or Reimbursement,'' to request reimbursements (along with the submission of receipts for expenditures, timesheets, and any other documentation to support the request for reimbursement);

c. Provide annual project performance activity reports until the expiration of the award;

d. Ensure that records are maintained to document all activities and expenditures utilizing DLT grant funds and matching funds (receipts for expenditures are to be included in this documentation);

e. Provide a final project performance report;

f. Comply with policies, guidance, and requirements as described in the following applicable Code of Federal Regulations, and any successor regulations:

i. 2 CFR parts 200 and 400 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements For Federal Awards); and

ii. 2 CFR parts 417 and 180 (Government-wide Debarment and Suspension (Nonprocurement); and

g. Sign Form AD–3031 (''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants'') (for corporate applicants only).

3. Reporting

a. Performance reporting. All recipients of DLT financial assistance must provide annual performance activity reports to RUS until the project is complete and the funds are expended. A final performance report is also required; the final report may serve as the last annual report. The final report must include an evaluation of the success of the project in meeting DLT Program objectives. *See* 7 CFR 1703.107 for additional information on these reporting requirements.

b. Financial reporting. All recipients of DLT financial assistance must provide an annual audit, beginning with the first year in which a portion of the financial assistance is expended. Audits are governed by United States Department of Agriculture audit regulations. Please *see* 7 CFR 1703.108 and Subpart F (Audit Requirements) of 2 CFR part 200 for a description of the financial reporting requirements of all recipients of DLT financial assistance.

c. Recipient and Subrecipient Reporting. The applicant must have the necessary processes and systems in place to comply with the reporting requirements for first-tier sub-awards and executive compensation under the Federal Funding Accountability and Transparency Act of 2006 in the event the applicant receives funding unless such applicant is exempt from such reporting requirements pursuant to 2 CFR part 170, § 170.110(b). The reporting requirements under the Transparency Act pursuant to 2 CFR part 170 are as follows:

i. First Tier Sub-Awards of $25,000 or more (unless they are exempt under 2 CFR part 170) must be reported by the Recipient to *http://www.fsrs.gov* no later than the end of the month following the month the obligation was made. Please note that currently underway is a consolidation of eight federal procurement systems, including the Sub-award Reporting System (FSRS), into one system, the System for Award Management (SAM). As result the FSRS will soon be consolidated into and accessed through *https://www.sam.gov/portal/public/SAM/*.

ii. The Total Compensation of the Recipient's Executives (5 most highly compensated executives) must be reported by the Recipient (if the Recipient meets the criteria under 2 CFR part 170) to *https://www.sam.gov/portal/public/SAM/* by the end of the month following the month in which the award was made.

iii. The Total Compensation of the Subrecipient's Executives (5 most highly compensated executives) must be reported by the Subrecipient (if the Subrecipient meets the criteria under 2 CFR part 170) to the Recipient by the end of the month following the month in which the subaward was made.

d. Record Keeping and Accounting. The grant contract will contain provisions relating to record keeping and accounting requirements.

G. Federal Awarding Agency Contacts

1. *Web site: http://www.rd.usda.gov/programs-services/distance-learning-telemedicine-grants.* The DLT Web site maintains up-to-date resources and contact information for DLT programs.

2. *Telephone:* 202–720–0800.

3. *Fax:* 202–205–2921.

4. *Email: dltinfo@wdc.usda.gov.*

5. *Main point of contact:* Shawn Arner, Deputy Assistant Administrator, Loan Origination and Approval Division, Rural Utilities Service.

H. Other Information

1. USDA Non-Discrimination Statement

USDA prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by USDA. (Not all prohibited bases will apply to all programs and/or employment activities.)

2. How To File a Complaint

If you wish to file an employment complaint, you must contact your agency's EEO Counselor within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional information can be found online at *http://www.ascr.usda.gov/complaint_filing_file.html.*

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complaint_filing_cust.html*, or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

3. *Persons With Disabilities*

Individuals who are deaf, hard of hearing or have speech disabilities and that wish to file either an EEO or program complaint may contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (*e.g.*, Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Dated: May 14, 2015.

Brandon McBride,

Administrator, Rural Utilities Service.

[FR Doc. 2015–12222 Filed 5–21–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: 2015 National Content Test

OMB Control Number: 0607–XXXX.

Form Number(s):

Questionnaire

DE–1A(E/S)
DE–1C(E/S)
DE–1D(E/S)
DE–1D2(E/S)
DE–1G(E/S)
DE–1H(E/S)
DE–1I(E/S)
DE–1W(E/S)
DE–1C(E/S)PR
DE–1I(E/S) PR

Instruction Card

DE–33
DE–33 PR

Questionnaire Cover Letters

DE–16(L1)
DE–16(L1)(FB)
DE–16(L1)(E/S)
DE–16(L1)(E/S)PR
DE–16(L2)
DE–16(L2)(F/B)
DE–16(L2)(E/S)
DE–16(L2)(E/S)PR
DE–17(L1)

DE–17(L1)(F/B)
DE–17(L1)(E/S)
DE–17(L2)
DE–17(L2)(F/B)
DE–17(L2)(E/S)
DE–17(L3)
DE–17(L3)(F/B)
DE–17(L3)(E/S)
DE–17(L4)
DE–17(L4)(F/B)
DE–17(L4)(E/S)
DE–17(L4)(E/S)PR
DE–17(L5)
DE–17(L5)(F/B)
DE–17(L5)(E/S)

Postcards

DE–9
DE–9(E/S)PR
DE–9(I)
DE–9(v2)
DE–9(v3)
DE–9(ES)(PR)
DE–9(v3)(E/S)(PR)
DE–9(2A)
DE–9(2A)(E/S)PR
DE–9(2B)
DE–9(2B)(E/S)PR
DE–9(2C)
DE–9(2D)

Envelopes

DE–6A(IN)
DE–6A(IN)(E/S)
DE–6A(1)(IN)
DE–6A(1)(IN)(E/S)
DE–8A
DE–8A(E/S)

Internet Instrument Spec
Reinterview Instrument Spec (Coverage)
Reinterview Instrument Spec (Race)
Wording for Emails and Text Messages

Type of Request: New Collection.

Number of Respondents: 1.3 million households.

Average Hours per Response: 0.2.

Burden Hours: 216,667.

ESTIMATED BURDEN HOURS FOR 2015 NATIONAL CONTENT TEST

	Total number of respondents	Estimated response time (minutes)	Estimated burden hours
Initial Response	1,200,000	10	200,000
Telephone Reinterview	100,000	10	16,667
Total	1,300,000	.....	216,667

Needs and Uses: During the years preceding the 2020 Census, the Census Bureau will pursue its commitment to reducing the cost of conducting the next decennial census while maintaining the highest data quality possible. A primary decennial census cost driver is the collection of data from members of the public for which the Census Bureau received no reply via initially offered response options. We refer to these cases as nonrespondents. Increasing the number of people who take advantage of self response options (such as completing a paper questionnaire and mailing it back to the Census Bureau, or responding via telephone or Internet alternatives) can contribute to a less costly census.

The 2015 National Content Test (NCT) is part of the research and development cycle leading up to the 2020 Census.

The first objective of this test is to evaluate and compare different versions of questions about such things as race and Hispanic origin, relationship, and within-household coverage. The 2015 NCT is the primary mid-decade opportunity to compare different versions of questions prior to making final decisions for the 2020 Census. The test will include a reinterview to further assess the accuracy and reliability of the question alternatives about race and origin and within-household coverage.

For the decennial census, the Census Bureau adheres to the U.S. Office of Management and Budget's (OMB) October 30, 1997 ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity'' (see *www.whitehouse.gov/omb/fedreg_1997standards*) for classifying racial and ethnic responses. There are five broad categories for data on race: ''White,'' ''Black or African American,'' ''American Indian or Alaska Native,'' ''Asian,'' and ''Native Hawaiian or Other Pacific Islander.'' There are two broad categories for data on ethnicity: ''Hispanic or Latino'' and ''Not Hispanic or Latino.'' The OMB standards advise that respondents shall be offered the option of selecting one or more racial designations. The OMB standards also advise that race and ethnicity are two distinct concepts; therefore, Hispanics or Latinos may be of any race.

Additionally, the 1997 OMB standards permit the collection of more detailed information on population groups, provided that any additional groups can be aggregated into the standard broad set of categories. Currently, the Census Bureau collects additional detailed information on Hispanic or Latino groups, American Indian and Alaska Native tribes, Asian groups, and Native Hawaiian and Other Pacific Islander groups.

For example, responses to the race question such as Navajo Nation, Nome Eskimo Community, and Mayan are collected and tabulated separately in Census Bureau censuses and surveys, but also are aggregated and tabulated into the total American Indian or Alaska Native population. Similarly, responses to the race question such as Chinese, Asian, Indian, and Vietnamese are collected and tabulated separately, but also aggregated and tabulated into the total Asian population, while responses such as Native Hawaiian, Chamorro, or Fijian are collected and tabulated separately, but also tabulated, and aggregated into the total Native Hawaiian or Other Pacific Islander population. Responses to the ethnicity question such as Mexican, Puerto Rican, and Cuban are collected and tabulated separately, but also are tabulated and aggregated in Census Bureau censuses and surveys, but also tabulated and aggregated into the total Hispanic or Latino population.

The 2015 NCT will test ways to collect and tabulate detailed information for the detailed groups, not just to the broad groups identified above. Detailed data for specific White population groups, such as German, Irish, and Polish, and Black population groups, such as African American, Jamaican, and Nigerian, will be collected and tabulated, and may be aggregated into the total ''White'' or ''Black or African American'' populations respectively.

The 2015 NCT also includes testing of a separate ''Middle Eastern or North African'' (MENA) category and the collection of data on detailed MENA groups, such as Lebanese, Egyptian, and Iranian. Currently, following the 1997 OMB standards, Middle Eastern and North African responses are classified under the White racial category, per OMB's definition of ''White.''

The second objective of the NCT is to test different contact strategies for optimizing self-response. The Census Bureau has committed to using the Internet as a primary response option in the 2020 Census. The 2015 NCT includes nine different approaches to encouraging households to respond and, specifically, to respond using the less costly and more efficient Internet response option. These approaches include altering the timing of the first reminder, use of email as a reminder, altering the timing for sending the mail questionnaire, use of a third reminder, and sending a reminder letter in place of a paper questionnaire to non-respondents.

One benefit of the Internet response mode is that it allows for more functionality and greater flexibility in designing questions compared to paper, which is constrained by space availability. The 2015 NCT will utilize web-based technology, such as the Internet, smart phones, and tablets to improve question designs, and to optimize reporting of detailed racial and ethnic groups (*e.g.,* Samoan, Iranian, Blackfeet Tribe, Filipino, Jamaican, Puerto Rican, Irish, etc.).

Web-based designs also provide much more utility and flexibility for using detailed checkboxes and write-in spaces to elicit and collect data for detailed groups than traditional paper questionnaires, and will help collect data for both the broader OMB categories, as well as more detailed responses across all groups.

Components of the Test

Race and Origin Content

The 2015 NCT builds on extensive research previously conducted by the Census Bureau as part of the 2010 Census. One major study was the 2010 Census Race and Hispanic Origin Alternative Questionnaire Experiment (AQE) (for details, see *www.census.gov/2010census/news/press-kits/aqe/aqe.html*). The 2010 AQE examined alternative strategies for improving the collection of data on a race and Hispanic origin, with four goals in mind:

1. Increasing reporting in the standard race and ethnic categories as defined by the U.S. Office of Management and Budget;
2. Decreasing item non-response for these questions;
3. Increasing the accuracy and reliability of the results for this question; and
4. Eliciting detailed responses for all racial and ethnic communities (*e.g.,* Chinese, Mexican, Jamaican, etc.).

Some of the findings from this research include:

- Combining race and ethnicity into one question did not change the proportion of people who reported as Hispanics, Blacks, Asians, American Indians and Alaska Natives, or Native Hawaiians and Other Pacific Islanders.
- The combined question yielded higher item response rates, compared with separate question approaches.
- The combined question increased reporting of detailed responses for most groups, but decreased reporting for others.

The successful strategies from the AQE research have been employed in the design of the Census Bureau's 2020 Census research. Four key dimensions of the questions on race and Hispanic origin are being tested in the 2015 NCT. These include question format, response categories, wording of the instructions, and question terminology.

Question Format

The 2015 NCT will evaluate the use of two alternative question approaches for collecting detailed data on race and ethnicity. One approach uses two separate questions: The first about Hispanic origin, and the second about race. The other approach combines the two items into one question about race and origin. The 2015 NCT research will test both approaches with new data collection methods, including Internet, telephone, and in-person response. Each approach is described below, with its associated data collection modes.

1. Separate Race and Origin Questions (Paper and Internet)

This is a modified version of the race and Hispanic origin approach used in the 2010 Census. Updates since the 2010 Census include added write-in spaces and examples for the White response category and the Black or African American response category, removal of the term ''Negro,'' and the addition of an instruction to allow for multiple responses in the Hispanic origin question.

2. Combined Question With Checkboxes and Write-Ins Visible at Same Time (Paper)

This is a modified version of the combined question approaches found to be successful in the 2010 AQE research. Checkboxes are provided for the U.S. Office of Management and Budget (OMB) broad categories (per the 1997 Standards for the Classification of Federal Data on Race and Ethnicity), with a corresponding write-in space for detailed response to each checkbox category. In this version, all checkboxes and write-in spaces are visible at all times. Each response category contains six example groups, which represent the diversity of the geographic definitions of the OMB category. For instance, the Asian category examples of Chinese, Filipino, Asian, Indian, Vietnamese, Korean, and Japanese represent the six largest detailed Asian groups in the United States, reflecting OMB's definition of Asian (''A person having origins in any of the original peoples of the Far East, Southeast Asia, and the Indian subcontinent.''). Respondents do not have to select an OMB checkbox, but may enter a detailed response in the write-in space without checking a category.

3. Combined Question With Major Checkboxes, Detailed Checkboxes, and Write-Ins (Paper)

This is a modified version of the combined question approaches found to be successful in the 2010 AQE. Checkboxes are provided for the OMB categories, along with a series of detailed checkboxes under each major category, and a corresponding write-in space and examples to elicit and collect all other detailed responses within the major category. In this version, all checkboxes and write-in spaces are visible at all times. Again, the detailed response categories represent the diversity of the geographic definitions of the OMB category.

For instance, under the Asian category (and major checkbox), a series of detailed checkboxes is presented for Chinese, Filipino, Asian Indian, Vietnamese, Korean, and Japanese, which represent the six largest detailed Asian groups in the United States. Then, instructions to enter additional detailed groups (with the examples of ''Pakistani, Thai, Hmong, etc.'') precede a dedicated write-in area to collect other detailed responses. Again, these detailed groups reflect OMB's definition of Asian (''A person having origins in any of the original peoples of the Far East, Southeast Asia, and the Indian subcontinent.''). Respondents do not have to select an OMB checkbox, but may enter a detailed response in the write-in space without checking a category.

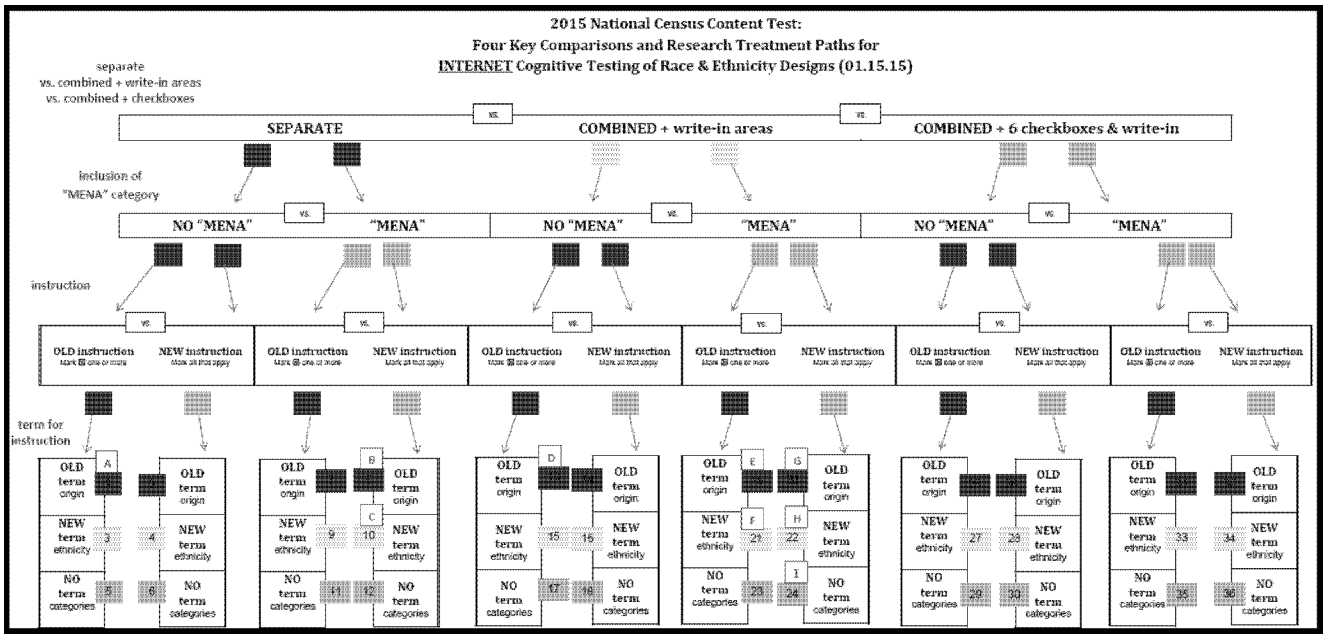
4. Combined Question With Major Checkboxes and Write-Ins on Separate Screens (Internet)

In this version, the detailed origin groups are solicited on subsequent screens after the OMB response categories have been selected. On the first screen, the OMB checkbox categories are shown along with their six representative example groups. Once

the OMB categories have been selected, one at a time, subsequent screens solicit further detail for each category that was chosen (*e.g.,* Asian), using a write-in space, with examples, to collect the detailed groups (*e.g.,* Korean and Japanese). The intent is to separate mouse click tasks (checkbox categories) and typing tasks (write-ins) in an attempt to elicit responses that are more detailed. This approach was used as one of three race and origin Internet panels in the 2014 Census Test.

5. Combined Question Branching With Detailed Checkbox Screens (Internet)

This version is an alternative method of soliciting detailed origin groups using separate screens, detailed checkboxes, and write-in spaces. On the first screen, the OMB checkbox categories are shown along with their six representative example groups. Once the OMB categories have been selected, one at a time, subsequent screens solicit further detail for each category, this time using a series of additional checkboxes for the six largest detailed groups (*e.g.,* Chinese, Filipino, Asian, Indian, Vietnamese, Korean, and Japanese) with a write-in space also provided to collect additional groups.



Race Response Categories

The 2015 NCT will also evaluate the use of a ''Middle Eastern or North African'' (''MENA'') response category. There will be two treatments for testing this dimension:

1. *Use of a MENA category:* This treatment tests the addition of a MENA checkbox category to the race question. The MENA category is placed within the current category lineup, based on estimates of population size, between the category for American Indians and Alaska Natives and the category for Native Hawaiians and Other Pacific Islanders. With the addition of this new category, the ''White'' example groups are revised. The Middle Eastern and North African examples of Lebanese and Egyptian are replaced with the European examples of Polish and French. The MENA checkbox category will have the examples of Lebanese, Iranian, Egyptian, Syrian, Moroccan, and Algerian. All other checkbox categories and write-in spaces remain the same.

2. *No separate MENA category:* This treatment tests approaches without a separate MENA checkbox category, and represents the current OMB definition of White (''A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.''). Here the category will provide examples of Middle Eastern and North African origins (*e.g.,* Lebanese; Egyptian) along with examples of European origins (*e.g.,* German; Irish) as part of the ''White'' racial category.

Wording of the Instructions

The 2015 NCT will evaluate the use of different approaches for wording the instructions used to collect data on race and ethnicity. The 2010 AQE research found that respondents frequently overlook the instruction to ''*Mark [X] one or more boxes*'' and have difficulty understanding the instructions. From the 2010 AQE qualitative research we learned that some respondents stop reading the instruction after noticing the visual cue [X] and proceed directly to do just that—*mark a box*—overlooking the remainder of the instruction. The new instruction being tested in the 2015 NCT (''*Mark all boxes that apply*'') is an attempt to improve the clarity of the question and make it more apparent that more than one group may be selected. The following options will be tested in the 2015 NCT.

1. ''*Mark [X] one or more*'': One version (old instructions) will advise respondents to, ''*Mark* [X] *one or more boxes AND print [origins/ethnicities/details].*''

2. ''*Mark all that apply*'': An alternative version (new instructions), will advise respondents to, ''*Mark all boxes that apply AND print [origins/ethnicities/details] in the spaces below. Note, you may report more than one group.*''

Instructions for American Indian and Alaska Native (AIAN) Write-In Area

The 2015 NCT will also examine different instructions to optimize detailed reporting within the AIAN write-in area. From the 2010 AQE research and recent 2014 qualitative research that the Census Bureau conducted with American Indians, Alaska Natives, and Central and South American Indian respondents, we know the instruction to ''*Print enrolled or principal tribe*'' causes confusion for many AIAN respondents and means

different things to different people. The research found that AIAN respondents were confused by the use of different terms and concepts (*e.g.,* ''enrolled'', ''affiliated,'' ''villages,'' ''race,'' ''origin,'' ''tribe,'' etc.) and there was disagreement among focus group participants as to what ''affiliated tribe'' or ''enrolled'' or ''villages'' meant.

The overwhelming sentiment from 2014 AIAN focus group participants was that they want to be treated equally with other race/ethnic groups, and this was accomplished by not using different terminology (*i.e.,* enrolled, affiliated, villages, etc.). Asking ''*What is your race or origin*?'' in conjunction with ''*Print, for example,* . . .'' (along with AIAN example groups) allowed the respondents to understand what the question asked them to report (their race or origin) and did not limit their write-in response by confounding the instructions with terms that mean different things to different people (*e.g.,* tribes, villages, etc.). Therefore, the instruction to, ''*Print, for example*, . . .'' presented a viable alternative for further exploration in 2015 NCT research.

Based on the findings and recommendations from this research, the 2015 NCT will test variations of the instructions for the AIAN write-in area. We plan to test the instruction, ''*Print enrolled or principal tribe, for example* . . .'' on control versions, and the instruction, ''*Print, for example* . . .'' on experimental versions, to see how they perform.

Question Terms

The 2015 NCT will evaluate the use of different conceptual terms (*e.g.,* origin, ethnicity, or no terms) in the wording of questions for collecting data on race and ethnicity. Recent qualitative focus groups and qualitative research (*e.g.,* 2010 AQE research; 2013 Census Test research; cognitive pre-testing for the 2016 American Community Survey (ACS) Content Test) found that the terms ''race,'' ''ethnicity,'' and ''origin'' are confusing or misleading to many respondents, and mean different things to different people. The 2010 AQE research tested the removal of the term ''race'' from the question, and showed no evidence that removal of the term had any effect on either unit or item response rates. Recent cognitive research for the 2016 ACS Content Test tested an open-ended instruction (''*Which categories describe you*?'') and found that respondents did not have issues with understanding what the question was asking. The following options will be tested in the 2015 NCT.

1. ''*Origin*'' *term:* The current version of the race and Hispanic origin questions, and the combined question, use the terms ''race'' and/or ''origin'' to describe the concepts and groups in the question stem and/or instructions. For instance, in the combined race and Hispanic origin approach, the question stem is ''*What is Person 1's race or origin?*''

2. ''*Ethnicity*'' *term:* One alternative option being explored tests the use of both the terms ''ethnicity'' along with ''race'' in the question stem and/or instructions (*e.g.,* ''*What is Person 1's race or ethnicity?*'').

3. *NO terms:* A second alternative option being explored tests the removal of the terms ''race,'' ''origin,'' and ''ethnicity'' from the question stem and instructions. Instead, a general approach asks, ''*Which categories describe Person 1*?''

Relationship Content

Two versions of the relationship question will be tested. Both versions are the same as those used in a split-sample in the 2014 Census Test, with no changes. These relationship categories were previously tested in other Census Bureau surveys including the American Housing Survey, American Community Survey, and the Survey of Income and Program Participation (currently used in production). Although research to date has been informative, leading to the development of the revised relationship question, additional quantitative testing is needed. Because the incidence of some household relationships—such as same-sex couples—is relatively low in the general population, the revised question needs to be tested with large, nationally representative samples prior to a final decision to include them in the 2020 Census questionnaire.

The first version uses the 2010 Census relationship question response options, but in a new order, starting with ''husband or wife'' and then the ''unmarried partner'' category. This version also re-introduces the foster child category, which was removed from the 2010 Census form due to space issues.

The second version includes the same basic response options as the 2010 Census version, but modifies/expands the ''husband or wife'' and ''unmarried partner'' categories to distinguish between same-sex and opposite-sex relationships.

Coverage Content (Internet Only)

The 2012 NCT experimented with several methods to improve within-household coverage for Internet respondents. One benefit of the online response mode is that it allows for more functionality and greater flexibility in designing questions compared to paper, which is constrained by space availability. The 2012 NCT included a coverage follow-up reinterview to evaluate the different Internet design options, but some results were inconclusive. In the 2015 NCT, two designs will be tested to compare different approaches for helping respondents provide a more accurate roster of household residents.

The first approach is the ''Rules-Based'' approach, and will allow us to see whether the presence of a question asking the number of people in the household, along with the residence rule instructions, helps respondents create an accurate roster. This is similar to the approach used across all modes in Census 2000 and the 2010 Census, where the respondent was expected to understand various applications of our residence rules and apply them to their household. The roster creation is followed by a household-level question that probes to determine if any additional people not listed originally should be included for consideration as residents of the household (several types of people and living situations are shown in a list).

The ''Question-Based'' approach allows us to ask guided questions to help improve resident responses. Respondents are not shown the residence rule instructions and are only asked to create an initial roster of people they consider to be living or staying at their address on Census Day. This is followed by several short household-level questions about types of people and living situations that might apply to people in the household that were not listed originally.

The materials mailed to the respondents will inform them that the survey is mandatory in accordance with Title 13, United States Code, Sections 141 and 193. This information also will be available via a hyperlink from within the Internet Instrument.

The results of the 2015 NCT will help guide the design of additional 2020 Census testing later this decade. The 2015 NCT will be the only opportunity to test content with a nationally representative sample prior to the 2020 Census. Testing in 2015 is necessary to establish recommendations for contact strategies, response options, and content options that can be further refined and tested in later tests. At this point in the decade, the Census Bureau needs to acquire evidence showing whether the strategies being tested can reduce the cost per housing unit during a decennial census, while providing high quality and accuracy of the census data. The nationally-representative sample is

designed to ensure that the unbiased estimates from this test accurately reflect the nation as a whole, across a variety of demographic characteristics.

Along with other results, the response rates to paper and Internet collection will be used to help inform 2020 Decennial program planning and cost estimation metrics values. In addition, several demographic questions and coverage probes are included in this test to achieve improved coverage by future decennial censuses and surveys.

Information quality is an integral part of the pre-dissemination review of the information disseminated by the Census Bureau (fully described in the Census Bureau's Information Quality Guidelines). Information quality is also integral to the information collections conducted by the Census Bureau and is incorporated into the clearance process required by the Paperwork Reduction Act.

Affected Public: Individuals or Households.

Frequency: One Time.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. 141 and 193.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

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* or fax to (202) 395–5806.

Dated: May 14, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–12140 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–20–2015]

Approval of Subzone Status; Roger Electric Corporation; Bayamon, Puerto Rico

On February 20, 2015, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Puerto Rico Trade & Export Company, grantee of FTZ 61, requesting subzone status subject to the existing activation limit of FTZ 61, on behalf of Roger Electric Corporation in Bayamon, Puerto Rico.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (80 FR 10456–10457, 02–26–2015). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board's Executive Secretary (15 CFR 400.36(f)), the application to establish Subzone 61O is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 61's 1,821.07-acre activation limit.

Dated: May 14, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–12516 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–04–2015]

Foreign-Trade Zone (FTZ) 26—Atlanta, Georgia; Authorization of Production Activity; Mizuno USA, Inc. (Golf Clubs), Braselton, Georgia

On January 15, 2015, Georgia Foreign-Trade Zone, Inc., grantee of FTZ 26, submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board on behalf of Mizuno USA, Inc., within Site 31 of FTZ 26, in Braselton, Georgia.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (80 FR 5507, 02–02–2015). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: May 15, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–12550 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–818]

Low Enriched Uranium From France: Final Results of Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) has granted an extension of time for the re-exportation of one specified entry of low enriched uranium (LEU) that entered under a narrow provision that conditionally excludes it from the scope of the antidumping (AD) order. The Department extends the exportation deadline until January 31, 2018.

DATES: *Effective date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

On February 17, 2015, the Department published the initiation and preliminary results of the changed circumstances review (CCR).[1] In the *Initiation and Preliminary Results* the Department preliminarily determined that changed circumstances did not exist, and that Eurodif SA and Areva Inc. (collectively AREVA) would not be granted an additional extension of time to re-export the specified entry of low-enriched uranium. Since the publication of the *Initiation and Preliminary Results,* the following events have taken place. AREVA, Centrus Energy Corporation (Petitioners), and the Nuclear Energy Institute submitted comments on March 17, 2015. Chubu Electric Power Company, Inc. submitted comments on March 24, 2015. No rebuttal comments were filed.

Scope of the Order

The product covered by the order is all low-enriched uranium. Low-enriched uranium is enriched uranium hexafluoride (UF_6) with a U^{235} product assay of less than 20 percent that has not been converted into another

[1] *See Low Enriched Uranium from France: Initiation of Expedited Changed Circumstances Review and Preliminary Results of Changed Circumstances Review,* 80 FR 8285 (February 17, 2015) (*Initiation and Preliminary Results).*

chemical form, such as UO_2, or fabricated into nuclear fuel assemblies, regardless of the means by which the LEU is produced (including low-enriched uranium produced through the down-blending of highly enriched uranium).[2]

Analysis of Comments Received

All issues raised by the parties in the case briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is appended to this notice. The Issues and Decision Memorandum is a public document and is available electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and it is available to all parties in the Central Records Unit of the main Commerce Building, room 7046. In addition, a complete version of the Issues and Decision Memorandum is also accessible on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Final Results of CCR

Upon review of the comments received in this case the Department has determined that the new regulatory requirements enacted by Japan's Nuclear Regulatory Authority since the previous CCR[3] do constitute new circumstances, and that it is appropriate to extend the deadline for re-exportation of this sole entry of low-enriched uranium. The Department is granting an extension for re-exportation of this sole entry until January 31, 2018. AREVA will be required to provide the Department with a report on the status of the relevant reactor semi-annually.[4] AREVA and the end-user will be required to submit amended certifications to U.S. Customs and Border Protection (CBP). The Department will release amended certifications to parties for comment before AREVA and the end-user are required to submit such certifications to CBP.

In the event that the deadline for re-export expires and the subject uranium has not been re-exported, and no further extension is granted, the Department will take appropriate action, which may include our reexamination of the cash deposit rate applied to all entries of AREVA's merchandise under the 18-month re-export provision.

Instructions to CBP

The Department will inform CBP that the deadline for re-exportation of the single entry at issue is extended until January 31, 2018. The Department will instruct CBP to collect amended certifications from AREVA and its end-user within 30 days of publication of these final results of CCR.

Notification Regarding Administrative Protective Orders

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3). 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.

We are issuing and publishing these final results in accordance with sections 751(b)(1) and 777(i)(1) and (2) of the Act and 19 CFR 351.216.

Dated: May 15, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—Topics in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Issues Allowing Further Extension of the Re-Export Deadline
V. Department Position
VI. Recommendation

[FR Doc. 2015–12547 Filed 5–21–15; 8:45 am]

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[2] For a full description of the scope of the order *see* ''Decision Memorandum for Final Results of Changed Circumstances Review of Low Enriched Uranium from France,'' (Issues and Decision Memorandum) from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Paul Piquado, Assistant Secretary for Enforcement and Compliance (Issues and Decision Memorandum), dated concurrently with these results and hereby adopted by this notice.

[3] *See Low Enriched Uranium From France: Final Results of Changed Circumstances Review,* 78 FR 66898 (November 7, 2013).

[4] *See* Issues and Decision Memorandum at page 3.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Final Results of 2013 Antidumping Duty New Shipper Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* May 22, 2015.

SUMMARY: On December 31, 2014, the Department of Commerce (''Department'') published the preliminary results of the antidumping duty new shipper review of xanthan gum from the People's Republic of China (''PRC'').[1] We invited interested parties to comment on our preliminary results. Following our analysis of the comments received, we made changes to our preliminary margin calculation for the new shipper Meihua Group International Trading (Hong Kong) Limited, Langfang Meihua Bio-Technology Co., Ltd., and Xinjiang Meihua Amino Acid Co., Ltd. (collectively, ''Meihua''). We continue to find that Meihua did not make sales of subject merchandise at less than normal value.

FOR FURTHER INFORMATION CONTACT: Brandon Farlander, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0182.

SUPPLEMENTARY INFORMATION:

Case History

The Department published the *Preliminary Results* on December 31, 2014.[2] On January 30, 2015, CP Kelco U.S., Inc.[3] submitted its case brief. On February 9, 2015, Meihua submitted a rebuttal brief.

Period of Review

The period of review (''POR'') for this new shipper review is July 19, 2013 through December 31, 2013. This POR corresponds to the period from the date

[1] *See Xanthan Gum From the People's Republic of China: Preliminary Results of 2013 Antidumping Duty New Shipper Review,* 79 FR 78797 (December 31, 2014) (''*Preliminary Results*'').

[2] Also adopted as part of the preliminary results was the Memorandum to Ronald K. Lorentzen entitled ''Decision Memorandum for the Preliminary Results of the 2013 Antidumping Duty New Shipper Review of Xanthan Gum from the People's Republic of China,'' dated December 18, 2014 (''Preliminary Decision Memorandum'').

[3] CP Kelco U.S., Inc. is the petitioner.

of suspension of liquidation to the end of the month immediately preceding the first semiannual anniversary month pursuant to 19 CFR 351.214(g)(1)(ii)(B).

Scope of the Order

The scope of the order covers dry xanthan gum, whether or not coated or blended with other products. Further, xanthan gum is included in this order regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber. Merchandise covered by the scope of this order is classified in the Harmonized Tariff Schedule (''HTS'') of the United States at subheading 3913.90.20. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope is dispositive.[4]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this new shipper review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/index.html*. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results Margin

The Department finds that the following weighted-average dumping margin exists for the exporter/producer combination listed below for the period July 19, 2013 through December 31, 2013:

Exporter	Producer	Weighted-average dumping margin (percent)
Meihua Group International Trading (Hong Kong) Limited/Langfang Meihua Bio-Technology Co., Ltd./Xinjiang Meihua Amino Acid Co., Ltd.	Meihua Group International Trading (Hong Kong) Limited/Langfang Meihua Bio-Technology Co., Ltd./Xinjiang Meihua Amino Acid Co., Ltd.	0.00

Disclosure

We intend to disclose to parties the calculations performed in this proceeding within five days of the date of public announcement of the results of this review in accordance with 19 CFR 351.224(b).

Assessment Rates

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. Because Meihua's weighted-average dumping margin is zero, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. For entries that were not reported in the U.S. sales database submitted by Meihua, the Department will instruct CBP to liquidate such entries at the NME-wide rate.[5]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this new shipper review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the ''Act''). For the exporter/producer combination listed above, the cash deposit rate will be 0.00 percent. This deposit requirement, when imposed, shall remain in effect until further notice.

Notification to Importers

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 POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding APO

This notice also serves as a reminder to the parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of business proprietary information (''BPI'') disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern BPI in this segment of the proceeding. Timely notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 751(a)(2)(B) and 777(i) of the Act.

Dated: May 18, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix—Issues for Final Results

Summary
Background
Period of Review
Scope of the order
Single company treatment
Bona fide analysis
List of Abbreviations and Acronyms
Discussion of Issues
  Issue 1: Corn starch intermediate input
  Issue 2: Corn SV
  Issue 3: Surrogate Financial Statements

[4] For a complete description of the Scope of the Order, *see* ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty New Shipper Review of Xanthan Gum from the People's Republic of China,'' (''Issues and Decision Memorandum''), dated concurrently with this notice.

[5] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Issue 4: Whether Meihua's energy allocation methodology is distortive

Recommendation

[FR Doc. 2015–12520 Filed 5–21–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 99–8A005]

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Amended Export Trade Certificate of Review for the California Almond Export Association, LLC, Application no. 99–8A005.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review to the California Almond Export Association, LLC (''CAEA'') on May 6, 2015. The previous amendment was issued on May 1, 2014.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325 (2015). OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary to publish a summary of the certificate in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of the Amendment to the Certificate: Remove the following company as a Member of CAEA's Certificate: Minturn Nut Company, Inc., Le Grand, CA.

CAEA's Export Trade Certificate of Review complete amended Membership is listed below:

Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Blue Diamond Growers, Sacramento, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Inc., Livingston, CA
Fair Trade Corner, Inc., Chico, CA
Fisher Nut Company, Modesto, CA
Hilltop Ranch, Inc., Ballico, CA
Hughson Nut, Inc., Hughson, CA
Mariani Nut Company, Winters, CA
Nutco, LLC d.b.a. Spycher Brothers, Turlock, CA
Paramount Farms, Inc., Los Angeles, CA
P–R Farms, Inc., Clovis, CA
Roche Brothers International Family Nut Co., Escalon, CA
South Valley Almond Company, LLC, Wasco, CA
Sunny Gem, LLC, Wasco, CA
Western Nut Company, Chico, CA

Dated: May 18, 2015.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration.

[FR Doc. 2015–12405 Filed 5–21–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–822]

Welded Line Pipe from the Republic of Turkey: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) preliminarily determines that welded line pipe from the Republic of Turkey (Turkey) is being, or is likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733(b) of the Tariff Act of 1930, as amended (the Act). The period of investigation (POI) is October 1, 2013, through September 30, 2014. The estimated weighted-average dumping margins of sales at LTFV are shown in the ''Preliminary Determination'' section of this notice. Interested parties are invited to comment on this preliminary determination.

DATES: *Effective Date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4682 or (202) 482–3693, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department initiated this investigation on November 5, 2014.[1] For a complete description of the events that followed the initiation of this investigation, see the memorandum that is dated concurrently with this determination and hereby adopted by this notice.[2] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The scope of the investigation covers welded line pipe, which is carbon and alloy steel pipe of a kind used for oil and gas pipelines, not more than 24 inches in nominal outside diameter. For a complete description of the scope of the investigation, see Appendix I.

Scope Comments

Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For discussion of those comments, see the Preliminary Decision Memorandum.

Methodology

The Department is conducting this investigation in accordance with section 731 of the Act. There are two mandatory respondents participating in this investigation, Çayirova Boru Sanayi ve Ticaret A.S./Yücel Boru Ithalat-Ihracat

[1] *See Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 79 FR 68213 (November 14, 2014) (*Initiation Notice*).

[2] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, entitled ''Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Welded Line Pipe from the Republic of Turkey'' (Preliminary Decision Memorandum), dated concurrently with this notice.

ve Pazarlama A.S. (collectively, Çayirova) and Tosçelik Profil ve Sac Endustrisi A.S./Tosyali Dis Ticaret A.S. (collectively, Tosçelik). Export price for these companies is calculated in accordance with section 772 of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary conclusions, see the Preliminary Decision Memorandum.

Because mandatory respondents Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (Borusan Mannesmann) and Borusan Istikbal Ticaret (Borusan Istikbal) failed to respond to the Department's questionnaire, we preliminarily determine to apply adverse facts available (AFA) to these respondents, in accordance with sections 776(a) and (b) of the Act and 19 CFR 351.308. For further discussion, see the Preliminary Decision Memorandum.

All-Others Rate

Consistent with sections 733(d)(1)(A)(ii) and 735(c)(5) of the Act, the Department also calculated an estimated all-others rate. Section 735(c)(5)(A) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, we calculated weighted-average dumping margins for both participating mandatory respondents that are above *de minimis* and which are not based on total facts available. However, because there are only two relevant weighted-average dumping margins for this preliminary determination, using a weighted average of these two rates risks disclosure of business proprietary data. Therefore, we calculated both a weighted average of the dumping margins calculated for the two cooperating mandatory respondents using publicly ranged quantities for their sales of subject merchandise and a simple average of these two dumping margins, and selected, as the all-others rate, the average that provides a more accurate proxy for the weighted-average margin of both companies calculated using business proprietary information.[3]

Preliminary Determination

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter/manufacturer	Weighted-average dumping margin (percent)
Borusan Istikbal Ticaret	9.85
Borusan Mannesmann Boru Sanayi ve Ticaret A.S.	9.85
Çayirova Boru Sanayi ve Ticaret A.S./Yücel Boru Ithalat-Ihracat ve Pazarlama A.S.	9.71
Tosçelik Profil ve Sac Endustrisi A.S./Tosyali Dis Ticaret A.S.	3.11
All Others	3.29

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of welded line pipe from Turkey as described in Appendix I of this notice, which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

In accordance with 19 CFR 351.205(d), we will instruct CBP to require a cash deposit equal to the weighted-average amount by which the NV exceeds U.S. price, as indicated in the chart above, adjusted for export subsidies found in the preliminary determination of the companion countervailing duty investigation.[4] Specifically, consistent with our longstanding practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit equal to the amount by which the NV exceeds the U.S. price, as indicated below, less the amount of the countervailing duty determined to constitute an export subsidy.[5] Therefore, for cash deposit purposes, we are subtracting from the applicable cash deposit rate that portion of the countervailing duty rate attributable to the export subsidies found in the preliminary affirmative countervailing duty determination. Accordingly, the export subsidy offsets are as follows: 0.82 percent for Tosçelik, and 0.77 percent for Çayirova and all others, and 0.42 percent for Borusan Istikbal and Borusan Mannesmann.[6] After this adjustment, the resulting cash deposit rates will be 9.43 percent for Borusan Istikbal and Borusan Mannesmann, 8.94 percent for Çayirova, 2.29 percent for Tosçelik, and 2.52 percent for all others. The suspension of liquidation instructions will remain in effect until further notice.

Disclosure

We will disclose the calculations performed to interested parties in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i) of the Act, we intend to verify information relied upon in making our final determination.

Public Comment

Interested parties are invited to comment on this preliminary determination. Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after

[3] *See* Memorandum to the File from David Crespo, Senior Analyst, entitled, ''Welded Line Pipe from the Republic of Turkey: Calculation of the Preliminary Margin for All Other Companies,'' dated concurrently with this memorandum (All Others Calculation Memorandum).

[4] *See Welded Line Pipe From the Republic of Turkey: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Determination,* 80 FR 14943 (March 20, 2015), and accompanying Preliminary Decision Memorandum.

[5] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India,* 69 FR 67306, 67307 (November 17, 2004); and *Notice of Final Determination of Sales at Less Than Fair Value and Negative Critical Circumstances Determination: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea,* 77 FR 17413 (March 26, 2012).

[6] *See* Memorandum to the File from Alice Maldonado, Senior Analyst, entitled, ''Placing Information on the Record: Export Subsidies Calculated in the Preliminary Determination of the Countervailing Duty Investigation of Welded Line Pipe from the Republic of Turkey,''dated May 14, 2015.

the deadline date for case briefs.[7] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce. All documents must be filed electronically using ACCESS. An electronically-filed request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.[8] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. 19 CFR 351.210(e)(2) requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

Çayirova and Tosçelik requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination by 60 days (*i.e.,* to 135 days after publication of the preliminary determination), and agreed to extend the application of the provisional measures prescribed under section 733(d) of the Act and 19 CFR 351.210(e)(2), from a four-month period to a period not to exceed six months.[9] In addition, certain petitioners [10] also requested that, in the event of a negative preliminary determination, the Department postpone its final determination to 135 days after the date of publication of the preliminary determination.[11]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) our preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, we are postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, we will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.[12]

International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our affirmative preliminary determination of sales at LTFV. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 14, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is circular welded carbon and alloy steel (other than stainless steel) pipe of a kind used for oil or gas pipelines (welded line pipe), not more than 24 inches in nominal outside diameter, regardless of wall thickness, length, surface finish, end finish, or stenciling. Welded line pipe is normally produced to the American Petroleum Institute (API) specification 5L, but can be produced to comparable foreign specifications, to proprietary grades, or can be non-graded material. All pipe meeting the physical description set forth above, including multiple-stenciled pipe with an API or comparable foreign specification line pipe stencil is covered by the scope of this investigation.

The welded line pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.5000, 7305.12.1030, 7305.12.5000, 7305.19.1030, 7305.19.5000, 7306.19.1010, 7306.19.1050, 7306.19.5110, and 7306.19.5150. The subject merchandise may also enter in HTSUS 7305.11.1060 and 7305.12.1060. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Period of Investigation
4. Postponement of Final Determination and Extension of Provisional Measures
5. Scope Comments
6. Affiliation and Single Entity
7. Discussion of Methodology
   a. Determination of the Comparison Method
   b. Results of the Differential Pricing Analysis
8. Date of Sale
9. Product Comparisons
10. Export Price
11. Duty Drawback
12. Normal Value
   a. Home Market Viability
   b. Level of Trade
   c. Cost of Production (COP) Analysis
   1. Calculation of COP
   2. Test of Comparison Market Sales Prices
   3. Results of the COP Test
   d. Calculation of NV Based on Comparison Market Prices
13. Facts Available
   a. Use of Facts Available
   b. Application of Facts Available With an Adverse Reference
   c. Selection and Corroboration of Adverse Facts Available (AFA) Rate
14. Currency Conversion

[FR Doc. 2015–12519 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–DS–P

[7] *See* 19 CFR 351.309.

[8] *See* 19 CFR 351.310(c).

[9] *See* letter from Çayirova and Tosçelik entitled, ''Line pipe from Turkey; request to extend the final determination,'' dated March 20, 2015.

[10] These companies include American Cast Iron Pipe Company, Energex Tube, a division of JMC Steel Group, Northwest Pipe Company, Stupp Corporation, a division of Stupp Bros., Inc., Tex-Tube Company, TMK IPSCO, and Welspun Tubular LLC USA (collectively, certain petitioners).

[11] *See* letter from certain of the petitioners entitled, ''Welded Line Pipe from Turkey: Contingent Request for Postponement of Final Determination,'' dated April 23, 2015.

[12] *See also* 19 CFR 351.210(e).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–876]

Welded Line Pipe From the Republic of Korea: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) preliminarily determines that welded line pipe from the Republic of Korea (Korea) is being, or is likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733(b) of the Tariff Act of 1930, as amended (the Act). The period of investigation (POI) is October 1, 2013, through September 30, 2014. The estimated weighted-average dumping margins of sales at LTFV are shown in the ''Preliminary Determination'' section of this notice. Interested parties are invited to comment on this preliminary determination.

DATES: *Effective date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Katherine Johnson, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–4929, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department initiated this investigation on November 5, 2014. For a complete description of the events that followed the initiation of this investigation, *see* the memorandum that is dated concurrently with this determination and hereby adopted by this notice.[1] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The scope of the investigation covers welded line pipe, which is carbon and alloy steel pipe of a kind used for oil and gas pipelines, not more than 24 inches in nominal outside diameter. For a complete description of the scope of the investigation, *see* Appendix I.

Scope Comments

Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.*[2] For discussion of those comments, *see* the Preliminary Decision Memorandum.

Methodology

The Department is conducting this investigation in accordance with section 731 of the Act. There are two respondents participating in this investigation, Hyundai HYSCO (HYSCO) and SeAH Steel Corporation (SeAH). Export price (EP) and constructed export price (CEP) are calculated in accordance with section 772 of the Act. Normal value (NV) is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

All-Others Rate

Consistent with sections 733(d)(1)(A)(ii) and 735(c)(5) of the Act, the Department also calculated an estimated all-others rate. Section 735(c)(5)(B) of the Act provides that the estimated all-others rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

In this investigation, we calculated weighted-average dumping margins for both mandatory respondents that are above *de minimis* and which are not based on total facts available. However, because there are only two relevant weighted-average dumping margins for these preliminary results, using a weighted-average of these two rates risks disclosure of business proprietary data. Therefore, the Department assigned a margin to the all-others rate companies based on the simple average of the two mandatory respondents' rates.[3]

Preliminary Determination

The Department preliminarily determines that the following weighted-average dumping margins exist:

Exporter/manufacturer	Weighted-average dumping margin (percent)
Hyundai HYSCO	2.52
SeAH Steel Corporation	2.67
All Others	2.60

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of welded line pipe from Korea, as described in the scope of the investigation section of this notice, which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

In accordance with 19 CFR 351.205(d), we will instruct CBP to require a cash deposit equal to the weighted-average amount by which the NV exceeds the U.S. price, as indicated in the chart above. Our longstanding practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, is to subtract the amount of countervailing duty determined to constitute an export subsidy from the amount by which NV exceeds U.S.

[1] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, ''Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Welded Line Pipe from the Republic of Korea,'' (Preliminary Decision Memorandum), dated concurrently with this notice.

[2] *See Welded Line Pipe from the Republic of Korea and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 79 FR 68213 (November 14, 2014) (*Initiation Notice*).

[3] With two respondents, we would normally calculate (A) a weighted-average of the dumping margins calculated for the mandatory respondents; (B) a simple average of the dumping margins calculated for the mandatory respondents; and (C) a weighted-average of the dumping margins calculated for the mandatory respondents using each company's publicly-ranged values for the merchandise under consideration. We would compare (B) and (C) to (A) and select the rate closest to (A) as the most appropriate rate for all other companies. *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). In this case, however, we do not have complete publicly ranged quantities for SeAH on the record to properly conduct this comparison. Therefore, we are using a simple-average of the dumping margins calculated for the mandatory respondents as the all-other's rate for this preliminary determination, and we intend to ask SeAH to provide a complete publicly ranged summary of its U.S. sales quantities for consideration in the final determination.

price.[4] In this case, although the product under investigation is also subject to a countervailing duty investigation, the Department preliminarily found no countervailing duty determined to constitute an export subsidy.[5] Therefore, we have not offset the cash deposit rates shown above for purposes of this preliminary determination.

Disclosure

We will disclose the calculations performed to interested parties in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i) of the Act, we intend to verify information relied upon in making our final determination.

Public Comment

Interested parties are invited to comment on this preliminary determination. Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the final verification report is issued in this proceeding, and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[6] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce. All documents must be filed electronically using ACCESS. An electronically-filed request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.[7] Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. 19 CFR 351.210(e)(2) requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

Certain of the petitioners[8] requested that, in the event of a negative preliminary determination, the Department postpone its final determination to 135 days after the date of publication of the preliminary determination.[9] In addition, both HYSCO and SeAH requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination and agreed to extend the application of the provisional measures prescribed under section 733(d) of the Act and 19 CFR 351.210(e)(2), from a four-month period to a period not to exceed six months.[10]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because (1) our preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, we are postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, we will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.[11]

International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our affirmative preliminary determination of sales at LTFV. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 14, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is circular welded carbon and alloy steel (other than stainless steel) pipe of a kind used for oil or gas pipelines (welded line pipe), not more than 24 inches in nominal outside diameter, regardless of wall thickness, length, surface finish, end finish, or stenciling. Welded line pipe is normally produced to the American Petroleum Institute (API) specification 5L, but can be produced to comparable foreign specifications, to proprietary grades, or can be non-graded material. All pipe meeting the physical description set forth above, including multiple-stenciled pipe with an API or comparable foreign specification line pipe stencil is covered by the scope of this investigation.

The welded line pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.5000, 7305.12.1030, 7305.12.5000, 7305.19.1030, 7305.19.5000, 7306.19.1010, 7306.19.1050, 7306.19.5110, and 7306.19.5150. The subject merchandise may also enter in HTSUS 7305.11.1060 and 7305.12.1060. While the HTSUS subheadings

[4] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India,* 69 FR 67306, 67307 (November 17, 2004); and *Notice of Final Determination of Sales at Less Than Fair Value and Negative Critical Circumstances Determination: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea,* 77 FR 17413 (March 26, 2012).

[5] *See Welded Line Pipe From the Republic of Korea: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 80 FR 14907 (March 20, 2015), and accompanying Decision Memorandum.

[6] *See* 19 CFR 351.309.

[7] *See* 19 CFR 351.310(c).

[8] These companies include American Cast Iron Pipe Company, Energex Tube, a division of JMC Steel Group, Northwest Pipe Company, Stupp Corporation, a division of Stupp Bros., Inc., Tex-Tube Company, TMK IPSCO, and Welspun Tubular LLC USA (collectively, the petitioners).

[9] *See* Letter from the petitioners, ''Line Pipe From Korea: Contingent Request for Postponement of Final Determination,'' dated April 23, 2015.

[10] *See* Letter from HYSCO, ''Welded Line Pipe from Korea: Request to Postpone the Final Determination,'' dated May 7, 2015; and Letter from SeAH, ''Antidumping Investigation of Welded Line Pipe from Korea-Request to Extend Deadline for Final Determination,'' dated May 8, 2015.

[11] *See also* 19 CFR 351.210(e).

are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Period of Investigation
4. Postponement of Final Determination and Extension of Provisional Measures
5. Scope Comments
6. Discussion of Methodology
   a. Determination of the Comparison Method
   b. Results of the Differential Pricing Analysis
7. Date of Sale
8. Product Comparisons
9. Export Price and Constructed Export Price
10. Normal Value
   a. Comparison Market Viability
   b. Affiliated-Party Transactions and Arm's-Length Test
   c. Level of Trade
   d. Cost of Production (COP) Analysis
   1. Calculation of COP
   2. Test of Comparison Market Sales Prices
   3. Results of the COP Test
   e. Calculation of NV Based on Comparison Market Prices
   f. Calculation of NV Based on CV
11. Currency Conversion
12. Conclusion

[FR Doc. 2015–12523 Filed 5–21–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–818]

Certain Steel Nails From the Socialist Republic of Vietnam: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain steel nails from the Socialist Republic of Vietnam (Vietnam) are being, or are likely to be, sold in the United States at less-than-fair value, as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The final weighted-average dumping margins of sales at less than fair value are listed below in the ''Final Determination Margins'' section of this notice.

DATES: *Effective date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Edythe Artman or Dena Crossland, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3931 or (202) 482–3362, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published its preliminary determination on December 29, 2014.[1] On January 2, 2015, United Nail Products Co., Ltd. (United Nail), a mandatory respondent in this investigation, filed a letter stating that it had decided to withdraw from the proceeding and would not be participating in a verification of its questionnaire responses. On January 7, 2015, the other mandatory respondent, Region Industries Co., Ltd. (Region Industries), filed a letter to the same effect. On February 18, 2015, we received a case brief from Petitioner, Mid-Continent Steel & Wire, Inc. We did not receive any rebuttal comments or requests for a hearing from interested parties. Based on the events that transpired after the preliminary determination and an analysis of the comments received, the Department has made changes to the *Preliminary Determination.*

Period of Investigation

The period of investigation is October 1, 2013, through March 31, 2014.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Vietnam. For a full description of the scope of the investigation, *see* Appendix I to this notice.

Since the *Preliminary Determination,* several interested parties (*i.e.,* IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, *see* the Issue and Decision Memorandum.[2] The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Verification

In light of each mandatory respondent's decision to withdraw from the investigation and not to participate in a verification, we conducted no verifications.

Analysis of Comments Received

Petitioner raised one issue in its case brief, which is addressed in the Issue and Decision Memorandum. A list of the contents of this memorandum is attached to this notice in Appendix II. The Issue and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to this system is available to registered and guest users at *http://access.trade.gov* and is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issue and Decision Memorandum can be accessed directly on the Internet at *http://www.trade.gov/enforcement/frn/index.html.* The signed and electronic versions of the Issue and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on consideration of the events that transpired after the preliminary determination and our analysis of the comments received, we find that Region Industries and United Nail are not separate from the Vietnam-wide entity and that the estimated dumping margin for the entity should be based on the adverse facts available on the record, pursuant to sections 776(a)(2)(A), (C) and (D) and section 776(b) of the Act. This rate, derived from the Petition,[3] was corroborated upon examination of the documentation supporting the Petition. For more details, *see* the accompanying Issue and Decision Memorandum and company-specific analysis memoranda for the final determination.

Separate Rate

Kosteel Vina Limited Company (Kosteel Vina) established its eligibility for a separate rate.[4] The Act and

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[1] *See Certain Steel Nails From the Socialist Republic of Vietnam: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination and Extension of Provisional Measures,* 79 FR 78058 (December 29, 2014) (*Preliminary Determination*) and the accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Abdelali Elouaradia, Acting Office Director, Office VI, Antidumping and Countervailing Duty Operations, regarding ''Issue and Decision Memorandum for the Final Determination of the Less-Than-Fair-Value Investigation of Certain Steel Nails from the Socialist Republic of Vietnam'' (Issue and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

[3] *See* Petitions for the Imposition of Antidumping and Countervailing Duties: Certain Steel Nails from India, the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam, dated May 29, 2014 (Petition).

[4] *See* the Preliminary Decision Memorandum at 7 and 8.

regulations do not address how we are to determine the dumping margin for separate rate companies not selected for individual examination. Normally, the Department's practice is to assign to separate-rate companies that were not individually examined a dumping margin equal to the average of the margins calculated for the individually examined respondents, excluding any margins that are zero, *de minimis,* or based entirely on facts available. If all dumping margins for the individually examined respondents are zero, *de minimis,* or based entirely on facts available, then we will use any reasonable method, including averaging the dumping margins for the individually examined respondents. In this investigation, the individually examined respondents are part of the Vietnam-wide entity, the rate for which is based entirely on facts available. We have no other reliable margin or data on the record to determine the separate rate for Kosteel Vina. Therefore, we have assigned the sole petition rate of 323.99 percent, which was corroborated by documentation supporting the petition, and is the only available rate on the record, to Kosteel Vina. For more details, see the Separate Rate memorandum for the final determination.[5]

Combination Rates

In the *Initiation Notice,* the Department stated that it would calculate combination rates for the respondents that are eligible for a separate rate in this investigation.[6] Policy Bulletin 05.1 sets forth this practice.[7]

Final Determination Margins

The Department determines that the following estimated weighted-average dumping margins exist for the period October 1, 2013, through March 31, 2014:

Exporter	Producer	Weighted-average dumping margin
Kosteel Vina Limited Company	Kosteel Vina Limited Company	323.99%
Vietnam-Wide Entity*		323.99%

* The Vietnam-wide entity includes the following exporters/producers: Region Industries Co., Ltd., United Nail Products Co., Ltd., Cong Ty Tnhh Cong Nghe Nhua A Chau, Kim Tin Group, Megastar Co., Ltd. and Simone Accessories Collection.

Disclosure

Normally, the Department discloses to interested parties the calculations performed in connection with a final determination within five days of the date of public announcement of the final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because the Department, in accordance with section 776 of the Act, applied adverse facts available to determine the estimated weighted-average dumping margin for the mandatory respondents in this investigation, there are no calculations to disclose to parties.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of subject merchandise, as described in the ''Scope of the Investigation'' section of this notice, from Vietnam that were entered or withdrawn from warehouse for consumption on or after December 29, 2014, the publication date of the *Preliminary Determination* in the **Federal Register**.

Consistent with our practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, we will instruct CBP to require a cash deposit equal to the amount by which the normal value exceeds the export price or constructed export price, adjusted where appropriate for export subsidies and estimated domestic subsidy pass-through.[8] In the final determination of the companion countervailing duty investigation of certain steel nails from Vietnam, the Department determined that the mandatory respondents and all other companies benefited from export subsidies.[9] Thus, we will offset the estimated weighted-average dumping margin of 323.99 percent for the Vietnam-wide entity and the separate-rate company by the countervailing duty rate of 33.59 percent attributable to export subsidies,[10] resulting in a cash-deposit rate of 290.40 percent for the Vietnam-wide entity and the separate-rate company.

With respect to the separate-rate company, Kosteel Vina, we find that an export subsidy adjustment of 33.59 percent to the cash deposit rate is warranted because this is the export subsidy rate included in the countervailing duty rate (*i.e.,* the ''All Others'' rate) to which the separate-rate company is subject in the companion countervailing duty proceeding. With respect to the Vietnam-wide entity, we find that an export-subsidy adjustment of 33.59 percent to the cash deposit rate is warranted because this is the export subsidy rate included in the countervailing duty rate to which Vietnam-wide entries are currently subject.

We are not adjusting the final determination rate for estimated domestic subsidy pass-through because we have no basis upon which to make such an adjustment.

Pursuant to 19 CFR 351.205(d), we will instruct CBP to require a cash deposit for all suspended entries at an

[5] *See* Memorandum to Brian Davis, Acting Program Manager, Office VI, from Edythe Artman, International Trade Compliance Analyst, Office VI, regarding ''Change in Rate for the Separate-Rate Company,'' dated May 13, 2015.

[6] *See Certain Steel Nails From India, the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, the Republic of Turkey, and the Socialist Republic of Vietnam: Initiation of Less-Than-Fair-Value Investigations,* 79 FR 36019 (June 25, 2014) (*Initiation Notice*).

[7] *See* Enforcement and Compliance Policy Bulletin No. 05.1 ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on the Department's Web site at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[8] *See* sections 772(c)(1)(C) and 777A(f) of the Act, respectively. Unlike in administrative reviews, the Department calculates the adjustment for export subsidies in less-than-fair-value investigations not in the margin-calculation program, but in the cash-deposit instructions issued to CBP. *See Notice of Final Determination of Sales at Less Than Fair Value, and Negative Determination of Critical Circumstances: Certain Lined Paper Products from India,* 71 FR 45012 (August 8, 2006), and accompanying Issues and Decision Memorandum at Comment 1.

[9] *See Certain Steel Nails From the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination,* and accompanying Issues and Decision Memorandum at 12–22, signed concurrently with this notice.

[10] *See id.* The following subsidy programs, countervailed for all companies in the final determination of the concurrent countervailing duty investigation, are export subsidies: Preferential Lending to Exporters (1.17 percent), Import Duty Exemptions and Reimbursements for Imported Raw Materials for Exported Goods (4.46 percent), Export Factoring (1.17 percent), Financial Guarantees (1.17 percent), Export Credits from the Vietnam Development Bank (0.21 percent) and Export Promotion Program (25.41 percent).

ad valorem rate equal to the weighted-average amount by which normal value exceeds U.S. price, with the above-noted adjustments, as follows: (1) The rate for the exporter/producer combinations listed in the chart above will be the rate we have determined in this final determination; (2) for all Vietnamese exporters of merchandise under consideration which have not received their own rate, the cash-deposit rate will be the rate established for the Vietnam-wide entity; and (3) for all non-Vietnamese exporters of merchandise under consideration and for all non-Vietnamese exporters of merchandise under consideration which have not received their own rate, the cash-deposit rate will be the rate applicable to the Vietnamese exporter/producer combination that supplied the non-Vietnamese exporter. These suspension-of-liquidation and cash-deposit instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of the final affirmative determination of sales at less than fair value. Because the final determination in this proceeding is affirmative, the ITC will make its final determination, in accordance with section 735(b)(2) of the Act, as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of certain steel nails from Vietnam no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, this proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, then the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

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(a)(3). 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.

Notification to Interested Parties

This determination and notice are issued and published in accordance with sections 735(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.[11] Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of (i) medical, surgical, dental or veterinary furniture; and (ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (*e.g.,* furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[11] The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

Appendix II

Contents of the Accompanying Final Issue and Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope of the Investigation
V. Scope Comments
VI. Discussion of Comments
Comment 1: Application of Adverse Facts Available to Mandatory Respondents
VII. Recommendation

[FR Doc. 2015–12254 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, June 10, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, June 11 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, June 12, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time. All sessions will be open to the public.

DATES: The meeting will be held on Wednesday, June 10, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, June 11, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, June 12, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time.

ADDRESSES: The meeting will take place at the National Cybersecurity Center of Excellence (NCCoE), 9600 Gudelsky Drive, Room B–105, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Annie Sokol, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, telephone: (301) 975–2006, or by email at: *annie.sokol@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, June 10, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, Thursday, June 11, 2015, from 8:30 a.m. until 5:00 p.m. Eastern Time, and Friday, June 12, 2015, from 8:30 a.m. until 12:00 p.m. Eastern Time. All sessions will be open to the public. The ISPAB is authorized by 15 U.S.C. 278g–4, as amended, and advises the National Institute of Standards and Technology (NIST), and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal government information systems, including thorough review of proposed standards and guidelines developed by NIST. Details regarding the ISPAB's activities are available at *http://csrc.nist.gov/groups/SMA/ispab/index.html.*

The agenda is expected to include the following items:

—Presentation from National Cybersecurity Center of Excellence (NCCoE),
—Updates from Deputy Undersecretary for Cybersecurity and Communications, U.S. Department of Homeland Security,
—Updates on OMB Circular No. A–130 Revised, Management of Federal Information Resources,
—Updates from Deputy Chief Technology Officer, the White House,
—Discussion on data security and privacy (auto-manufacturer communication and usability) with National Highway Safety Administration (NHTSA),
—Presentation from Federal Bureau of Investigation (FBI) on information collection,
—Presentation on Quantum Cybersecurity,
—Discussion on Data Breach and Supply Chain Security,
—Discussion on Executive Order 13694—Blocking the Property of Certain Persons Engaging in Significant Malicious Cyber-enabled Activities,
—Discussion on Executive Order 13691—Promoting Private Sector Cybersecurity Information Sharing,
—Panel presentation—Inspector General (IG) Reporting on Federal Information Security Management Act (FISMA),
—Presentation on the Communication Security, Reliability and Interoperability Council (CSRIC) Report on the Cybersecurity Framework, and
—Updates on NIST Computer Security Division.

Note that agenda items may change without notice. The final agenda will be posted on the Web site indicated above. Seating will be available for the public and media. Although pre-registration is not required to attend this meeting, all attendees must sign-in to obtain site access.

Public Participation: The ISPAB agenda will include a period of time, not to exceed thirty minutes, for oral comments from the public (Friday, June 12, 2015, between 10:00 a.m. and 10:30 a.m.). Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes. Questions from the public will not be considered during this period. Members of the public who are interested in speaking are requested to contact Annie Sokol at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements. In addition, written statements are invited and may be submitted to the ISPAB at any time. All written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930.

Kevin Kimball,

Chief of Staff.

[FR Doc. 2015–12424 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Notice of Open Federal Advisory Committee Meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee), will hold a meeting via teleconference on Thursday, July 2, 2015 from 3:30 p.m. to 5:30 p.m. Eastern Time. The purpose of this meeting is to discuss the NCST Advisory Committee's draft annual report to Congress. A copy of the draft report will be posted prior to the meeting on the NCST Advisory Committee's Web site at *http://www.nist.gov/el/disasterstudies/ncst/index.cfm.* Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number.

DATES: The NCST Advisory Committee will hold a meeting via teleconference on Thursday, July 2, 2015 from 3:30 p.m. to 5:30 p.m.

ADDRESSES: Questions regarding the meeting should be sent to Dr. Long Phan, Acting Director of the Disaster and Failure Studies Program at the following address: National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, Maryland 20899–8611. For instructions on how to participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Dr. Long Phan, Acting Director, Disaster and Failure Studies, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8611, Gaithersburg, Maryland 20899–8611, email: *long.phan@nist.gov,* phone: (301) 975–6077.

SUPPLEMENTARY INFORMATION: The NCST Advisory Committee was established pursuant to Section 11 of the National Construction Safety Team Act (15 U.S.C. 7301 *et seq.*). The NCST Advisory Committee is comprised of nine members, appointed by the Director of NIST, who were selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues affecting NCST Teams established under the NCST Act. The NCST Advisory Committee advises the Director of NIST on (1) the functions and composition of NCST Teams established under the NCST Act, (2) the exercise of authorities enumerated in the NCST Act, and (3) the procedures developed to implement the NCST Act. The NCST reports are issued under section 8 of the NCST Act. Background information on the NCST Act and information on the NCST Advisory Committee is available at *http://www.nist.gov/el/disasterstudies/ncst.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will hold a meeting via teleconference on Thursday, July 2, 2015 from 3:30 p.m. to 5:30 p.m. Eastern Time. There will be no central meeting location. Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number. The primary purpose of this meeting is to discuss the NCST Advisory Committee's draft annual report to Congress. A copy of the draft report will be posted on the NCST Advisory Committee's Web site at *http://www.nist.gov/el/disasterstudies/ncst/index.cfm.*

Approximately fifteen minutes will be reserved from 5:15 p.m.–5:30 p.m. Eastern Time for public comments; speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be 3 minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to participate are invited to submit written statements to the National Construction Safety Team Advisory Committee, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899–8604, via fax at (301) 975–4032, or electronically by email to *ncstac@nist.gov.*

All participants in the meeting are required to pre-register. Anyone wishing to participate must register by 5:00 p.m. Eastern Time on Wednesday July 1st to be included. In order to register please submit your name, email address, and phone number to Dr. Long Phan, at *long.phan@nist.gov.* Questions can also be directed to Dr. Phan at 301–975–6077. After registering, participants will be provided with detailed instructions on how to dial in from a remote location in order to participate.

Kevin Kimball,

Chief of Staff.

[FR Doc. 2015–12425 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Earthquake Hazards Reduction (ACEHR or Committee), will hold an open meeting via webinar on Friday, June 12, 2015, from 1:00 p.m. to 3:00 p.m. Eastern Time. The primary purpose of this meeting is to finalize the Committee's 2015 Report on the Effectiveness of the National Earthquake Hazards Reduction Program (NEHRP). The agenda may change to accommodate Committee business. The final agenda and any draft meeting materials will be posted prior to the meeting on the NEHRP Web site at *http://nehrp.gov/.* Interested members of the public will be able to participate in the meeting from remote locations by calling into a central phone number.

DATES: The ACEHR will hold a meeting via webinar on Friday, June 12, 2015, from 1:00 p.m. until 3:00 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: Questions regarding the meeting should be sent to National Earthquake Hazards Reduction Program Director, National Institute of Standards and Technology (NIST), 100 Bureau Drive, Mail Stop 804, Gaithersburg, Maryland 20899–8604. For instructions on how to participate in the meeting via webinar, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tina Faecke, Management and Program Analyst, National Earthquake Hazards Reduction Program, Engineering Laboratory, NIST, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, Maryland 20899–8604. Ms. Faecke's email address is *tina.faecke@nist.gov* and her phone number is (301) 975–5911.

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the requirements of Section 103 of the NEHRP Reauthorization Act of 2004 (Public Law 108–360). The Committee is composed of 15 members appointed by the Director of NIST, who were selected for their established records of distinguished service in their professional community, their knowledge of issues affecting NEHRP, and to reflect the wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. In addition, the Chairperson of the U.S. Geological Survey (USGS) Scientific Earthquake Studies Advisory Committee (SESAC) serves as an ex-officio member of the Committee.

The Committee assesses:

- Trends and developments in the science and engineering of earthquake hazards reduction;
- the effectiveness of NEHRP in performing its statutory activities;
- any need to revise NEHRP; and
- the management, coordination, implementation, and activities of NEHRP.

Background information on NEHRP and the Advisory Committee is available at *http://nehrp.gov/.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the ACEHR will hold an open meeting via webinar on Friday, June 12, 2015, from 1:00 p.m. to 3:00 p.m. Eastern Time. There will be no central meeting location. Interested members of the

public will be able to participate in the meeting from remote locations by calling into a central phone number. The primary purpose of this meeting is to finalize the Committee's 2015 Report on the Effectiveness of the NEHRP. The agenda may change to accommodate Committee business. The final agenda and any meeting materials will be posted prior to the meeting on the NEHRP Web site at *http://nehrp.gov/.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda and detailed instructions on how to join the webinar from a remote location in order to participate by submitting their request to Felicia Johnson at *felicia.johnson@nist.gov* or 301–975–5324 no later than 5:00 p.m. Eastern Time, Tuesday, June 9, 2015. Approximately 15 minutes will be reserved from 2:45 p.m.–3:00 p.m. Eastern Time for public comments; speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about three minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated, and those who were unable to participate are invited to submit written statements to ACEHR, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899–8604, via fax at (301) 975–4032, or electronically by email to *info@nehrp.gov.*

All participants of the meeting are required to pre-register. Anyone wishing to participate must register by 5:00 p.m. Eastern Time, Tuesday, June 9, 2015, in order to be included. Please submit your full name, email address, and phone number to Felicia Johnson at *felicia.johnson@nist.gov* or (301) 975–5324. After pre-registering, participants will be provided with detailed instructions on how to join the webinar from a remote location in order to participate.

Kevin Kimball,

Chief of Staff.

[FR Doc. 2015–12423 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Board of Overseers of the Malcolm Baldrige National Quality Award and Judges Panel of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: The Board of Overseers of the Malcolm Baldrige National Quality Award (Board of Overseers) and the Judges Panel of the Malcolm Baldrige National Quality Award (Judges Panel) will meet together in open session on Thursday, June 11, 2015, from 8:30 a.m. to 3:00 p.m. Eastern time. The Board of Overseers, appointed by the Secretary of Commerce, reports the results of the Malcolm Baldrige National Quality Award (Award) activities to the Director of The National Institute of Standards and Technology (NIST) each year, along with its recommendations for the improvement of the Award process. The Judges Panel, also appointed by the Secretary of Commerce, ensures the integrity of the Award selection process and recommends Award recipients to the Secretary of Commerce. The purpose of this meeting is to discuss and review information received from the National Institute of Standards and Technology and from the Chair of the Judges Panel. The agenda will include: Baldrige Program Update, Baldrige Fundraising Update, Baldrige Judges Panel Update, Ethics Review, Applicants and Eligibility, and New Business/Public Comment.

DATES: The meeting will be held on Thursday, June 11, 2015 from 8:30 a.m. Eastern time until 3:00 p.m. Eastern time. The meeting will be open to the public.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Building 101, Lecture Room A, 100 Bureau Drive, Gaithersburg, Maryland 20899. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, Maryland 20899–1020, telephone number (301) 975–2360, or by email at *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION:

Authority: 15 U.S.C. 3711a(d)(1), 15 U.S.C. 3711a(d)(2)(B) and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the Board of Overseers and the Judges Panel will meet together in open session on Thursday, June 11, 2015 from 8:30 a.m. to 3:00 p.m. Eastern time. The Board of Overseers, composed of approximately eleven members preeminent in the field of organizational performance excellence and appointed by the Secretary of Commerce, make an annual report on the results of Award activities to the Director of the National Institute of Standards and Technology (NIST), along with its recommendations for improvement of the Award process. The Judges Panel consists of twelve members with balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. The Panel includes members familiar with the quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, and educational institutions. The Judges Panel recommends Malcolm Baldrige National Quality Award recipients to the Secretary of Commerce.

The purpose of this meeting is to discuss and review information received from the National Institute of Standards and Technology and from the Chair of the Judges Panel of the Malcolm Baldrige National Quality Award. The agenda will include: Baldrige Program Update, Baldrige Fundraising Update, Baldrige Judges Panel Update, Ethics Review, Applicants and Eligibility, and New Business/Public Comment. The agenda may change to accommodate the Judges Panel and Board of Overseers business. The final agenda will be posted on the NIST Baldrige Performance Excellence Web site at *http://www.nist.gov/baldrige/community/overseers.cfm.* The meeting is open to the public. Individuals and representatives of organizations who would like to offer comments and suggestions related to the Board's affairs and/or the Panel of Judges' general process are invited to request a place on the agenda. On June 11, 2015, approximately one-half hour will be reserved in the afternoon for public comments, and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be about 3 minutes each. The exact time for public comments will be included in

the final agenda that will be posted on the Baldrige Performance Excellence Program Web site at *http://www.nist.gov/baldrige/community/overseers.cfm.* Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak, but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the Baldrige Performance Excellence Program, Attention Nancy Young, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, Maryland, 20899–1020, via fax at 301–975–4967 or electronically by email to *nancy.young@nist.gov.*

All visitors to the National Institute of Standards and Technology site will have to pre-register to be admitted. Please submit your name, time of arrival, email address and phone number to Nancy Young no later than 4:00 p.m. Eastern time, Thursday, June 4, 2015, and she will provide you with instructions for admittance. Non-U.S. citizens must submit additional information; please contact Nancy Young. Contact Ms. Young, by email at *nancy.young@nist.gov* or by phone at (301) 975–2361. Also, please note that under the REAL ID Act of 2005 (Pub. L. 109–13), federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if issued by states that are REAL ID compliant or have an extension. NIST also currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Ms. Young or visit: *http://www.nist.gov/public_affairs/visitor/.*

Kevin Kimball,

Chief of Staff.

[FR Doc. 2015–12571 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD956

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council's (Council) Executive Committee will meet to review scientific information affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: The meeting will be held on Monday, June 8, 2015, beginning at 9 a.m.

ADDRESSES: The meeting will be held at the Sheraton Harborside Hotel, 250 Market Street, Portsmouth, NH 03801; telephone: (603) 431–2300; fax: (603) 433–5649.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda Items

The Executive Committee will meet to review proposed changes to the National Standard Guidelines (80 **Federal Register** 2786). The Committee will develop recommended comments that will be discussed by the full Council at its June 16–18, 2015 meeting. Subsequent to that discussion, the Committee will discuss administrative issues of the Council and address other business as necessary.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least 5 days prior to the meeting date.

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

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12493 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD960

Gulf of Mexico Fishery Management Council (Council); Public Meeting

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

ACTION: Notice of public meeting of the Gulf of Mexico Fishery Management Council.

SUMMARY: The Gulf of Mexico Fishery Management Council (GMFMC) will hold meetings of the: Sustainable Fisheries/Ecosystem, Mackerel, and Data Collection Committees, Full Council (Closed Session) Scientific and Statistical and Reef Fish Advisory Panel Selection; Reef Fish, Shrimp and Joint Coral and Habitat Management Committees; in conjunction with a meeting of the Full Council. The Council will also hold a formal public comment session.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, June 8 until 4 p.m. on Friday, June 12, 2015.

ADDRESSES:

Meeting address: The meeting will be held at the Marriott Beachside Hotel, 3841 North Roosevelt Boulevard, Key West, FL 33040 (305) 296–8100.

Council address: Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Gregory, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630; fax: (813) 348–1711; email: *doug.gregory@gulfcouncil.org.*

SUPPLEMENTARY INFORMATION: The agenda items for discussion during each individual management committee meeting are as follows:

Sustainable Fisheries/Ecosystem Committee Agenda, Monday, June 8, 2015, 8:30 a.m. until 9:30 a.m.:

- Review of Draft Letter on National Standard 1 Proposed Revisions
- Review of Council Coordinating Committee (CCC) National Environmental Policy Act (NEPA) White Paper

Mackerel Management Committee Agenda, Monday, March 30, 2015, 9:30 a.m. until 11:30 a.m.:

- Final Action on Coastal Migratory Pelagics (CMP) Framework Amendment 3: Gulf of Mexico King Mackerel Gillnet Fishery Management Modifications
- Joint Draft Options Paper for CMP Amendment 26: Modifications to Allocations, Stock Boundaries, and Sale provisions for Gulf of Mexico and Atlantic Migratory Groups of *King Mackerel*
- Discussion of Potential CMP Amendment 28: Separating Permits for Gulf of Mexico and Atlantic Migratory Groups of *King Mackerel*

- Scoping Workshop Summaries on Proposed CMP Amendments 26 and 28

Data Collection Management Committee Agenda, Monday, June 8, 2015, 1 p.m. until 2:30 p.m.:

- Joint Options Paper for Electronic Charter Vessel Reporting
- Marine Recreational Information Program (MRIP) Fishing Effort Transition Plan

Scientific and Statistical Management Selection Committee Agenda, Full Council—CLOSED SESSION, Monday, June 8, 2015, 2:30 p.m. until 4:30 p.m.:

- Appointments to Scientific and Statistical Committees (SSC)

Reef Fish Advisory Panel Selection Committee Agenda, Full Council—CLOSED SESSION, Monday, June 8, 2015, 4:30 p.m. until 5:30 p.m.:

- Appointments to the Restructured Reef Fish Advisory Panel (AP)

— Recess —

Reef Fish Management Committee Agenda, Tuesday, June 9, 2015, 8:30 a.m. until 11:30 a.m. and 1 p.m. until 5 p.m.:

- SSC Review of Alternative *Red Snapper* Maximum Sustainable Yield (MSY) Proxies
- SSC Review of the effect of recalibrated recreational removals and recreational selectivity on estimates of Overfishing Limits (OFL), Acceptable Biological Catch (ABC), and MSY for Gulf *Red Snapper*
- Options Paper—Framework Action to set *Gag* Annual Catch Limit (ACL) and Recreational Season
- SSC Recommendations for *Hogfish* and *Mutton Snapper* OFL and ABC
- Options Paper—Joint Generic South Florida Management
- Updated Draft Amendment 28: *Red Snapper* Allocation
- Draft Framework Action to Allow NMFS to withhold a Portion of the Commercial *Red Snapper* Quota
- Revised Alternatives—Amendment 39: Regional Management of Recreational *Red Snapper*
- Scoping Summaries on Amendment 36: *Red Snapper* Individual Fishing Quota (IFQ) Modifications
- Grouper/Tilefish IFQ 5-Year Review

— Recess —

Reef Fish Management Committee Agenda continued, Wednesday, June 10, 2015, 8:30 a.m. until 9:30 a.m.:

- Report of the Ad Hoc *Red Snapper* Charter For-Hire Advisory Panel (AP)
- Report of the Ad Hoc Reef Fish Headboat AP
- Other Business

Shrimp Management Committee Agenda, Wednesday, June 10, 2015, 9:30 a.m. until 11 a.m.:

- Final Action on Shrimp Amendment 15: Status Determination Criteria for *Penaeid Shrimp* and Adjustments to the Shrimp Framework Procedure
- Draft Options Paper for Shrimp Amendment 17: Addressing the Expiration of the Shrimp Permit Moratorium

Joint Coral and Habitat Management Committee Agenda, Wednesday, June 10, 2015, 11 a.m. until 12 noon:

- Coral SSC and AP Summary Report

Council Session Agenda, Wednesday, June 10, 2015, 1:30 p.m. until 5:30 p.m.

1:30 p.m.–1:45 p.m.: Call to Order, Announcements, Introductions, Adoption of Agenda and Approval of Minutes

1:45 p.m.–2 p.m.: Review of and Vote on Exempted Fishing Permits (EFPs), if any.

2:15 p.m.–3:30 p.m.: The Council will receive presentations reviewing changes from proposed to final rule implementation of the Gulf Aquaculture Fishery Management Plan (FMP), Florida Keys National Marine Sanctuary Issues, Spawning Potential Ratios, and Southeast Data Assessment and Review (SEDAR).

3:30 p.m.–5:30 p.m.: The Council will receive public testimony for Final Action on Framework Action: Modifications to the Commercial *King Mackerel* Gillnet Fishery in the Gulf of Mexico, Final Action on Shrimp Amendment 15: Status Determination Criteria for *Penaeid Shrimp* and Adjustments to the Shrimp Framework Procedure, Revised Reef Fish Amendment 28—*Red Snapper* Allocation; and open public comment regarding other fishery issues or concerns.

— Recess —

Joint Council Session with South Atlanta Council Agenda (Doubletree Hotel), Thursday, June 11, 2015, 8:45 a.m. until 5:30 p.m.:

8:45 a.m.–5:30 p.m.: The councils will receive committee reports from the Data Collection, Mackerel and Reef Fish Management Committees.

Council Session Agenda, Friday, June 12, 2015, 8:30 a.m.—4 p.m.:

8:30 a.m.–12 noon: The Council will continue to receive committee reports from Reef Fish, Mackerel, and Sustainable Fisheries/Ecosystem Management Committees.

— Recess —

1:30 p.m.–3:30 p.m.: The Council will receive a committee report from the Shrimp, Joint Habitat/Coral, and SSC Panelists and AP Members Selected.

3:30 p.m.–4 p.m.: The Council will review Other Business. A presentation on the Gulf of Mexico Habitat Mapping and Water Quality Monitoring Project.

— Adjourn —

The Agenda is subject to change, and the latest version will be posted on the Council's file server, which can be accessed by going to the Council Web site at *http://www.gulfcouncil.org* and clicking on FTP Server under Quick Links. For meeting materials see folder ''Briefing Books/Briefing Book 2015–06'' on Gulf Council file server. The username and password are both ''gulfguest''. The meetings will be Webcast over the Internet. A link to the Webcast will be available on the Council's Web site, *http://www.gulfcouncil.org*.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Council Office (see **ADDRESSES**), at least 5 working days prior to the meeting.

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

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12507 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

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: Application Forms for Membership on a National Marine Sanctuary Advisory Council.

OMB Control Number: 0648–0397.

Form Number(s): NA.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 520.

Average Hours per Response: 1 hour.

Burden Hours: 520.

Needs and Uses: This request is for a revision and extension Section 315 of the National Marine Sanctuaries Act (16 U.S.C. 1445a) allows the Secretary of Commerce to establish one or more advisory councils to provide advice to the Secretary regarding the designation and management of national marine sanctuaries. Advisory councils are individually chartered for each sanctuary to meet the needs of that sanctuary. Once an advisory council has been chartered, the sanctuary superintendent starts a process to recruit members for that council by providing notice to the public and requesting interested parties to apply for the available seat(s) (*e.g.,* Research, Education) and position(s) (*i.e.,* council member or alternate). The information obtained through this application process will be used to determine the qualifications of the applicant for membership on the sanctuary advisory council.

Two application forms are currently associated with this information collection: (a) National Marine Sanctuary Advisory Council Application form; and (b) National Marine Sanctuary Advisory Council Youth Seat Application form. These application forms are currently being revised to ensure consistency between forms, as well as clarify the information and supplemental materials to be submitted by applicants. Application form instructions will specify requirements imposed upon the agency when reviewing applicants as potential council members or alternates, including the need to assess potential conflicts of interest (or other issues) and the applicant's status as a federally registered lobbyist. Specific questions posed to applicants will be reordered, reworded and, at times, condensed to improve the organization of applicant responses and, thereby, simplify the applicant review process.

Affected Public: Individuals or households; not-for-profit institutions; business or other for-profit organizations; Federal government.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

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* or fax to (202) 395–5806.

Dated: May 19, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–12565 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD958

Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet June 10–16, 2015. The Pacific Council meeting will begin on Friday, June 12, 2015 at 8 a.m., reconvening each day through Tuesday, June 16, 2015. All meetings are open to the public, except a closed session will be held at 8 a.m. on Friday, June 12 to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: The meetings of the Council and its advisory entities will be held at the Doubletree by Hilton Spokane City Center, 322 N. Spokane Falls Court, Spokane, WA 99201; telephone: (509) 455–9600.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220. Instructions for attending the meeting via live stream broadcast are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. McIsaac, Executive Director; telephone: (503) 820–2280 or (866) 806–7204 toll free; or access the Pacific Council Web site, *http://www.pcouncil.org/council-operations/council-meetings/current-meeting/* for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The June 12–16, 2015 meeting of the Pacific Fishery Management Council will be streamed live on the Internet. The live meeting will be broadcast daily starting at 9 a.m. Pacific Time (PT) beginning on Friday, June 12, 2015 through Tuesday, June 16, 2015. The broadcast will end daily at 6 p.m. PT or when business for the day is complete. Only the audio portion, and portions of the presentations displayed on the screen at the Council meeting, will be broadcast. The audio portion is listen-only; you will be unable to speak to the Council via the broadcast. Join the meeting by visiting this link *http://www.gotomeeting.com/online/webinar/join-webinar*, enter the Webinar ID for this meeting, which is 159–274–491, and enter your email address as required. It is recommended that you use a computer headset as GoToMeeting allows you to listen to the meeting using your computer headset and speakers. If you do not have a headset and speakers, you may use your telephone for the audio portion of the meeting by dialing this TOLL number (1–646) 307–1720 (not a toll free number); entering the phone audio access code 574–408–270; and then entering your Audio Pin which will be shown to you after joining the webinar. The webinar is broadcast in listen only mode.

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as ''(Final Action)'' refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to the Secretary of Commerce, under sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, and meeting rooms, is described in Agenda Item A.4, Proposed Council Meeting Agenda, and will be in the advance June 2015 briefing materials and posted on the Council Web site *http://www.pcouncil.org/council-operations/council-meetings/current-briefing-book/*.

A. Call to Order
  1. Opening Remarks
  2. Roll Call
  3. Executive Director's Report

4. Approve Agenda
B. Open Comment Period
1. Comments on Non-Agenda Items
C. Habitat
1. Current Habitat Issues
D. Groundfish Management
1. National Marine Fisheries Service Report
2. Permit Stacking Cost Recovery Report (Final Action)
3. Salmon Endangered Species Act (ESA) Reconsultation Update
4. Non-Salmon ESA Report (Final Action)
5. Specifications Process for 2017–18 Fisheries
6. Groundfish Essential Fish Habitat and Rockfish Conservation Area Update
7. Inseason Adjustments (Final Action)
8. Final Stock Assessments and Catch Reports (Final Action)
9. Blackgill and Slope Rockfish Quota Share Allocation
10. Rebuilding Revision Rules
E. Highly Migratory Species Management
1. International Issues Including Inter-American Tropical Tuna Commission Meeting and North Pacific Albacore Management Strategy Evaluation
2. Final Approval of Resubmitted Exempted Fishing Permit Application (Final Action)
3. Swordfish Management and Monitoring Plan Hardcaps (Final Action)
F. Administrative Matters
1. Legislative Matters
2. Fiscal Matters
3. Approval of Council Meeting Minutes
4. Membership Appointments and Council Operating Procedures
5. Future Council Meeting Agenda and Workload Planning
G. Coastal Pelagic Species Management
1. National Marine Fisheries Service Report
2. Pacific Mackerel Assessment and Management Measures (Final Action)
3. Anchovy Update
4. Litigation Settlement Discussion
H. Ecosystem Management
1. Lenfest Taskforce and Ocean Modeling Forum Update

Advisory body agendas will include discussions of relevant issues that are on the Council agenda for this meeting, and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Council Web site (*www.pcouncil.org*) prior to their meeting date.

Schedule of Ancillary Meetings

Day 1—Wednesday, June 10, 2015
Scientific and Statistical Committee Groundfish Subcommittee—8 a.m.
Day 2—Thursday, June 11, 2015
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Scientific and Statistical Committee—8 a.m.
Budget Committee—8:30 a.m.
Habitat Committee—8 a.m.
Legislative Committee—3 p.m.
Day 3—Friday, June 12, 2015
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
Scientific and Statistical Committee (SSC)—8 a.m.
Enforcement Consultants—3 p.m.
Chairman's Reception—6 p.m.
Day 4—Saturday, June 13, 2015
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
SSC Groundfish and Economic Subcommittees—8 a.m.
Enforcement Consultants—Ad hoc
Stock Assessment Question and Answer Session—7 p.m.
Day 5—Sunday, June 14, 2015
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
Enforcement Consultants—Ad hoc
Day 6—Monday, June 15, 2015
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Coastal Pelagic Species Advisory Subpanel—8 a.m.
Coastal Pelagic Species Management Team—8 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Enforcement Consultants—Ad hoc
Day 7—Tuesday, June 16, 2015
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Coastal Pelagic Species Advisory Subpanel—8 a.m.
Coastal Pelagic Species Management Team—8 a.m.
Enforcement Consultants—Ad hoc

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subject of formal Council action during these meetings. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Carolyn Porter at (503) 820–2280 at least 5 days prior to the meeting date.

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12506 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD932

South Atlantic Fishery Management Council (SAFMC); Public Meeting

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

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the: Habitat Protection and Ecosystem-Based Management Committee; Protected Resources Committee; Shrimp Committee; Southeast Data, Assessment and Review (SEDAR) Committee; Golden Crab Committee; Personnel Committee (Closed Session); Scientific and Statistical Committee (SSC) Selection Committee; Law Enforcement Committee (partially closed); Data Collection Committee; King and Spanish Mackerel Committee; Executive Finance Committee; Snapper Grouper Committee; and a meeting of the Full Council. The Council will also hold a Council Member Visioning Workshop for the Snapper Grouper Fishery and conduct a joint Council Session with the Gulf of Mexico Fishery Management Council. The Council will take action as necessary. The Council will also hold a formal public comment session.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, June 8, 2015 until 3 p.m. on Friday, June 12, 2015.

ADDRESSES:

Meeting address: The meeting will be held at the Doubletree Grand Key Resort, 3990 S. Roosevelt Blvd., Key West, FL 33040; phone: (800) 222–8733 or (305) 293–1818; fax: (305) 296–6962.

Council address: South Atlantic Fishery Management Council, 4055

Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The items of discussion in the individual meeting agendas are as follows:

Council Member Visioning Workshop: Monday, June 8, 2015, 8:30 a.m. Until 12 Noon

1. Council members will receive a recap of the March 2015 Visioning Workshop, an overview of the draft Snapper Grouper Vision Blueprint, review public input, promotional materials and strategies, and discuss planning for public input schedules on the Draft Vision Blueprint.

2. Council members will discuss next steps and provide guidance to staff.

Habitat Protection and Ecosystem-Based Management Committee: Monday, June 8, 2015, 1:30 p.m. Until 3 p.m.

1. The committee will receive a report from the Habitat Advisory Panel, a status report on the Fishery Ecosystem Plan II Development, a report on the South Atlantic Ecosystem Modeling Workshop, and review analyses associated with the northern extension of the Oculina Bank Coral Habitat Area of Particular Concern as it pertains to the rock shrimp fishery.

2. The committees will develop recommendations and provide guidance to staff.

Protected Resources Committee: Monday, June 8, 2015, 3 p.m. Until 4 p.m.

1. The committee will receive an update from NOAA Fisheries on protected resource-related issues, a briefing on the Acropora (coral) recovery plan, an overview of the Coastal Migratory Pelagics Fishery Biological Opinion, and an overview of the NOAA Fisheries guidance on the Endangered Species Act/Magnuson-Stevens Fishery Conservation Act Integration Agreement.

2. The committee will develop recommendations for the Council.

Shrimp Committee: Monday, June 8, 2015, 4:00 p.m. Until 4:30 p.m.

1. The committee will review the Shrimp and Deepwater Shrimp Advisory Panel report, discuss, and provide guidance to staff.

SEDAR Committee: Monday, June 8, 2015, 4:30 p.m. Until 5 p.m.

1. The committee will approve Terms of Reference for red grouper, approve the Council's Annual Research and Monitoring Plan, and receive an update on the Marine Recreational Information Transition Plan.

Golden Crab Committee: Monday, June 8, 2015, 5 p.m. Until 5:30 p.m.

1. The committee will receive an update on the status of commercial catch versus annual catch limit (ACL) for golden crab, the status of Amendment 9 to the Golden Crab Fishery Management Plan (FMP), and a report on available data for golden crab. The committee will discuss and take action as necessary.

Personnel Committee: Tuesday, June 9, 2015, 8 a.m. Until 9 a.m. (Closed Session)

1. The committee will review a staff retirement health insurance proposal and provide recommendations.

SSC Selection Committee: Tuesday, June 9, 2015, 9 a.m. Until 9:30 a.m. (Closed Session)

1. The committee will review applications for the SSC and provide recommendations for appointments.

Law Enforcement Committee: Tuesday, June 9, 2015, 9:30 a.m. Until 10:30 a.m. (Partially Closed Session)

1. The committee will review nominations for Law Enforcement Officer of the Year (closed session) and receive a report from the Law Enforcement Advisory Panel.

2. The committee will provide recommendations as appropriate.

Data Collection Committee: Tuesday, June 9, 2015, 10:30 a.m. Until 11 a.m.

1. The committee will receive a presentation on the status of work on bycatch reporting in the Southeast, an overview of the status of the implementation plan for commercial electronic logbook reporting, a presentation on the status of the commercial electronic logbook pilot project, an overview of the Joint South Atlantic and Gulf Council Generic Charterboat Reporting Amendment including the status of the Gulf Council recommendations and next steps, and review the Decision Document for the amendment.

2. The committee will discuss, approve next steps, and provide guidance to staff.

King and Spanish Mackerel Committee: Tuesday, June 9, 2015, 11 a.m. Until 12 Noon

1. The committee will receive a report on the status of commercial catch versus ACLs for king mackerel, Spanish mackerel and cobia, the status of amendments currently under Secretarial Review, discuss Framework Amendment 2 to the Coastal Migratory Pelagic FMP, and receive a report from the Mackerel Advisory Panel.

2. The committee will review Coastal Migratory Pelagic FMP Amendment 26 addressing modifications to management/stock boundaries, management parameters for king mackerel including changes to ACLs, revisions to commercial quotas and allocations in the Gulf of Mexico, and allowing the sale of king mackerel caught within the shark gillnet fishery. The committee will modify the amendment as necessary, and select preferred management alternatives.

3. The committee will review the Discussion Document for Coastal Migratory Pelagic FMP Amendment 28 addressing options for separating the joint FMP between the Gulf of Mexico and South Atlantic Fishery Management Councils.

4. The committee will provide recommendations and direction to staff as appropriate.

Executive Finance Committee: Tuesday, June 9, 2015, 1:30 p.m. Until 3 p.m.

1. The committee will receive an update on the status of the Calendar Year 2015 budget expenditures and review the Council Follow-up and priorities.

2. The committee will review and approve the Calendar Year 2015 budget.

3. The committee will also receive an update on the Joint South Florida Committee Issues and an overview of the Citizen Science Program and review the Statement of Work.

4. The committee will provide recommendations and address other issues as appropriate.

Snapper Grouper Committee: Tuesday, June 9, 2015, 3 p.m. Until 5:30 p.m. and Wednesday, June 10, 2015, 8:30 a.m. Until 5 p.m.

1. The committee will receive updates on the status of catches versus quotas under annual catch limits (ACLs), actions under formal review, Southeast Reef Fish Survey, and presentations on the 2015 red snapper season and Marine Recreational Information Program (MRIP) ''Rare Event'' sampling.

2. The committee will receive reports from the Snapper Grouper Advisory Panel (AP) and the SSC.

3. The committee will review the following amendments to the Snapper Grouper FMP and provide recommendations as appropriate: (1) Regulatory Amendment 16 addressing modifications to the current seasonal closure for the commercial black sea bass pot fishery. The committee will modify the amendment, choose preferred alternatives as appropriate and approve the amendment for public hearings; (2) Amendment 36 addressing Spawning Special Management Zones (SMZs.). The committee will consider public hearing comments and the draft System Management Plan, modify the document as appropriate, and approve the amendment for a second round of public hearings; (3) Amendment 35 to remove species from the management unit and address measures for the commercial golden tilefish endorsement. The committee will modify the document and codified text as needed and approve for formal review;

4. The committee will review the following amendments, provide guidance to staff and develop recommendations for approving for public scoping: (1) Amendment 38 pertaining to blueline tilefish management measures; (2) Amendment 37 addressing measures for hogfish; (3) Regulatory Amendment 23 addressing measures for golden tilefish; and (4) Regulatory Amendment 24 addressing measures for multiple species in the snapper grouper management complex.

Note: A formal public comment session will be held on Wednesday, June 10, 2015 beginning at 5:30 p.m. Public comment will be accepted on any items on the Council agenda including items on the joint Council session. The Chairman, based on the number of individuals wishing to comment, will determine the amount of time provided to each commenter.

Joint Council Session: South Atlantic and Gulf of Mexico Fishery Management Councils, Thursday, June 11, 2015, 8:30 a.m. Until 5:30 p.m.

8:30 a.m.–8:45 a.m.: Call the meeting to order, adopt the agenda, welcome and introductions

8:45–10 a.m.: The Councils will receive an overview of the Decision Document for the Joint South Atlantic and Gulf of Mexico Generic Charterboat Reporting Amendment addressing reporting requirements for federally permitted charterboats in the South Atlantic and Gulf of Mexico. The Councils will discuss measures and vote on actions as appropriate.

10 a.m.–12 noon: The Councils will review the Joint Draft Options Paper and Decision Document for Amendment 26 to the Coastal Migratory Pelagics FMP addressing king mackerel management measures including modifications to stock boundaries, allocations, and sale provisions. The Councils will discuss measures and vote on actions as appropriate.

1:30 p.m.–2:30 p.m.: The Councils will review the Decision Document for Amendment 28 to the Coastal Migratory Pelagic FMP addressing options for separating management of coastal migratory species (king mackerel, Spanish mackerel and cobia) between the Gulf of Mexico and South Atlantic Council's area of jurisdiction. The species are currently managed jointly through the FMP. The Councils will discuss measures and vote on actions as appropriate.

2:30 p.m.–5 p.m.: The Councils will review the Joint South Florida Amendment including issues, goals and objectives. The amendment includes measures to modify management of yellowtail snapper, mutton snapper and black grouper, seasonal closures, circle hook requirements and other measures designed to minimize conflicting regulations for South Florida. The Councils will review the Decision Document for the amendment and vote on actions as appropriate.

5 p.m.–5:30 p.m.: The Councils will review a Decision Document for management measures addressing hogfish following a recent stock assessment. The Councils will discuss measures and vote on actions as appropriate. The Councils will also address Other Business as appropriate.

Council Session: Friday, June 12, 2015, 8:30 a.m. Until 3 p.m.

8:30 a.m.–8:45 a.m.: Call the meeting to order, adopt the agenda, and approve the March 2014 minutes.

8:45 a.m.–9:45 a.m.: The Council will receive a report from the Snapper Grouper Committee and is scheduled to approve Snapper Grouper Amendment 35 for formal Secretarial review. The Council will approve/disapprove Regulatory Amendment 16 for public hearings and Amendment 36 for a second round of public hearings. The Council is scheduled to approve or disapprove the following amendments for public scoping: Snapper Grouper Amendment 37, Amendment 38, Regulatory Amendment 23 and Regulatory Amendment 24. The Council will consider other committee recommendations and take action as appropriate.

9:45 a.m.–10 a.m.: The Council will receive a report from the King and Spanish Mackerel Committee, consider committee recommendations and take action as appropriate.

10 a.m.–10:15 a.m.: The Council will receive a report from the SSC Selection Committee, appoint members to the SSC and the SSC's Socio-Economic Panel, consider other committee recommendations and take action as appropriate.

10:15 a.m.–10:30 a.m.: The Council will receive a report from the Council Member Visioning Workshop, consider recommendations and take action as appropriate.

10:30 a.m.–10:45 a.m.: The Council will receive a report from the Habitat Protection and Ecosystem-Based Management Committee, consider committee recommendations and take action as appropriate.

10:45 a.m.–11 a.m.: The Council will receive a report from the Protected Resources Committee, consider committee recommendations and take action as appropriate.

11 a.m.–11:15 a.m.: The Council will receive a report from the SEDAR Committee, approve or disapprove the red grouper terms of reference, the Council's annual Research and Monitoring Plan, consider committee recommendations and take action as appropriate.

11:15 a.m.–11:30 a.m.: The Council will receive a report from the Executive Finance Committee, approve the Council Follow Up and Priorities, approve the Calendar Year 2015 budget, take action on the South Florida Management issues as appropriate, consider other committee recommendations and take action as appropriate.

11:30 a.m.–11:45 a.m.: The Council will receive a report from the Golden Crab Committee, consider committee recommendations, and take action as appropriate.

11:45 a.m.–12 noon: The Council will receive a report from the Data Collection Committee, consider recommendations and take action as appropriate.

1 p.m.–1:15 p.m.: The Council will receive a report from the Shrimp Committee, consider committee recommendations and take action as appropriate.

1:15 p.m.–1:30 p.m.: The Council will receive a report from the Law Enforcement Committee, select the Law Enforcement Officer of the Year, consider other committee recommendations, and take action as appropriate.

1:30 p.m.–1:45 p.m.: The Council will receive a report from the Personnel Committee, approve/disapprove the staff retirement health insurance plan, consider other committee

recommendations, and take action as appropriate.

1:45 p.m.–3 p.m.: The Council will receive status reports from NOAA Fisheries Southeast Regional Office and the Southeast Fisheries Science Center. The Council will review and develop recommendations on Experimental Fishing Permits as necessary; review agency and liaison reports; and discuss other business and upcoming meetings.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12492 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Northeast Multispecies Amendment 16N

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 21, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Aja Szumylo, (978) 281–9195 or *Aja.szumylo@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a current information collection. Under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), the Secretary of Commerce has the responsibility for the conservation and management of marine fishery resources. We, National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS), and the Regional Fishery Management Councils are delegated the majority of this responsibility. The New England Fishery Management Council (Council) develops management plans for fishery resources in New England.

In 2010, we implemented a new suite of regulations for the Northeast (NE) multispecies fishery through Amendment 16 to the Multispecies Fishery Management Plan (Amendment 16). This action updated status determination criteria for all regulated NE multispecies or ocean pout stocks; adopted rebuilding programs for NE multispecies stocks newly classified as being overfished and subject to overfishing; revised management measures, including significant revisions to the sector management measures, necessary to end overfishing, rebuild overfished regulated NE multispecies and ocean pout stocks, and mitigate the adverse economic impacts of increased effort controls. It also implemented new requirements under Amendment 16 for establishing acceptable biological catch (ABC), annual catch limits (ACLs), and accountability measures (AMs) for each stock managed under the FMP, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Revisions

This revision incorporates a number of recent changes related to regulatory actions. Framework Adjustment 48 to the FMP (78 FR 26118; May 3, 2013) proposed to exempt sector vessels targeting monkfish from the additional at-sea monitoring coverage necessary to monitor groundfish catch. This measure was intended to allocate limited at-sea monitoring resources to monitor those trips that catch the most groundfish. To implement this measure, NMFS added a question to both the pre-trip notification and Northeast Fisheries Observer Program notification to allow fishermen to indicate what fishery they intend to participate in. This change allowed NMFS to identify trips that may qualify for this exemption, in order to deploy observers and at-sea monitors appropriately to achieve the coverage levels required by the FMP. Framework 48 also eliminated the dockside monitoring program established under Amendment 16 because NMFS determined dealer reporting combined with dockside intercepts by enforcement personnel are sufficient to ensure reliable landings data. Elimination of the dockside monitoring program was not included in the applicable non-substantive change request and thus this change will be included in the revision/extension.

As part of Framework Adjustment 53 to the FMP (80 FR 25110; May 1, 2015), NMFS implemented a requirement that vessels that declare trips into the Gulf of Maine Broad Stock Area and any other broad stock area (*i.e.,* Georges Bank or Southern New England) on the same trip submit a daily catch report via vessel monitoring system (VMS). We determined the daily VMS trip reports were necessary to ensure accurate apportionment of catch and help enforcement efforts. This requirement was approved temporarily through emergency PRA approval. We are proposing to permanently adjust this information collection to include this reporting requirement.

II. Method of Collection

Respondents must submit either paper forms via postal service, or electronic forms submitted via the internet or a vessels' vessel monitoring system (VMS).

III. Data

OMB Control Number: 0648–0605.

Form Number: None.

Type of Review: Regular submission (revision and extension of a current information collection).

Affected Public: Business or for-profit organizations.

Estimated Number of Respondents: 1,482.

Estimated Time per Response: Sector operations plan and associated National Environmental Policy Act (NEPA) analysis, 640 hr/response; Monitoring service provider initial application, 10 hr/response; Monitoring service provider response to application disapproval, 10 hr/response; Data entry for sector discard monitoring system, 3 min/response; Sector weekly catch report, 4 hr/response; Sector annual report, 12 hr/response; Notification of expulsion from a sector, 30 min/response; Request to transfer Annual Catch Entitlement (ACE), 5 min/response; VMS certification form, 10 min/response; VMS confirmation call, 5 min/response; VMS area and DAS declaration, 5 min/response; VMS trip-level catch report; VMS daily catch reports when fishing in multiple broad stock areas, 15 min/response; Daily VMS catch reports when fishing in the U.S./Canada Management Area and CA II SAPs, 15 min/response; Daily VMS catch reports when fishing in the CA I Hook Gear Haddock SAP, 15 min/response; Daily VMS catch reports when fishing in the Regular B DAS Program, 15 min/response; Pre-trip hail report, 2 min/response; Trip-end hail report, 15 min/response; Forward trip start/end hails to NMFS, 2 min/response; ASM Pre-Trip Notification, 2 min/response; Vessel notification of selection for at-sea monitoring coverage, 5 min/response; at-sea monitor deployment report, 10 min/response; at-sea monitoring service provider catch report to NMFS upon request, 5 min/response; at-sea monitor report of harassment and other issues, 30 min/response; at-sea monitoring service provider contract upon request, 30 min/response; at-sea monitoring service provider information materials upon request, 30 min/response; OLE debriefing of at-sea monitors, 2 hr/response; ASM Database and Data Entry Requirements, 3 min/response; Observer program pre-trip notification, 2 min/response; DAS Transfer Program, 5 min/response; Expedited Submission of Proposed SAPs, 20 hr/response; NAFO Reporting Requirements, 10 min/response.

Estimated Total Annual Burden Hours: 81,126.

Estimated Total Annual Cost to Public: $ 4,298,000 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 19, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–12461 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD727

Takes of Marine Mammals Incidental to Specified Activities; Low-Energy Marine Geophysical Survey in the Southwest Pacific Ocean, East of New Zealand, May to June 2015

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

ACTION: Notice; issuance of an Incidental Harassment Authorization (IHA).

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA), notification is hereby given that NMFS has issued an IHA to the Scripps Institution of Oceanography (SIO), on behalf of SIO and the U.S. National Science Foundation (NSF), to take marine mammals, by Level B harassment, incidental to conducting a low-energy marine geophysical (seismic) survey in the Southwest Pacific Ocean, East of New Zealand, May to June 2015.

DATES: Effective May 18, 2015 to July 30, 2015.

ADDRESSES: A copy of the IHA and the application are available by writing to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910 or by telephone to the contacts listed below (see **FOR FURTHER INFORMATION CONTACT**).

An electronic copy of the IHA application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed here (see **FOR FURTHER INFORMATION CONTACT**) or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/*. Documents cited in this notice, including the IHA application, may also be viewed by appointment, during regular business hours, at the aforementioned address.

An *Environmental Analysis of a Low-Energy Marine Geophysical Survey by the R/V Roger Revelle in the Southwest Pacific Ocean, East of New Zealand, May to June 2015* (Environmental Analysis) in accordance with the National Environmental Policy Act (NEPA) and the regulations published by the Council of Environmental Quality (CEQ), has been prepared on behalf of NSF and SIO. It is posted at the foregoing site. NMFS has independently evaluated the Environmental Analysis and has prepared a separate NEPA analysis titled *Environmental Assessment on the Issuance of an Incidental Harassment Authorization to the Scripps Institution of Oceanography to Take Marine Mammals by Harassment Incidental to a Low-Energy Marine Geophysical Survey in the Southwest Pacific Ocean, East of New Zealand, May to June 2015*. NMFS also issued a Biological Opinion under section 7 of the Endangered Species Act (ESA) to evaluate the effects of the low-energy seismic survey and IHA on marine species listed as threatened or endangered. The NMFS Biological Opinion is available online at: *http://www.nmfs.noaa.gov/pr/consultations/opinion.htm*.

FOR FURTHER INFORMATION CONTACT: Howard Goldstein or Jolie Harrison, Office of Protected Resources, NMFS, 301–427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA, (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (Secretary) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by United States citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds

that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) of the MMPA establishes a 45-day time limit for NMFS's review of an application, followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the public comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On December 15, 2014, NMFS received an application from SIO, on behalf of SIO and NSF, requesting that NMFS issue an IHA for the take, by Level B harassment only, of small numbers of marine mammals incidental to conducting a low-energy marine seismic survey as well as heat-flow measurements in the Southwest Pacific Ocean, at three sites off the east coast of New Zealand, during May to June 2015. The sediment coring component of the planned project, which was described in the IHA application and NSF and SIO's Environmental Analysis, was not funded and no piston or gravity coring for seafloor samples would be conducted during the low-energy seismic survey. The low-energy seismic survey will take place within the Exclusive Economic Zone (EEZ) and outside the territorial waters of New Zealand. On behalf of SIO, the U.S. Department of State is seeking authorization from New Zealand for clearance to work within the EEZ.

The research will be conducted by Oregon State University and funded by the U.S. National Science Foundation (NSF). SIO plan to use one source vessel, the R/V *Roger Revelle* (*Revelle*), and a seismic airgun array and hydrophone streamer to collect seismic data in the Southwest Pacific Ocean, East of New Zealand. SIO plans to use conventional low-energy, seismic methodology to perform marine-based studies in the Southwest Pacific Ocean (see Figure 1). The studies will involve a low-energy seismic survey and heat-flow measurements from the seafloor to meet a number of research goals. In addition to the proposed operations of the seismic airgun array and hydrophone streamer, SIO intends to operate two additional acoustical data acquisition systems—a multi-beam echosounder and sub-bottom profiler continuously throughout the low-energy seismic survey. NMFS published a notice making preliminary determinations and proposing to issue an IHA on March 20, 2015 (80 FR 15060). The notice initiated a 30-day public comment period.

Acoustic stimuli (*i.e.,* increased underwater sound) generated during the operation of the seismic airgun array have the potential to cause behavioral disturbance for marine mammals in the proposed study area. This is the principal means of marine mammal taking associated with these activities, and SIO requested an authorization to take 35 species of marine mammals by Level B harassment. Take is not expected to result from the use of the multi-beam echosounder and sub-bottom profiler, as the brief exposure of marine mammals to one pulse, or small numbers of signals, to be generated by these instruments in this particular case as well as their characteristics (*e.g.,* narrow-shaped, downward-directed beam emitted from the bottom of the ship) is not likely to result in the harassment of marine mammals. Also, NMFS does not expect take to result from collision with the source vessel because it is a single vessel moving at a relatively slow, constant cruise speed of 5 knots ([kts]; 9.3 kilometers per hour [km/hr]; 5.8 miles per hour [mph]) during seismic acquisition within the study area, for a relatively short period of time (approximately 27 operational days). It is likely that any marine mammal will be able to avoid the vessel.

Description of the Specified Activity

Overview

SIO plans to use one source vessel, the *Revelle,* a two GI airgun array and one hydrophone streamer to conduct the conventional seismic survey as part of the NSF-funded research project *Collaborative Research: The Thermal Regime of the Hikurangi Subduction Zone and Shallow Slow Slip Events, New Zealand*. In addition to the airguns, SIO intends to conduct a bathymetric survey and heat-flow measurements at three sites off the southwest coast of North Island and northeast coast of South Island, New Zealand from the *Revelle* during the low-energy seismic survey.

Dates and Duration

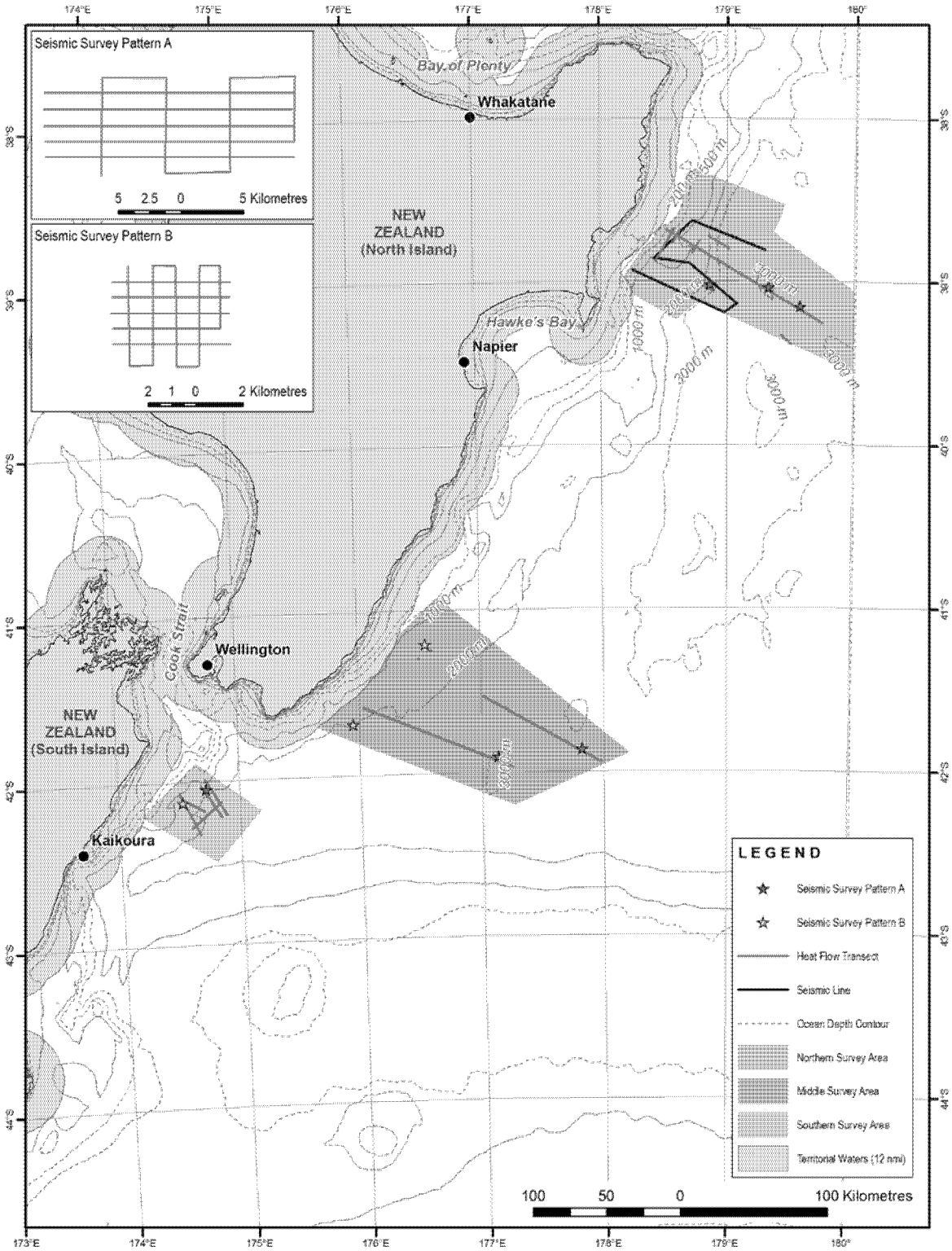
The *Revelle* is expected to depart from Auckland, New Zealand on approximately May 18, 2015 and arrive at Napier, New Zealand on approximately June 18, 2015. Airgun operations will take approximately 135 hours in total, and the remainder of the time will be spent in transit and collecting heat-flow measurements and cores. The total distance the *Revelle* will travel in the region to conduct the proposed research activities (*i.e.,* seismic survey, bathymetric survey, and transit to heat-flow measurement locations) represents approximately 2,000 km (1,079.9 nmi). Some minor deviation from this schedule is possible, depending on logistics and weather (*e.g.,* the cruise may depart earlier or be extended due to poor weather; or there could be additional days of airgun operations if collected data are deemed to be of substandard quality).

Specified Geographic Region

The planned project and survey sites are located off the southeast coast of North Island and northeast coast of the South Island, New Zealand in selected regions of the Southwest Pacific Ocean. The planned survey sites are located between approximately 38.5 to 42.5° South and approximately 174 to 180° East off the east coast of New Zealand, in the EEZ of New Zealand and outside of territorial waters (see Figure 1). Water depths in the study area are between approximately 200 to 3,000 m (656.2 to 9,842.5 ft). The proposed low-energy seismic survey will be collected in a total of nine grids of intersecting lines of two sizes (see Figure 1) at exact locations to be determined in the field during May to June 2015. Figure 1 also illustrates the general bathymetry of the proposed study area. The proposed low-energy seismic survey would be within an area of approximately 1,154 km^2

(336.5 nmi²). This estimate is based on the maximum number of kilometers for the low-energy seismic survey (1,250 km) multiplied by the area ensonified around the planned tracklines (2 x 0.6 km in intermediate water depths and 2 x 0.4 km in deep water depths). The ensonified area is based on the predicted rms radii (m) based on modeling and empirical measurements (assuming 100% use of the two 45 in³ GI airguns in 100 to 1,000 m or greater than 1,000 m water depths), which was calculated to be 600 m (1,968.5 ft) or 400 m (1,312.3 ft).

Figure 1. Locations of the planned low-energy seismic survey and heat-flow probe measurement sites east of New Zealand, May to June 2015.



Detailed Description of the Specified Activity

In support of a research project put forward by Oregon State University (OSU) and to be funded by NSF, SIO plans to conduct a low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand, from May to June 2015. In addition to the low-energy seismic survey, scientific research activities will include conducting a bathymetric profile survey of the seafloor using transducer-based instruments such as a multi-beam echosounder and sub-bottom profiler; and heat-flow measurements from the seafloor using various methods and equipment at three sites off the southeast coast of North Island and northeast coast of South Island, New Zealand. Water depths in the survey area are approximately 200 to 3,000 meters (m) (656.2 to 9,842.5 feet [ft]). The low-energy seismic survey is scheduled to occur for a total of approximately 135 hours over the course of the entire cruise, which would be for approximately 27 operational days in May to June 2015. The planned low-energy seismic survey will be conducted during the day (from nautical twilight-dawn to nautical twilight-dusk) and night, and for up to approximately 72 hours of continuous operations at a time. The operation hours and survey length will include equipment testing, ramp-up, line changes, and repeat coverage. Some minor deviation from these dates will be possible, depending on logistics and weather. The Principal Investigators are Dr. R. N. Harris and Dr. A. Trehu of OSU.

The planned surveys will allow the development of a process-based understanding of the thermal structure of the Hikurangi subduction zone, and the expansion of this understanding by using regional observations of gas hydrate-related bottom simulating reflections. To achieve the planned project's goals, the Principal Investigators plan to collect low-energy, high-resolution multi-channel system profiles, heat-flow measurements, and sediment cores along transects seaward and landward of the Hikurangi deformation front. Heat-flow measurements will be made in well-characterized sites, increasing the number of publicly available heat-flow and thermal conductivity measurements from this continental margin by two orders of magnitude. Seismic survey data will be used to produce sediment structural maps and seismic velocities to achieve the project objectives. Data from sediment cores will detect and estimate the nature and sources of fluid flow through high permeability pathways in the overriding plate and along the subduction thrust; characterize the hydrocarbon and gas hydrate system to assist with estimates of heat flow from Bottom Simulating Reflectors (BSR), their role in slope stability, and fluid source; and elucidate the response of microbes involved in carbon cycling to changes in methane flux.

The low-energy seismic survey will be collected in a total of 9 grids of intersecting lines of two sizes (see Figure 1) at exact locations to be determined in the field. The water depths will be very similar to those at the nominal survey locations shown in Figure 1. The northern and middle sites off the North Island will be the primary study areas, and the southern site off the South Island will be a contingency area that will only be surveyed if time permits. SIO's calculations assume that 7 grids at the primary areas and two grids at the southern site will be surveyed. The total trackline distance of the low-energy seismic survey will be approximately 1,250 km (including the two South Island contingency sites), almost all in water depths greater than 1,000 m.

The procedures to be used for the survey will be similar to those used during previous low-energy seismic surveys by SIO and NSF and will use conventional seismic methodology. The planned low-energy seismic survey would involve one source vessel, the *Revelle.* SIO will deploy a two Sercel Generator Injector (GI) airgun array (each with a discharge volume of 45 in^3 [290.3 cm^3], in one string, with a total volume of 90 in^3 [580.6 cm^3]) as an energy source, at a tow depth of up to 2 m (6.6 ft) below the surface (more information on the airguns can be found in SIO's IHA application). The airguns in the array will be spaced approximately 8 m (26.2 ft) apart and 21 m (68.9 ft) astern of the vessel. The receiving system will consist of one 600 m (1,968.5 ft) long, 48-channel hydrophone streamer(s) towed behind the vessel (see Table 1). Data acquisition is planned along a series of predetermined lines, almost all (approximately 95%) of which would be in water depths greater than 1,000 m. As the GI airguns are towed along the survey lines, the hydrophone streamer will receive the returning acoustic signals and transfer the data to the onboard processing system. The seismic surveys will be conducted while the heat-flow probe is being recharged. All planned seismic data acquisition activities will be conducted by technicians provided by SIO, with onboard assistance by the scientists who have proposed the study. The vessel will be self-contained, and the crew will live aboard the vessel for the entire cruise.

The planned low-energy seismic survey (including equipment testing, start-up, line changes, repeat coverage of any areas, and equipment recovery) will consist of approximately 1,250 kilometers (km) (674.9 nautical miles [nmi]) of transect lines (including turns) in the study area in the Southwest Pacific Ocean (see Figures 1 of the IHA application). Approximately 95% of the low-energy seismic survey will occur in water depths greater than 1,000 m. In addition to the operation of the airgun array and heat-flow measurements, a multi-beam echosounder and a sub-bottom profiler will also likely be operated from the *Revelle* continuously throughout the cruise. There will be additional airgun operations associated with equipment testing, ramp-up, and possible line changes or repeat coverage of any areas where initial data quality is sub-standard. In SIO's estimated take calculations, 25% has been added for those additional operations.

TABLE 1—PLANNED LOW-ENERGY SEISMIC SURVEY ACTIVITIES IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND

Survey length (km)	Total duration (hr) [1]	Airgun array total volume	Time between airgun shots (distance)	Streamer length (m)
1,250 (674.9 nmi)	~135	2 x 45 = 90 in^3 (2 x 1474.8 cm^3)	6 to 10 seconds (18.5 to 31 m or 60.7 to 101.7 ft).	600 (1,968.5 ft)

[1] Airgun operations are planned for no more than approximately 72 continuous hours at a time.

NMFS outlined the purpose of the program in a previous notice of the proposed IHA (80 FR 15060, March 20, 2015). The activities to be conducted have not changed between the proposed IHA notice and this final notice announcing the issuance of the IHA. For a more detailed description of the authorized action, including vessel and acoustic source specifications, metrics, characteristics of airgun pulses, predicted sound levels of airguns, bathymetric survey, heat-flow measurements, etc., we refer the reader to the notice of the proposed IHA (80 FR 15060, March 20, 2015), the IHA application, EA, and associated documents referenced above this section.

Comments and Responses

A notice of preliminary determinations and proposed IHA for SIO's low-energy seismic survey was published in the **Federal Register** on March 20, 2015 (80 FR 15060). During the 30-day public comment period, NMFS received comments from one private citizen, Dr. Elisabeth Slooten of Otago University, and the Marine Mammal Commission (Commission). The comments are posted online at: *http://www.nmfs.noaa.gov/pr/permits/incidental/*. Following are the substantive comments and NMFS's responses:

Comment 1: The Commission recommends that NMFS adjust density estimates used to estimate the numbers of potential takes by incorporating some measure of uncertainty when available density data originate from other geographical areas and temporal scales and that NMFS formulate a policy or other guidance setting forth a consistent approach for how applicants should incorporate uncertainty in density estimates.

Response: The availability of representative density information for marine mammal species varies widely across space and time. Depending on survey locations and modeling efforts, it may be necessary to consult estimates that are from a different area or season, that are at a non-ideal spatial scale, or that are several years out of date. We continue to evaluate available density information and are continuing progress on guidance that would outline a consistent general approach for addressing uncertainty in specific situations where certain types of data are or are not available.

Comment 2: The Commission recommends that NMFS follow a consistent approach in assessing the potential for taking by Level B harassment from exposure to specific types of sound sources (*e.g.,* echosounders, sub-bottom profilers, side-scan sonar, and fish-finding sonar) by all applicants who propose to use them. SIO will be using such sources during its activities off New Zealand, including when the airgun array will not be in use. The Commission understands that NMFS plans to develop clearer policies and guidance to address these concerns and would welcome to opportunity to work with NMFS as it develops these broadly applicable policies.

Response: NMFS acknowledges the Commission's recommendation and we continue to work on a consistent approach for addressing potential impacts from active acoustic sources. For this low-energy seismic survey, NMFS assessed the potential for multi-beam echosounder and sub-bottom profiler operations to impact marine mammals with the concurrent operation of the airgun array. We assume that, during simultaneous operations of the airgun array and the other active acoustic sources, a marine mammal close enough to be affected by the other active acoustic sources would already be affected by the airguns. Take is not expected to result from the use of the multi-beam echosounder and sub-bottom profiler, as the brief exposure of marine mammals to one pulse, or small number of signals, to be generated by these instruments in this particular case as well as their characteristics (*e.g.,* narrow-shaped, downward-directed beam emitted from the bottom of the ship) is less likely to result in the harassment of marine mammals. Accordingly, NMFS has not authorized take from these other sound sources.

Comment 3: The Commission is concerned that the Lamont-Doherty Earth Observatory of Columbia University's (L–DEO) acoustic modeling used for this low-energy seismic survey is not based on the best available science and does not support its continued use. Therefore, the Commission recommends that NMFS require SIO to have L–DEO re-estimate the proposed exclusion and buffer zones and associated takes of marine mammals using site-specific environmental (including sound speed profiles, bathymetry, and sediment characteristics at a minimum) and operational (including number/type of airguns, tow depth) parameters for the proposed IHA. The reflective/refractive arrivals are the very measurements that ultimately determine underwater sound propagation and should be accounted for in site-specific modeling. Either empirical measurements from the particular survey site or a model that accounts for the conditions in the proposed survey area should be used to estimate exclusion and buffer zones because L–DEO failed to verify the applicability of its model to conditions outside of the Gulf of Mexico. The Commission recommends that NMFS impose the same requirements for all future IHAs submitted by SIO, NSF, Antarctic Support Contract (ASC), L–DEO, USGS, or any other relevant entity. The Commission also continues to believe that SIO and related entities should be held to the same standard as other action proponents (*i.e.,* U.S. Navy, Air Force, Bureau of Ocean Energy Management, and the oil and gas industry).

Response: NMFS acknowledges the Commission's concerns about L–DEO's current acoustic modeling approach for estimating buffer and exclusion zones and also acknowledge that L–DEO did not incorporate site-specific sound speed profiles, bathymetry, and sediment characteristics of the action area in the current approach to estimates those buffer and exclusion zones for this low-energy seismic survey.

In 2015, L–DEO explored solutions to this issue by conducting a retrospective sound power analysis of one of the lines acquired during L–DEO's truncated seismic survey offshore New Jersey in 2014 (Crone, 2015). NMFS presented this information in the notice of the proposed IHA (80 FR 13961, March 17, 2015) for L–DEO's seismic survey. Briefly, Crone's (2015) preliminary analysis, specific to the survey site offshore New Jersey, confirmed that in-situ measurements and estimates of the 160- and 180 dB (rms) isopleths collected by the R/V *Marcus G. Langseth*'s hydrophone streamer in shallow water were smaller that the predicted buffer and exclusion zones proposed for use in the 2015 seismic survey.

SIO's IHA application and NSF and SIO's Environmental Analysis describe the approach to establishing buffer and exclusion zones used for mitigation. In summary, L–DEO acquired field measurements for several array configurations at shallow- and deep-water depths during acoustic verification studies conducted in the northern Gulf of Mexico in 2003 (Tolstoy *et al.,* 2004) and in 2007 and 2008 (Tolstoy *et al.,* 2009). Based on the empirical data from those studies, L–DEO developed a sound propagation modeling approach that conservatively predicts received sound levels as a function of distance from a particular airgun array configuration in deep water. For this low-energy seismic

survey, L–DEO developed the intermediate- and deep-water buffer and exclusion zones for the airgun array based on the empirically-derived measurements from the Gulf of Mexico calibration survey. Following is a summary of two additional analyses of in-situ data that support L–DEO's use of the modeled exclusion zones in this particular case.

In 2010, L–DEO assessed the accuracy of their modeling approach by comparing the sound levels of the field measurements in the Gulf of Mexico study to their model predictions (Diebold *et al.,* 2010). They reported that the observed sound levels from the field measurements fell almost entirely within the predicted mitigation radii curve for deep water (greater than 1,000 m) (Diebold *et al.,* 2010).

In 2012, L–DEO used a similar process to develop mitigation radii (*i.e.,* buffer and exclusion zones) for a shallow-water seismic survey in the northeast Pacific Ocean offshore Washington in 2012. L–DEO conducted the shallow-water seismic survey using an airgun configuration that was approximately 98 percent larger than the total discharge volume planned for this intermediate and deep water survey *(i.e.,* 6,600 cubic inches [in^3] compared to 90 in^3) and recorded the received sound levels on the shelf and slope off Washington using the *Langseth's* 8-km hydrophone streamer. Crone *et al.* (2014) analyzed those received sound levels from the 2012 seismic survey and reported that the actual distances for the buffer and exclusion zones were two to three times smaller than what L–DEO's modeling approach predicted. While the results confirm bathymetry's role in sound propagation, Crone *et al.* (2014) were able to confirm that the empirical measurements from the Gulf of Mexico calibration survey (the same measurements used to inform L–DEO's modeling approach for this survey in shallow water) overestimated the size of the buffer and exclusion zones for the shallow-water 2012 seismic survey off Washington and were thus precautionary, in that particular case.

In summary, at present, L–DEO cannot adjust their modeling methodology to add the environmental and site-specific parameters as requested by the Commission. NMFS will continue to work with the NSF to address this issue of incorporating site-specific information to further inform the analysis and development of mitigation measures in oceanic and coastal areas for future seismic surveys with L–DEO, SIO, and NSF. NMFS will continue to work with L–DEO, SIO, NSF, and the Commission on continuing to verify the accuracy of their modeling approach. However, L–DEO's current modeling approach represents the best available information to reach our determinations for the IHA. As described earlier, the comparisons of L–DEO model results and the field data collected in the Gulf of Mexico, offshore Washington, and offshore New Jersey illustrate a degree of conservativeness built into L–DEO's model for deep water, which NMFS expects to offset some of the limitations of the model to capture the variability resulting from site-specific factors.

L–DEO has conveyed to NMFS that additional modeling efforts to refine the process and conduct comparative analysis may be possible with the availability of research fund and other resources. Obtaining research funds is typically through a competitive process, including those submitted to federal agencies. The use of models for calculating buffer and exclusion zone radii and for developing take estimates is not a requirement of the MMPA Incidental Take Authorization process. Furthermore, NMFS does not provide specific guidance on model parameters nor prescribes a specific model for applicants as part of the MMPA Incidental Take Authorization process. There is a level of variability not only with parameters in the models, but also the uncertainty associated with data used in models, and therefore the quality of the model results submitted by applicants. NMFS, however, considers this variability when evaluating applications. Applicants use models as a tool to evaluate potential impacts, estimate the number of and type of takes of marine mammals, and for designing mitigation. NMFS takes into consideration the model used and its results in determining the potential impacts to marine mammals; however, it is just one component of our analysis during the MMPA consultation process as we also take into consideration other factors associated with the proposed action, (*e.g.,* geographic location, duration of activities, context, intensity, etc.).

There are many different modeling products and services commercially available that applicants could potentially use in developing their take estimates and analyses for MMPA Incidental Take Authorizations. These different models range widely in cost, complexity, and the number of specific factors that one can consider in any particular modeling run. NMFS does not believe that it is appropriate to prescribe the use of any particular modeling package. Rather, NMFS evaluates each applicant's approach independently in the context of their activity. In cases where an applicant uses a simpler model and there is concern that a model might not capture the variability across a parameter(s) that is not represented in the model, conservative choices are often made at certain decision points in the model to help ensure that modeled estimates are buffered in a manner that would not result in the agency underestimating takes or effects. In this case, results have shown that L–DEO's model reliably and conservatively estimates mitigation radii in intermediate and deep water. First, the observed sound levels from the field measurements fell almost entirely below L–DEO's estimated mitigation radii for deep water (Diebold *et al.,* 2010). These conservative mitigation radii are the foundation for SIO's intermediate and deep water radii used in this low-energy seismic survey. Based on Crone *et al.'s* (2014) findings, NMFS finds that L–DEO reasonably estimates sound exposures for this low-energy seismic survey.

Comment 4: The Commission states that NMFS indicated that it discounted 18 marine mammal species with ranges that may potentially occur in the Southwest Pacific Ocean and/or are in the stranding record—NMFS based the presumption on Baker *et al.* (2010) and their categorizing those species as ''vagrants.'' However, many other action proponents include certain species (including Arnoux's beaked whales, pygmy beaked whales, and Risso's dolphins) in their marine mammal impact assessments for seismic activities off New Zealand. Those species also are present in the New Zealand Department of Conservation's sighting database for marine mammals present (either alive or stranded) in New Zealand's waters. Because Arnoux's and pygmy beaked whales are not thoroughly studied and their habitat ranges are poorly understood, the Commission believes that it would have been prudent for NMFS to include them in the proposed IHA since they have been observed dead-stranded in New Zealand. Similarly, the range of Risso's dolphins does overlap with New Zealand waters based on information on various government Web sites, including NMFS's Web site. Further, Risso's dolphins have been observed in New Zealand both alive and dead. The Commission believes the potential to take those marine mammal species exists and recommends that NMFS include Arnoux's beaked whales, pygmy beaked whales, and Risso's dolphins in its IHA and authorize the associated takes.

Response: In Baker *et al.* (2010), the term ''vagrant'' is defined as ''taxa that

are found unexpectedly in New Zealand and whose presence in this region is naturally transitory, or migratory species with fewer than 15 individuals known or presumed to visit per year.'' Based on this, NMFS agrees with the Commission's recommendation that the potential to encounter Arnoux's and pygmy beaked whales and Risso's dolphins exists and has included authorized takes, which are based on encountering an average group size of animals, in the IHA issued to SIO and NSF. Also, as required in the IHA, if any marine mammal species are encountered during airgun operations that are not authorized for take and are likely to be exposed to sound pressure levels greater than or equal to 160 dB re 1 μPa (rms) for airgun operations, then SIO must alter speed or course or shut-down the airguns to prevent take.

Comment 4: The Commission believes that g(0) and f(0) values should be based on the ability of PSOs to detect marine mammals rather than on hypothetically optimal estimates derived from scientific surveys (*e.g.,* from NMFS's shipboard abundance surveys). The Commission also understands that L–DEO (and relevant entities) has been collecting for many years sightings data when the airguns are active and inactive. Those data could be pooled amongst similar survey types (*e.g.,* based on geographical location, array configuration, airgun activity status, vessel-specific observational parameters) to determine rudimentary g(0) and f(0) values—an analysis that has been discussed with NMFS, L–DEO and relevant entities in the past. The Commission acknowledges that those values may not be as accurate as using a well-planned, randomized sampling design typically used during marine mammal scientific surveys, but believes adjusting by those rudimentary values would be preferable to assuming that only those animals detected during the survey equated to the total numbers taken, which is clearly an underestimate of reality.

The Commission recommends that NMFS consult with SIO and other relevant entities (*e.g.,* NSF, ASC, L–DEO, and USGS) to develop, validate, and implement a monitoring program that provides a scientifically sound, reasonably accurate assessment of the types of marine mammal takes and reliable estimates of the numbers of marine mammals taken by incorporating applicable g(0) and f(0) values derived from PSO data collected during seismic surveys. Although the Commission has made this recommendation in numerous previous letters, the Commission believes that NMFS may have misinterpreted it. NMFS recently stated that it does not generally believe it is appropriate to require NSF to collect information in the field to support the development of survey-specific correction factors (80 FR 4892, January 29, 2015). The Commission never suggested that correction factors be developed for every seismic survey. Rather, it is important for NSF, L–DEO, and other relevant entities to continue to collect appropriate sightings data in the field to be pooled to determine g(0) and f(0) values relevant to the various seismic survey types.

Response: NMFS's implementing regulations require that applicants include monitoring that will result in ''an increased knowledge of the species, the level of taking or impacts on populations of marine mammals that are expected to be present while conducting activities . . .'' This could be qualitative or relative in nature, or it could be more directly quantitative. Scientists use g(0) and f(0) values in systematic marine mammal surveys to account for the undetected animals indicated above, however, these values are not simply established and the g(0) value varies across every observer based on their sighting acumen. While NMFS does not generally believe that post-activity take estimates using f(0) and g(0) are required to meet the monitoring requirement of the MMPA, in the context of NSF and SIO's monitoring plan, NMFS agrees that developing and incorporating a way to better interpret the results of their monitoring (perhaps a simplified or generalized version of g(0) and f(0)) is desirable. NMFS is continuing to examine this issue with NSF to develop ways to improve their post-survey take estimates. NMFS will continue to consult with the Commission and NMFS scientists prior to finalizing any future recommendations.

NMFS notes that current monitoring measures for past and current IHAs for research seismic surveys require the collection of visual observation data by PSOs prior to, during, and after airgun operations. This data collection may contribute to baseline data on marine mammals (presence/absence) and provide some generalized support for estimated take numbers (as well as providing data regarding behavioral responses to seismic operation that are observable at the surface). However, it is unlikely that the information gathered from these cruises alone would result in any statistically robust conclusions for any particular species because of the small number of animals typically observed.

Comment 5: Dr. Slooten states that a dedicated large-scale marine mammal survey in the action area is required as no current regional population estimates exist for New Zealand waters (previous surveys have only focused on inshore waters). The estimated potential number of marine mammals affected and the population-level impacts should be assessed using data and analysis from a dedicated marine mammal survey before the start of the low-energy seismic survey. Depending on the result of the dedicated marine mammal survey, NSF and SIO's Environmental Analysis Alternatives 1 (Alternative Survey Timing) or 2 (No Action) may be the appropriate decision and the northern and/or southern survey areas should be removed from the proposed action.

Response: While regional population estimates are not available for waters offshore of New Zealand, in this case, NMFS does not agree that dedicated marine mammal assessment surveys are needed prior to issuing an IHA. When information is unavailable on a local marine mammal population size, NMFS uses either stock or species information on abundance. Also, while information may be lacking for many species of cetaceans or pinnipeds, information on some of the locally-found species is found in SIO's IHA application and Environmental Analysis, see those documents for more information. NSF and SIO are not planning on conducting a large-scale dedicated marine mammal survey in New Zealand prior to the planned low-energy seismic survey and NMFS has not made this a requirement in the IHA.

Comment 6: Dr. Slooten and the Commission state that in the absence of scientifically robust marine mammal data, SIO and NMFS have used anecdotal information from various sources (*i.e.,* including marine mammals survey data from California, Oregon, and Washington [California Current], Eastern Tropical Pacific Ocean, and Southern Ocean) to describe the occurrence of marine mammals and potential takes that are not applicable to New Zealand waters. In this instance, various extrapolations and adjustments are based on numerous assumptions in the absence of applicable density data off New Zealand.

Response: No marine mammal density data are available for the waters east of New Zealand. The waters of New Zealand are likely to have a high diversity of marine mammal species and the impacts on marine mammals should be assessed on the (worldwide or region) population or stock unit level whenever possible. SIO's IHA

application provides information on abundance in the waters of New Zealand (when available), larger water bodies (such as the Pacific Ocean or Southern Ocean), and off of California, Oregon, and Washington (if data were unavailable). NMFS believes that these data are the best scientific information available for estimating impacts on affected marine mammal species and stocks. This is consistent with Congress' recognition that information on marine mammal stock abundance may not always be satisfactory. When information is lacking to define a particular population or stock of marine mammals then impacts are to be assessed with respect to the species as a whole (54 FR 40338, September 29, 1989).

Comment 7: Dr. Slooten states that important information is lacking on the potential for further population fragmentation of Maui's dolphins from SIO and NSF's low-energy seismic survey.

Response: NMFS has reviewed Hamner *et al.* (2012, 2013), cited in the comment. The population of Maui's dolphin is located along approximately 300 km (162 nmi) of the west coast of the North Island of New Zealand, and does not overlap with the planned action area for SIO and NSF's low-energy seismic survey occurring off the east coast of New Zealand. Also, Hector's dolphins (of which Maui's dolphins are a sub-species) are highly coastal and the low-energy seismic survey will occur at least approximately 22.2 km (12 nmi) offshore the east coast of New Zealand. This short-duration low-energy seismic survey is scheduled to occur for a total of approximately 135 hours (approximately 72 hours of continuous operations at a time) over the course of the entire cruise, which would be for approximately 27 operational days in May to June 2015. NMFS anticipates and has authorized takes by Level B (behavioral) harassment of marine mammals to noise exposure from the low-energy seismic survey, which may include temporary avoidance of habitat. No fragmentation of Maui's or Hector's dolphin populations is anticipated.

Comment 8: Dr. Elisabeth Slooten states that SIO did not make contact with marine mammal scientists (*e.g.,* Otago University Marine Mammal Research Group) earlier, in order to obtain sighting data, or reach out about the proposed low-energy seismic survey at the Society of Marine Mammalogy 20th Biennial Conference held in Dunedin, New Zealand during December 2013. Also, many of the Society of Marine Mammalogy's members have active research collaborations with marine mammal scientists in New Zealand and Australia.

Response: SIO and NSF consulted with NMFS's Permits and Conservation Division regarding the IHA and NMFS's Endangered Species Act Interagency Cooperation Division regarding a Biological Opinion under section 7 of the ESA for the low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand. NMFS consulted and corresponded with New Zealand's Department of Conservation and Dr. Elisabeth Slooten beginning in January 2015. LGL Limited, Environmental Research Associates, on behalf of SIO and NSF, also contacted New Zealand's Department of Conservation and requested the New Zealand cetacean sightings database as well as additional information that might be pertinent to the Environmental Analysis (such as marine mammal densities and habitat modeling). NMFS is not aware if SIO contacted any researchers at the Society of Marine Mammalogy 20th Biennial Conference regarding the low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand. NMFS has considered the best available information to support the findings for SIO's low-energy seismic survey.

Comment 9: Dr. Slooten states that the use of alternative technologies (Alternative E2 in NSF and SIO's Environmental Analysis) should be further considered and discussed (*e.g.,* commercial viability, feasibility, purpose, financial cost, environmental impacts, etc.) before the start of the low-energy seismic survey.

Response: NMFS issued its IHA for taking marine mammals incidental to the specified activity as described in SIO and NSF's IHA application. As discussed in the NSF/USGS PEIS (Section 2.6), alternative technologies to airguns were considered but eliminated from further analysis as those technologies were not commercially viable. NSF and SIO continue to closely monitor the development and progress of these types of systems; however, at this point and time, these systems are still not commercially available. Geo-Kinetics as a potentially viable option for marine vibroseis does not have a viable towable array and its current testing is limited to transition zone settings. Other possible vibroseis developments lack even prototypes to test. Similarly, engineering enhancements to airguns to reduce high frequencies are currently being developed by the oil, gas, and energy industry, however, at present, these airguns are still not commercially available. NSF, SIO, and L–DEO have maintained contact and are in communication with a number of developers and companies to express a willingness to serve as a test-bed for any such new technologies. As noted in the NSF/USGS PEIS, should new technologies to conduct marine seismic surveys become available, NSF and SIO would consider whether they would be effective tools to meet research goals (and assess any potential environmental impacts).

Of the various technologies cited in the 2009 Okeanos workshop report on alternative technologies to seismic airgun surveys for oil and gas exploration and their potential for reducing impacts on marine mammals, few if any have reached operational viability. While the marine vibrator technology has been long discussed and evaluated, the technology is still unrealized commercially. According to Pramik (2013), the leading development effort by the Joint Industry Programme ''has the goal of developing three competing designs within the next few years.'' Geo-Kinetics has recently announced a commercial product called AquaVib, but that product produces relatively low-power, and is intended for use in very shallow water depths in sensitive environments and the vicinity of pipelines or other infrastructure. The instrument is entirely unsuited to deep-water, long-offset reflection profiling. The BP North America staggered burst technique would have to be developed well beyond the patent stage to be remotely practicable and would require extensive modification and testing of the *Revelle* sound source and recording systems. None of the other technologies considered (*i.e.,* gravity, electromagnetic, Deep Towed Acoustics/Geophysics System developed by the U.S. Navy [DTAGS], etc.) can produce the resolution or sub-seafloor penetration required to resolve sediment thickness and geologic structure at the requisite scales. Improving the streamer signal to noise through improved telemetry (*e.g.,* fiber optic cable) while desirable, would involve replacing the *Revelle's* streamers and acquisition units, requiring a major capital expenditure.

Comment 10: Dr. Slooten states that NMFS, NSF, and SIO should clarify the probability and effectiveness of using PSOs for detecting marine mammals in the proposed action area, especially when considering the distances to which noise from the airgun array propagates. A single PSO would only be able to visually sight a small fraction of the marine mammals in the action area and even close to the vessel (Barlow and Gisiner, 2006). A representative of the

oil and gas industry (*i.e.,* John Hughes, geophysical operations adviser at The Northwood Resource) recently described PSOs on seismic vessels as ''window dressing'' at the New Zealand Petroleum Summit 2015 (Hughes, 2015). The representative's presentation *Myths about Marine Seismic Surveys are Not Facts* can be found online at: *http://webcast.gigtv.com.au/Mediasite/Play/b90807c8ea8641bb93c57f435d4334841d?catalog=44162ae3%E2%80%90ca94%E2%80%904a9bb60c%E2%80%903b08c9b325ef.*

Response: NMFS acknowledges that PSO effectiveness is not 100%, particularly for some deep-diving species of marine mammals (such as beaked whales and *Kogia* spp.), which may be found in the study area and are cryptic at the sea surface and difficult to observe. The *Revelle* will carry three qualified and experienced PSOs. PSOs are appointed by SIO with NMFS concurrence. PSOs aboard the vessel will have had training to detect protected species and two PSOs will be on visual watch during airgun operations, except during mealtimes and restroom breaks, if needed. Also, the vessel's crew will be instructed to observe from the bridge and decks for opportunistic sightings.

Comment 11: Dr. Slooten states that NMFS, NSF, and SIO should describe the effectiveness and biological meaningful reductions in environmental impacts of the mitigation measures (*e.g.,* ramp-up and shut-down) that rely on PSOs visually detecting marine mammals and support these conclusions using scientific evidence.

Response: NMFS is currently unaware of any studies that meaningfully quantitatively describe the general effectiveness of monitoring and mitigation measures in the scientific literature. NMFS acknowledges Dr. Slooten's suggestion for analysis of monitoring and mitigation measures to help identify the effectiveness for seismic surveys. The purpose of a ramp-up is to ''warn'' marine mammals in the vicinity of the airguns and to provide the time for them to leave the area, avoiding any potential injury or impairment of their hearing abilities. The purpose of a shut-down is to turn off the airgun array if a marine mammal enters or is about to enter the exclusion zone, which would avoid exposing the animal to levels of sound that could potentially be injurious. Based on information in monitoring reports from previous NSF-funded seismic surveys, NMFS believes that implementing shut-downs as a mitigation measure reduced incidents of exposures from higher levels of sound from airgun operations on marine mammals. The IHA requires PSOs on the *Revelle* to conduct visual monitoring as well as the establishment of buffer and exclusion zones, ramp-up procedures, shut-down procedures, speed or course alteration, and additional measures for airgun operations in nearshore waters and during low-light hours. NMFS requires SIO and NSF to gather all data that could potentially provide information regarding the effectiveness of mitigation measures it its monitoring report. The information gathered may not result in any statistically robust conclusions for this particular low-energy seismic survey, but over the long term, these requirements may provide information regarding the effectiveness of monitoring and mitigation measures, provided PSOs detect animals.

Comment 12: Dr. Slooten states that NMFS should require shut-downs of the airgun array and other sound sources (*i.e.,* multi-beam echosounder and sub-bottom profiler) during poor visibility and/or nighttime conditions. A cautious approach should be used during poor visibility and/or nighttime conditions as a PSO would be unable to detect marine mammals near the vessel at those times.

Response: NMFS disagrees with the commenters' assessment. NMFS has measures in place and required by the IHA for airgun operations that we believe minimize potential impacts to marine mammals during poor visibility and/or nighttime conditions. No initiation of airgun operations is permitted from a shut-down position at night or during low-light hours (such as in dense fog or heavy rain) when the entire relevant exclusion zone cannot be effectively monitored by the PSO(s) on duty. However, airgun operations may continue into night and low-light hours if the segment(s) of the survey is initiated when the entire relevant exclusion zones are visible and can be effectively monitored. Limiting or suspending the low-energy seismic survey in low visibility conditions or at night would significantly extend the duration of the low-energy seismic survey. NMFS has not specified measures in the IHA requiring a shut-down for other sound sources (*i.e.,* multi-beam echosounder and sub-bottom profiler) during poor visibility and/or nighttime conditions. Take is not expected to result from the use of the multi-beam echosounder and sub-bottom profiler, as the brief exposure of marine mammals to one pulse, or small numbers of signals, to be generated by these instruments in this particular case as well as their characteristics (*e.g.,* narrow-shaped, downward-directed beam emitted from the bottom of the ship) is not likely to result in the harassment of marine mammals.

Comment 13: Dr. Slooten states that NSF and SIO should use and NMFS should require the use of passive acoustic monitoring (PAM) for marine mammals during the low-energy seismic survey, as it should be a routine requirement in U.S. waters.

Response: The NSF/USGS PEIS states that a towed PAM system is used normally for high-energy seismic surveys, and implied that it was not used for low-energy seismic surveys since towing PAM equipment is not practicable in some cases. For high-energy seismic surveys, PAM is practicable because the system is installed on the vessel used for such surveys. These PAM systems are expensive and are not portable from one vessel to another, requires complex logistics, and additional PSOs to be trained to operate the equipment, software, etc. SIO's project in the Southwest Pacific Ocean, East of New Zealand, is considered a low-energy marine seismic survey and is, furthermore, of short duration; therefore, NMFS and SIO has determined that it is not practicable and a towed PAM system will not be used for this specific project. SIO has appointed three PSOs onboard the *Revelle,* with NMFS's concurrence, to monitor and mitigate the buffer and exclusion zones during daylight. Also, NMFS believes that a towed PAM system is not needed to augment visual observations as the buffer and exclusion zones are less than 1,000 m (3,280.1 ft) and can be effectively monitored for marine mammals so that mitigation measures may be implemented, if needed.

Comment 14: Dr. Slooten states that NSF and SIO's Environmental Analysis fails to include several important publications, including Barlow and Gisiner's *Mitigating, monitoring and assessing the effects of anthropogenic sound on beaked whales* (2006).

Response: Barlow and Gisiner (2006) was addressed in the NSF/USGS PEIS (2011) and is therefore not cited specifically in NSF and SIO's Environmental Analysis (2014) or NMFS's EA. A comprehensive literature review on the potential effects of seismic surveys is provided in the NSF/USGS PEIS (2011), and the NSF and SIO Environmental Analysis and NMFS's EA refers to that document. The NSF and SIO Environmental Analysis only includes new relevant publications that were not included in the NSF/USGS PEIS, as noted in Section IV of that document.

NMFS believes that SIO's visual monitoring efforts are successful for detecting marine mammals and, through the implementation of mitigation, successful at minimizing the likelihood of injury or potentially more severe behavioral responses. NMFS expects that the impacts of the seismic survey on marine mammals will be temporary in nature and not result in substantial impacts to marine mammals or to their role in the ecosystem. The IHA anticipates and authorizes, Level B harassment only, in the form of temporary behavioral disturbance, of species of cetaceans. Neither Level A harassment (injury), serious injury, nor mortality is anticipated or authorized, and Level B harassment is not expected to affect biodiversity or ecosystem function. NMFS believes that SIO and NSF's short duration low-energy seismic survey will have a negligible impact on the affected species or stocks of marine mammals in the action area.

Comment 15: Dr. Slooten states that in general, NSF and SIO's Environmental Analysis tends to understate the potential impacts of the proposed action. A second draft of the Environmental Analysis should be prepared, with a more comprehensive literature review including key recent scientific publications that highlight the potential impacts of seismic surveys, to avoid over-representing literature that downplays the impacts.

Response: NMFS disagrees with Dr. Slooten's statement that a second or revised draft Environmental Analysis is warranted to consider any additional scientific literature. Prior to the conduct of the planned low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand, a comprehensive literature review and potential impacts based on scientific publications are described in the NSF/USGS PEIS (2011), NSF and SIO Environmental Analysis, and NMFS EA. The commenter has not identified any particular potential impacts or studies that have been ''downplayed.'' These documents have been posted on NSF's Environmental Compliance and NMFS's Web sites at: *https://www.nsf.gov/geo/oce/envcomp/index.jsp http://www.nmfs.noaa.gov/pr/permits/incidental/research.htm#scripps_nz_2015.* Also, the commenter has not identified any key scientific publications supporting their statement and did not provide references supporting their statement which limits our ability to respond to the commenter's statements.

Comment 16: Dr. Slooten states that the southern survey area, off New Zealand's South Island is described as a ''contingency area that would only be surveyed if time permits.'' On the basis of currently available scientific data, this is a high risk area in terms of marine mammal density. In addition, the southern survey area has steep depth contours relatively close to shore.

Response: Dr. Slooten provided a brief summary of cetacean sightings off Kaikoura, New Zealand by members of Otago University's Marine Mammal Research Group between 1990 and 2015. The information on the cetacean species present in the action area included year-round resident, frequent visitors (more than 2 sightings per year, every year), and occasional sightings (1 or 2 sightings per year and not every year). The commenter did not provide references or data supporting their statement which limits our ability to respond to the commenter's statement that the southern area off the South Island is ''high risk'' based on marine mammal density. For the concerns regarding the steep depth contours relatively close to shore in the southern survey area, NMFS has added the requirement in the IHA that, to the maximum extent practicable (in consideration of time, fuel, and other operational constraints), SIO will conduct the low-energy seismic survey (especially when near land) from the coast (inshore) and proceed towards the sea (offshore) in order to avoid herding or trapping marine mammals in shallow water.

Comment 17: Dr. Slooten states that NMFS should consider the potential risk factors of a vessel moving from deep water towards a shallower coastal area, and the ship using a multi-beam echosounder and sub-bottom profiler in addition to airguns, based on the stranding of beaked whales in Mexico (Gulf of California) during a NSF-funded seismic survey in 2002 (Taylor, 2004). The multi-beam echosounder and sub-bottom profiler could have been a contributing factor in forcing the beaked whales into shallower water. The beaked whales could have been herded ahead of the ship and found themselves in water that was too shallow to allow them to regulate their nitrogen levels. They may have out-gassed and died from the bends, or travelled rapidly towards the shore to avoid the noise resulting in a stranding.

Response: The multi-beam echosounder and sub-bottom profiler that is currently installed on the *Revelle* was evaluated in the NSF/USGS PEIS and in NSF and SIO's Environmental Analysis, and has been used on at least 6 research low-energy seismic surveys throughout the world (*e.g.,* Eastern Tropical Pacific Ocean, Indian Ocean, Louisville Ridge, South Pacific Ocean, Tropical Western Pacific Ocean) since 2004 without association to any marine mammal strandings.

Regarding the 2002 stranding in the Gulf of California, the multi-beam echosounder and sub-bottom profiler systems were on a different vessel, the R/V *Maurice Ewing* (*Ewing*), and is no longer operated by L–DEO. Although Dr. Slooten suggests that the multi-beam echosounder or sub-bottom profiler system or other acoustic sources on the *Ewing* may have been associated with the 2002 stranding of 2 beaked whales, as noted in Cox *et al.* (2006), ''whether or not this survey caused the beaked whales to strand has been a matter of debate because of the small number of animals involved and a lack of knowledge regarding the temporal and spatial correlation between the animals and the sound source.'' As noted by Yoder (2002), there was no scientific linkage to the event with the *Ewing's* activities and the acoustic sources being used. Hildebrand (2006) has noted that ''the settings for these stranding are strikingly consistent: An island or archipelago with deep water nearby, appropriate for beaked whale foraging habitat. The conditions for mass stranding may be optimized when the sound source transits a deep channel between two islands, such as in the Bahamas (2000), and apparently in the Madeira (2000) incident.''

The tracklines for the current low-energy seismic survey are planned to occur in intermediate and deep water and will not be conducted in a manner that is likely to result in the ''herding of sensitive species'' into canyons and other similar areas. The IHA has included the requirement that to the maximum extent practicable, SIO will conduct the low-energy seismic survey (especially when near land) from the coast (inshore) and proceed towards the sea (offshore) in order to avoid herding or trapping marine mammals in shallow water. Also, this low-energy seismic survey is of short duration and spread out over space and time as it is scheduled to occur for a total of approximately 135 hours (approximately 72 hours of continuous operations at a time) over the course of the entire cruise, which would be for approximately 27 operational days in May to June 2015. Given these conditions, NMFS does not anticipate strandings of marine mammals from use of the planned multi-beam echosounder or sub-bottom profiler.

Comment 18: One private citizen opposed the issuance of an IHA by NMFS and the conduct of the low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand. The

commenter stated that NMFS should protect marine life from harm.

Response: As described in detail in the notice of the proposed IHA (80 FR 15060, March 20, 2015), as well as in this document, NMFS does not believe SIO's low-energy seismic survey will cause injury, serious injury, or mortality to marine mammals, and no take by injury, serious injury, or mortality is authorized. The required monitoring and mitigation measures that SIO will implement during the low-energy seismic survey will further reduce the potential impacts on marine mammals to the lowest level practicable. NMFS anticipates only behavioral disturbance to occur during the conduct of the low-energy seismic survey.

Description of the Marine Mammals in the Specified Geographic Area of the Specified Activity

Few scientific systematic surveys for marine mammals have been conducted in the waters of New Zealand, and these mainly consist of single-species surveys in shallow coastal waters (*e.g.,* Dawson *et al.,* 2004; Slooten *et al.,* 2004, 2006). Large-scale, multi-species marine mammal surveys are lacking. Various sources for data on sightings in the planned study area were used to describe the occurrence of marine mammals in the waters of New Zealand, such as opportunistic sighting records presented in previous reports (including the New Zealand Department of Conservation marine mammals sighting database) considered in evaluating potential marine mammals in the planned action area.

New Zealand is considered a ''hotspot'' for marine mammal species richness (Kaschner *et al.,* 2011). The marine mammals that generally occur in the proposed action area belong to three taxonomic groups: mysticetes (baleen whales), odontocetes (toothed whales), and pinnipeds (seals and sea lions). The marine mammal species that could potentially occur within the Southwest Pacific Ocean in proximity to the planned action area East of New Zealand include 33 species of cetaceans (24 odontocetes and 9 mysticetes) and 2 species of pinnipeds (35 total species of marine mammals).

Marine mammal species likely to be encountered in the planned study area that are listed as endangered under the U.S. Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*), are the southern right (*Eubalaena australis*), humpback (*Megaptera novaeangliae*), sei (*Balaenoptera borealis*), fin (*Balaenoptera physalus*), blue (*Balaenoptera musculus*), and sperm (*Physeter macrocephalus*) whale. The Maui's dolphin (*Cephalorhynchus hectori maui*) and New Zealand sea lion (*Phocartos hookeri*) are two other species are ranked as ''nationally critical'' in New Zealand (Baker *et al.,* 2010). Maui's dolphin is only found along the west coast of the North Island. The northern range of the New Zealand sea lion is not expected to extend to the planned study area based on New Zealand's National Aquatic Biodiversity Information System (NABIS, 2014) and is not considered further.

In addition to the marine mammal species known to occur in the Southwest Pacific Ocean off the east coast of New Zealand, there are 18 species of marine mammals (12 cetacean and 6 pinniped species) with ranges that are known to potentially occur in the waters of the planned study area, but they are categorized as ''vagrant'' under the New Zealand Threat Classification System (Baker *et al.,* 2010). These include: Dwarf sperm whale (*Kogia sima*), Arnoux's beaked whale (*Berardius arnouxi*), ginkgo-toothed beaked whale (*Mesoplodon ginkgodens*), pygmy beaked whale (*Mesoplodon peruvianis*), Type B, C, and D killer whale (*Orcinus orca*), melon-headed whale (*Peponocephala electra*), Risso's dolphin (*Grampus griseus*), Fraser's dolphin (*Lagenodelphis hosei*), pantropical spotted dolphin (*Stenella attenuata*), striped dolphin (*Stenella coeruleoalba*), rough-toothed dolphin (*Steno bredanensis*), spectacled porpoise (*Phocoena dioptrica*), Antarctic fur seal (*Arctocephalus gazelle*), Subantarctic fur seal (*Arctocephalus tropicalis*), crabeater seal (*Lobodon carcinophagus*), leopard seal (*Hydrurga leptonyx*), Ross seal (*Ommatophoca rossi*), and Weddell seal (*Leptonychotes weddellii*). According to Jefferson *et al.* (2008), the distributional range of Hubb's beaked whale (*Mesoplodon carlhubbsi*) and True's beaked whale (*Mesoplodon mirus*) may also include New Zealand waters. There are no records of Hubb's beaked whale in New Zealand, and only a single record of True's beaked whale, which stranded on the west coast of South Island in November 2011 (Constantine *et al.,* 2014). The spinner dolphin's (*Stenella longirostris*) range includes tropical and subtropical zones 40° North to 40° South, but would be considered vagrant as well. However, these species are not expected to occur where the planned activities will take place. Except for Arnoux's beaked whale, pygmy beaked whale, and Risso's dolphin, these species are not considered further in this document. Table 2 (below) presents information on the habitat, occurrence, distribution, abundance, population, and conservation status of the species of marine mammals that may occur in the planned study area during May to June 2015.

TABLE 2—THE HABITAT, OCCURRENCE, RANGE, REGIONAL ABUNDANCE, AND CONSERVATION STATUS OF MARINE MAMMALS THAT MAY OCCUR IN OR NEAR THE LOW-ENERGY SEISMIC SURVEY AREA IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND (SEE TEXT AND TABLES 2 IN SIO'S IHA APPLICATION FOR FURTHER DETAILS)

Species	Habitat	Occurrence	Range	Population estimate	ESA [1]	MMPA [2]
Mysticetes						
Southern right whale (*Eubalaena australis*).	Coastal, shelf, pelagic	Common	Circumpolar 20 to 55° South.	8,000 [3] to 15,000 [4]—Worldwide. 12,000 [12]—Southern Hemisphere. 2,700 [12]—Sub-Antarctic New Zealand.	EN	D
Pygmy right whale (*Caperea marginata*).	Pelagic and coastal	Rare	Circumpolar 30 to 55° South.	NA	NL	NC
Humpback whale (*Megaptera novaeangliae*).	Pelagic, nearshore waters, and banks.	Common	Cosmopolitan Migratory	35,000 to 42,000 [3 12]—Southern Hemisphere.	EN	D
Minke whale (*Balaenoptera acutorostrata* including dwarf sub-species).	Pelagic and coastal	Uncommon	Circumpolar—Southern Hemisphere to 65° South.	720,000 to 750,000 [12 14 15]—Southern Hemisphere.	NL	NC

TABLE 2—THE HABITAT, OCCURRENCE, RANGE, REGIONAL ABUNDANCE, AND CONSERVATION STATUS OF MARINE MAMMALS THAT MAY OCCUR IN OR NEAR THE LOW-ENERGY SEISMIC SURVEY AREA IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND (SEE TEXT AND TABLES 2 IN SIO'S IHA APPLICATION FOR FURTHER DETAILS)—Continued

Species	Habitat	Occurrence	Range	Population estimate	ESA [1]	MMPA [2]
Antarctic minke whale (*Balaenoptera bonaerensis*).	Pelagic, ice floes, coastal	Uncommon	7° South to ice edge (usually 20 to 65° South).	720,000 to 750,000 [12 14 15]—Southern Hemisphere.	NL	NC
Bryde's whale (*Balaenoptera edeni*).	Pelagic and coastal	Rare	Circumglobal—Tropical and Subtropical Zones.	At least 30,000 to 40,000 [3]—Worldwide. 21,000 [12]—Northwestern Pacific Ocean. 48,109 [13]	NL	NC
Sei whale (*Balaenoptera borealis*).	Primarily offshore, pelagic	Uncommon	Migratory, Feeding Concentration 40 to 50° South.	80,000 [3]—Worldwide 10,000 [14]—South of Antarctic Convergence.	EN	D
Fin whale (*Balaenoptera physalus*).	Continental slope, pelagic	Uncommon	Cosmopolitan, Migratory	140,000 [3]—Worldwide 15,000 [14]—South of Antarctic Convergence.	EN	D
Blue whale (*Balaenoptera musculus;* including pygmy blue whale [*Balaenoptera musculus brevicauda*]).	Pelagic, shelf, coastal	Uncommon	Migratory Pygmy blue whale—North of Antarctic Convergence 55° South.	8,000 to 9,000 [3]—Worldwide. 2,300 [12]—True Southern Hemisphere. 1,500 [14]—Pygmy	EN	D
Odontocetes						
Sperm whale (*Physeter macrocephalus*).	Pelagic, deep sea	Common	Cosmopolitan, Migratory	360,000 [3]—Worldwide 30,000 [13]—South of Antarctic Convergence.	EN	D
Dwarf sperm whale (*Kogia sima*).	Shelf, Pelagic	Vagrant	Circumglobal—Tropical and Temperate Zones.	NA	NL	NC
Pygmy sperm whale (*Kogia breviceps*).	Shelf, Pelagic	Uncommon	Circumglobal—Temperate Zones.	NA	NL	NC
Arnoux's beaked whale (*Berardius arnuxii*).	Pelagic	Vagrant	Circumpolar in Southern Hemisphere, 24 to 78° South.	NA	NL	NC
Cuvier's beaked whale (*Ziphius cavirostris*).	Pelagic	Uncommon	Cosmopolitan	600,000 [14 16]	NL	NC
Southern bottlenose whale (*Hyperoodon planifrons*).	Pelagic	Rare	Circumpolar—30° South to ice edge.	500,000 [3]—South of Antarctic Convergence. 600,000 [14 16]	NL	NC
Shepherd's beaked whale (*Tasmacetus shepherdi*).	Pelagic	Rare	Circumpolar—Cold temperate waters Southern Hemisphere.	600,000 [14 16]	NL	NC
Andrew's beaked whale (*Mesoplodon bowdoini*).	Pelagic	Rare	Circumpolar—temperate waters of Southern Hemisphere, 32 to 55° South.	600,000 [14 16]	NL	NC
Blainville's beaked whale (*Mesoplodon densirostris*).	Pelagic	Rare	Circumglobal—tropical and temperate waters.	600,000 [14 16]	NL	NC
Ginkgo-toothed beaked whale (*Mesoplodon ginkgodens*).	Pelagic	Vagrant	Tropical and Temperate waters—Indo-Pacific Ocean.	NA	NL	NC
Gray's beaked whale (*Mesoplodon grayi*).	Pelagic	Common	30° South to Antarctic waters.	600,000 [14 16]	NL	NC
Hector's beaked whale (*Mesoplodon hectori*).	Pelagic	Rare	Circumpolar—cool temperate waters of Southern Hemisphere.	600,000 [14 16]	NL	NC
Hubb's beaked whale (*Mesoplodon carlhubbsi*).	Pelagic	Vagrant	North Pacific Ocean	NA	NL	NC
Pygmy beaked whale (*Mesoplodon peruvianis*).	Pelagic	Vagrant	28° North to 30° South in Pacific Ocean.	NA	NL	NC
Spade-toothed beaked whale (*Mesoplodon traversii*).	Pelagic	Rare	Circumantarctic	600,000 [14 16]	NL	NC
Strap-toothed beaked whale (*Mesoplodon layardii*).	Pelagic	Uncommon	30° South to Antarctic Convergence.	600,000 [14 16]	NL	NC
True's beaked whale (*Mesoplodon mirus*).	Pelagic	Vagrant	Anti-tropical in Northern and Southern Hemisphere.	NA	NL	NC
Killer whale (*Orcinus orca*)	Pelagic, shelf, coastal, pack ice.	Common	Cosmopolitan	80,000 [3]—South of Antarctic Convergence.	NL	NC
False killer whale (*Pseudorca crassidens*).	Pelagic, shelf, coastal	Uncommon	Circumglobal—tropical and warmer temperate water.	NA	NL	NC
Long-finned pilot whale (*Globicephala melas*).	Pelagic, shelf, coastal	Common	Circumpolar—19 to 68° South in Southern Hemisphere.	200,000 [3 5 14]—South of Antarctic Convergence.	NL	NC
Short-finned pilot whale (*Globicephala macrocephalus*).	Pelagic, shelf, coastal	Uncommon	Circumglobal—50° North to 40° South.	At least 600,000 [3]—Worldwide.	NL	NC
Melon-headed whale (*Peponocephala electra*).	Pelagic, shelf, coastal	Vagrant	Circumglobal—40° North to 35° South.	45,000 [3]—Eastern Tropical Pacific Ocean.	NL	NC
Bottlenose dolphin (*Tursiops truncatus*).	Coastal, shelf, offshore	Common	45° North to 45° South	At least 614,000 [3]—Worldwide.	NL C—Fjordland population.	NC

TABLE 2—THE HABITAT, OCCURRENCE, RANGE, REGIONAL ABUNDANCE, AND CONSERVATION STATUS OF MARINE MAMMALS THAT MAY OCCUR IN OR NEAR THE LOW-ENERGY SEISMIC SURVEY AREA IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND (SEE TEXT AND TABLES 2 IN SIO'S IHA APPLICATION FOR FURTHER DETAILS)—Continued

Species	Habitat	Occurrence	Range	Population estimate	ESA [1]	MMPA [2]
Dusky dolphin (*Lagenorhynchus obscurus*).	Shelf, slope	Common	Temperate waters—Southern Hemisphere.	12,000 to 20,000 [17]—New Zealand.	NL	NC
Fraser's dolphin (*Lagenodelphis hosei*).	Pelagic	Vagrant	Pantropical—30° North to 30° South.	289,000 [3]—Eastern Tropical Pacific Ocean.	NL	NC
Hector's dolphin (*Cephalorhynchus hectori;* including Maui's dolphin subspecies [*C. h. maui*]).	Nearshore	Rare	Shallow coastal waters—New Zealand (Maui's dolphin—west North Island).	7,400 [17] 55 [19]—Maui's	C	NC
Hourglass dolphin (*Lagenorhynchus cruciger*).	Pelagic, ice edge	Uncommon	33° South to pack ice	144,000 [3] to 150,000 [14]—South of Antarctic Convergence.	NL	NC
Pantropical spotted dolphin (*Stenella attenuata*).	Coastal, shelf, slope	Vagrant	Circumglobal—40° North to 40° South.	At least 2,000,000 [3]—Worldwide.	NL	NC
Spinner dolphin (*Stenella longirostris*).	Mainly nearshore	Vagrant	Circumglobal—40° North to 40° South.	At least 1,200,000 [3]—Worldwide.	NL	NC
Striped dolphin (*Stenella coeruleoalba*).	Off continental shelf, convergence zones, upwelling.	Vagrant	Circumglobal—50 to 40 South.	At least 1,100,000 [3]—Worldwide.	NL	NC
Risso's dolphin (*Grampus griseus*).	Slope, Pelagic	Vagrant	Circumglobal—Tropical and Temperate waters.	At least 330,000 [3]—Worldwide.	NL	NC
Rough-toothed dolphin (*Steno bredanensis*).	Pelagic	Vagrant	Circumglobal—40° North to 35° South.	NA	NL	NC
Short-beaked common dolphin (*Delphinus delphis*).	Pelagic	Common	Circumglobal—tropical and warm temperate waters.	At least 3,500,000 [3]—Worldwide.	NL	NC
Southern right whale dolphin (*Lissodelphis peronii*).	Pelagic	Uncommon	12 to 65° South	NA	NL	NC
Spectacled porpoise (*Phocoena dioptrica*).	Coastal, pelagic	Vagrant	Circumpolar—Southern Hemisphere.	NA	NL	NC
Pinnipeds						
Crabeater seal (*Lobodon carcinophaga*).	Coastal, pack ice	Vagrant	Circumpolar—Antarctic	5,000,000 to 15,000,000 [3 6]—Worldwide.	NL	NC
Leopard seal (*Hydrurga leptonyx*).	Pack ice, sub-Antarctic islands.	Vagrant	Sub-Antarctic islands to pack ice.	220,000 to 440,000 [3 7]—Worldwide.	NL	NC
Ross seal (*Ommatophoca rossii*).	Pack ice, smooth ice floes, pelagic.	Vagrant	Circumpolar—Antarctic	130,000 [3] 20,000 to 220,000 [11]—Worldwide.	NL	NC
Weddell seal (*Leptonychotes weddellii*).	Fast ice, pack ice, sub-Antarctic islands.	Vagrant	Circumpolar—Southern Hemisphere.	500,000 to 1,000,000 [3 8]—Worldwide.	NL	NC
Southern elephant seal (*Mirounga leonina*).	Coastal, pelagic, sub-Antarctic waters.	Uncommon	Circumpolar—Antarctic Convergence to pack ice.	640,000 [9] to 650,000 [3]—Worldwide 470,000—South Georgia Island [11]. 607,000 [17]	NL	NC
Antarctic fur seal (*Arctocephalus gazella*).	Shelf, rocky habitats	Vagrant	Sub-Antarctic islands to pack ice edge.	1,600,000 [10] to 3,000,000 [3]—Worldwide.	NL	NC
New Zealand fur seal (*Arctocephalus forsteri*).	Rocky habitats, sub-Antarctic islands.	Common	North and South Islands, New Zealand. Southern and Western Australia.	135,000 [3]—Worldwide 50,000 to 100,000 [18]—New Zealand.	NL	NC
Subantarctic fur seal (*Arctocephalus tropicalis*).	Shelf, rocky habitats	Vagrant	Subtropical front to sub-Antarctic islands and Antarctica.	Greater than 310,000 [3]—Worldwide.	NL	NC
New Zealand sea lion (*Phocarctos hookeri*).	Shelf, rocky habitats	Rare	Sub-Antarctic islands south of New Zealand.	12,500 [3]	NL	NC

NA = Not available or not assessed.
[1] U.S. Endangered Species Act: EN = Endangered, T = Threatened, DL = Delisted, NL = Not listed, C = Candidate.
[2] U.S. Marine Mammal Protection Act: D = Depleted, S = Strategic, NC = Not Classified.
[3] Jefferson *et al.,* 2008.
[4] Kenney, 2009.
[5] Olson, 2009.
[6] Bengston, 2009.
[7] Rogers, 2009.
[8] Thomas and Terhune, 2009.
[9] Hindell and Perrin, 2009.
[10] Arnould, 2009.
[11] Academic Press, 2009.
[12] IWC, 2014.
[13] IWC, 1981.
[14] Boyd, 2002.
[15] Dwarf and Antarctic minke whale combined.
[16] All Antarctic beaked whales combined.
[17] New Zealand Department of Conservation.
[18] Suisted and Neale, 2004.
[19] 95% confidence interval (48 to 69 animals) from Hamner *et al.* 2012, 2013.

Refer to sections 3 and 4 of SIO's IHA application for detailed information regarding the abundance and distribution, population status, and life history and behavior of these marine mammal species and their occurrence in the planned action area. The IHA application also presents how SIO calculated the estimated densities for the marine mammals in the planned study area. NMFS has reviewed these data and determined them to be the best available scientific information for the purposes of the IHA.

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.,* seismic airgun operation, vessel movement, and gear deployment) are believed to impact marine mammals. This section is intended as a background of potential effects and does not fully consider either the specific manner in which this activity would be carried out or the mitigation that would be implemented, and how either of those would shape the anticipated impacts from this specific activity. The ''Estimated Take by Incidental Harassment'' section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The ''Negligible Impact Analysis'' section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the ''Estimated Take by Incidental Harassment'' section, the ''Mitigation'' section, and the ''Anticipated Effects on Marine Mammal Habitat'' section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been derived using auditory evoked potentials, anatomical modeling, and other data. Southall *et al.* (2007) designate ''functional hearing groups'' for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (though animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range):

- Low-frequency cetaceans (13 species of mysticetes): Functional hearing is estimated to occur between approximately 7 Hz and 30 kHz;
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (eight species of true porpoises, six species of river dolphins, *Kogia* spp., the franciscana [*Pontoporia blainvillei*], and four species of cephalorhynchids): Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; and
- Phocid pinnipeds in water: Functional hearing is estimated to occur between approximately 75 Hz and 100 kHz;
- Otariid pinnipeds in water: Functional hearing is estimated to occur between approximately 100 Hz and 40 kHz.

As mentioned previously in this document, 35 marine mammal species (33 cetacean and 2 pinniped species) are likely to occur in the low-energy seismic survey area. Of the 30 cetacean species likely to occur in SIO's action area, 9 are classified as low-frequency cetaceans (southern right, pygmy right, humpback, minke, Antarctic minke, Bryde's, sei, fin, and blue whale), 20 are classified as mid-frequency cetaceans (sperm, Cuvier's beaked, Shepherd's beaked, southern bottlenose, Andrew's beaked, Blainville's beaked, Gray's beaked, Hector's beaked, spade-toothed beaked, strap-toothed beaked, killer, false killer, long-finned pilot, and short-finned pilot whale, and bottlenose, dusky, Hector's, hourglass, short-beaked common, and southern right whale dolphin), and 1 is classified as high-frequency cetaceans (pygmy sperm whale) (Southall *et al.,* 2007). Of the 2 pinniped species likely to occur in SIO's proposed action area, 1 is classified as phocid (southern elephant seal) and 1 is classified as otariid (New Zealand fur seal) (Southall *et al.,* 2007). A species functional hearing group is a consideration when we analyze the effects of exposure to sound on marine mammals.

Acoustic stimuli generated by the operation of the airguns, which introduce sound into the marine environment, have the potential to cause Level B harassment of marine mammals in the study area. The effects of sounds from airgun operations might include one or more of the following: Tolerance, masking of natural sounds, behavioral disturbance, temporary or permanent hearing impairment, or non-auditory physical or physiological effects (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007). Although the possibility cannot be entirely excluded, it is unlikely that the proposed project would result in any cases of temporary or permanent hearing impairment, or any significant non-auditory physical or physiological effects. Based on the available data and studies described in the notice of the proposed IHA (80 FR 15060, March 20, 2015, some behavioral disturbance is expected. A more comprehensive review of these issues can be found in the NSF/USGS PEIS (2011) and L–DEO's *Final Environmental Assessment of a Marine Geophysical Survey by the R/V Marcus G. Langseth in the Atlantic Ocean off Cape Hatteras, September to October 2014.*

The notice of the proposed IHA (80 FR 15060, March 20, 2015) included a discussion of the effects of sounds from airguns, bathymetric surveys, heat-flow measurements, and other acoustic devices and sources on mysticetes and odontocetes, including tolerance, masking, behavioral disturbance, hearing impairment, and other non-auditory physical effects. The notice of the proposed IHA (80 FR 15060, March 20, 2015) also included a discussion of the effects of vessel movement and collisions as well as entanglement. NMFS refers the readers to SIO's IHA application and Environmental Analysis for additional information on the behavioral reactions (or lack thereof) by all types of marine mammals to seismic vessels.

Anticipated Effects on Marine Mammal Habitat, Fish, and Invertebrates

NMFS included a detailed discussion of the potential effects of this action on marine mammal habitat, including physiological and behavioral effects on marine fish and invertebrates, in the notice of the proposed IHA (80 FR 15060, March 20, 2015). The low-energy seismic survey is not anticipated to have any permanent impact on habitats used by the marine mammals in the study area, including the food sources they use (*i.e.,* fish and invertebrates). Additionally, no physical damage to any habitat is anticipated as a result of conducing airgun operations during the low-energy seismic survey. While NMFS anticipates that the specified activity may result in marine mammals avoiding certain areas due to temporary ensonification, this impact is temporary

and reversible, and was considered in further detail in the notice of the proposed IHA (80 FR 15060, March 20, 2015), as behavioral modification. The main impact associated with the planned activity will be temporarily elevated noise levels and the associated direct effects on marine mammals.

Mitigation

In order to issue an Incidental Take Authorization (ITA) under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and the availability of such species or stock for taking for certain subsistence uses (where relevant).

SIO reviewed the following source documents and incorporated a suite of appropriate mitigation measures into the project description.

(1) Protocols used during previous NSF and USGS-funded seismic research cruises as approved by NMFS and detailed in the ''Final Programmatic Environmental Impact Statement/ Overseas Environmental Impact Statement for Marine Seismic Research Funded by the National Science Foundation or Conducted by the U.S. Geological Survey;''

(2) Previous IHA applications and IHAs approved and authorized by NMFS; and

(3) Recommended best practices in Richardson *et al.* (1995), Pierson *et al.* (1998), and Weir and Dolman, (2007).

To reduce the potential effects from acoustic stimuli associated with the planned activities, SIO must implement the following mitigation measures for marine mammals:

(1) Exclusion zones around the sound source;

(2) Speed and course alterations;

(3) Shut-down procedures; and

(4) Ramp-up procedures.

Exclusion Zones—During pre-planning of the cruise, the smallest airgun array was identified that could be used and still meet the geophysical scientific objectives. SIO use radii to designate exclusion and buffer zones and to estimate take for marine mammals. Table 3 (see below) shows the distances at which one would expect to receive three sound levels (160, 180, and 190 dB) from the two GI airgun array. The 180 and 190 dB level shut-down criteria are applicable to cetaceans and pinnipeds, respectively, as specified by NMFS (2000) and will be used to establish the exclusion and buffer zones.

TABLE 3—PREDICTED AND MODELED (TWO 45 IN^3 GI AIRGUN ARRAY) DISTANCES TO WHICH SOUND LEVELS ≥160, 180, AND 190 DB RE 1 μPA (RMS) COULD BE RECEIVED IN INTERMEDIATE AND DEEP WATER DURING THE PROPOSED LOW-ENERGY SEISMIC SURVEY IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND, MAY TO JUNE 2015

Source and total volume	Tow depth (m)	Water depth (m)	Predicted RMS radii distances (m) for 2 GI airgun array		
			160 dB	180 dB	190 dB
Two 45 in^3 GI Airguns. (90 in^3)	2	Intermediate (100 to 1,000).	600 (1,968.5 ft)	100 (328.1 ft)	15 (49.2 ft) *100 would be used for pinnipeds as described in NSF/USGS PEIS.*
Two 45 in^3 GI Airguns (90 in^3).	2	Deep (>1,000)	400 (1,312.3 ft)	100 (328.1 m)	10 (32.8 ft) *100 would be used for pinnipeds as described in NSF/USGS PEIS.*

Based on the NSF/USGS PEIS and Record of Decision, for situations which incidental take of marine mammals is anticipated, SIO has established exclusion zones of 100 m for cetaceans and pinnipeds for all low-energy acoustic sources in water depths greater than 100 m would be implemented.

Received sound levels were modeled by L–DEO for a number of airgun configurations, including two 45 in^3 Nucleus G airguns, in relation to distance and direction from the airguns (see Figure 2 of the IHA application). In addition, propagation measurements of pulses from two GI airguns have been reported for shallow water (approximately 30 m [98.4 ft] depth) in the Gulf of Mexico (Tolstoy *et al.,* 2004). However, measurements were not made for the two GI airguns in deep water. The model does not allow for bottom interactions, and is most directly applicable to deep water. Based on the modeling, estimates of the maximum distances from the GI airguns where sound levels are predicted to be 190, 180, and 160 dB re 1 μPa (rms) in intermediate and deep water were determined (see Table 3 above).

Empirical data concerning the 190, 180, and 160 dB (rms) distances were acquired for various airgun arrays based on measurements during the acoustic verification studies conducted by L–DEO in the northern Gulf of Mexico in 2003 (Tolstoy *et al.,* 2004) and 2007 to 2008 (Tolstoy *et al.,* 2009). Results of the 18 and 36 airgun arrays are not relevant for the two GI airguns to be used in the proposed low-energy seismic survey because the airgun arrays are not the same size or volume. The empirical data for the 6, 10, 12, and 20 airgun arrays indicate that, for deep water, the L–DEO model tends to overestimate the received sound levels at a given distance (Tolstoy *et al.,* 2004). Measurements were not made for the two GI airgun array in deep water; however, SIO proposed to use the safety radii predicted by L–DEO's model for the planned GI airgun operations in intermediate and deep water, although they are likely conservative given the empirical results for the other arrays.

Based on the modeling data, the outputs from the pair of 45 in^3 GI airguns planned to be used during the low-energy seismic survey are considered a low-energy acoustic source in the NSF/USGS PEIS (2011) for marine seismic research. A low-energy seismic source was defined in the NSF/USGS PEIS as an acoustic source whose received level is less than or equal to 180 dB at 100 m (including any single or any two GI airguns and a single pair of clustered airguns with individual volumes of less than or equal to 250 in^3). The NSF/USGS PEIS also established for these low-energy sources a standard exclusion zone of 100 m for all low-energy sources in water depths greater than 100 m. This standard 100 m exclusion zone will be used during the proposed low-energy seismic survey using the pair of 45 in^3 GI airguns. The 180 and 190 dB (rms) radii are the current Level A harassment criteria applicable to cetaceans and pinnipeds, respectively; these levels were used to establish exclusion zones. Therefore, the assumed 180 and 190 dB radii are 100

m for intermediate and deep water. If the PSO detects a marine mammal within or about to enter the appropriate exclusion zone, the airguns will be shut-down immediately.

Speed and Course Alterations—If a marine mammal is detected outside the exclusion zone and, based on its position and direction of travel (relative motion), is likely to enter the exclusion zone, changes of the vessel's speed and/or direct course will be considered if this does not compromise operational safety or damage the deployed equipment. This will be done if operationally practicable while minimizing the effect on the planned science objectives. For marine seismic surveys towing large streamer arrays, course alterations are not typically implemented due to the vessel's limited maneuverability. However, the *Revelle* will be towing a relatively short hydrophone streamer, so its maneuverability during operations with the hydrophone streamer will not be as limited as vessels towing long streamers, thus increasing the potential to implement course alterations, if necessary. After any such speed and/or course alteration is begun, the marine mammal activities and movements relative to the seismic vessel would be closely monitored to ensure that the marine mammal does not approach within the applicable exclusion zone. If the marine mammal appears likely to enter the exclusion zone, further mitigation actions will be taken, including further speed and/or course alterations, and/or shut-down of the airgun(s). Typically, during airgun operations, the source vessel is unable to change speed or course, and one or more alternative mitigation measures will need to be implemented.

Shut-down Procedures—If a marine mammal is detected outside the exclusion zone for the airgun(s) but is likely to enter the exclusion zone, and the vessel's speed and/or course cannot be changed to avoid having the animal enter the exclusion zone, SIO will shut-down the operating airgun(s) before the animal is within the exclusion zone. Likewise, if a marine mammal is already within the exclusion zone when first detected, the airguns will be shut-down immediately.

Following a shut-down, SIO will not resume airgun activity until the marine mammal has cleared the exclusion zone, or until the PSO is confident that the animal has left the vicinity of the vessel. SIO will consider the animal to have cleared the exclusion zone if:

- A PSO has visually observed the animal leave the exclusion zone, or
- A PSO has not sighted the animal within the exclusion zone for 15 minutes for species with shorter dive durations (*i.e.,* small odontocetes and pinnipeds), or 30 minutes for species with longer dive durations (*i.e.,* mysticetes and large odontocetes, including sperm, dwarf and pygmy sperm, killer, and beaked whales).

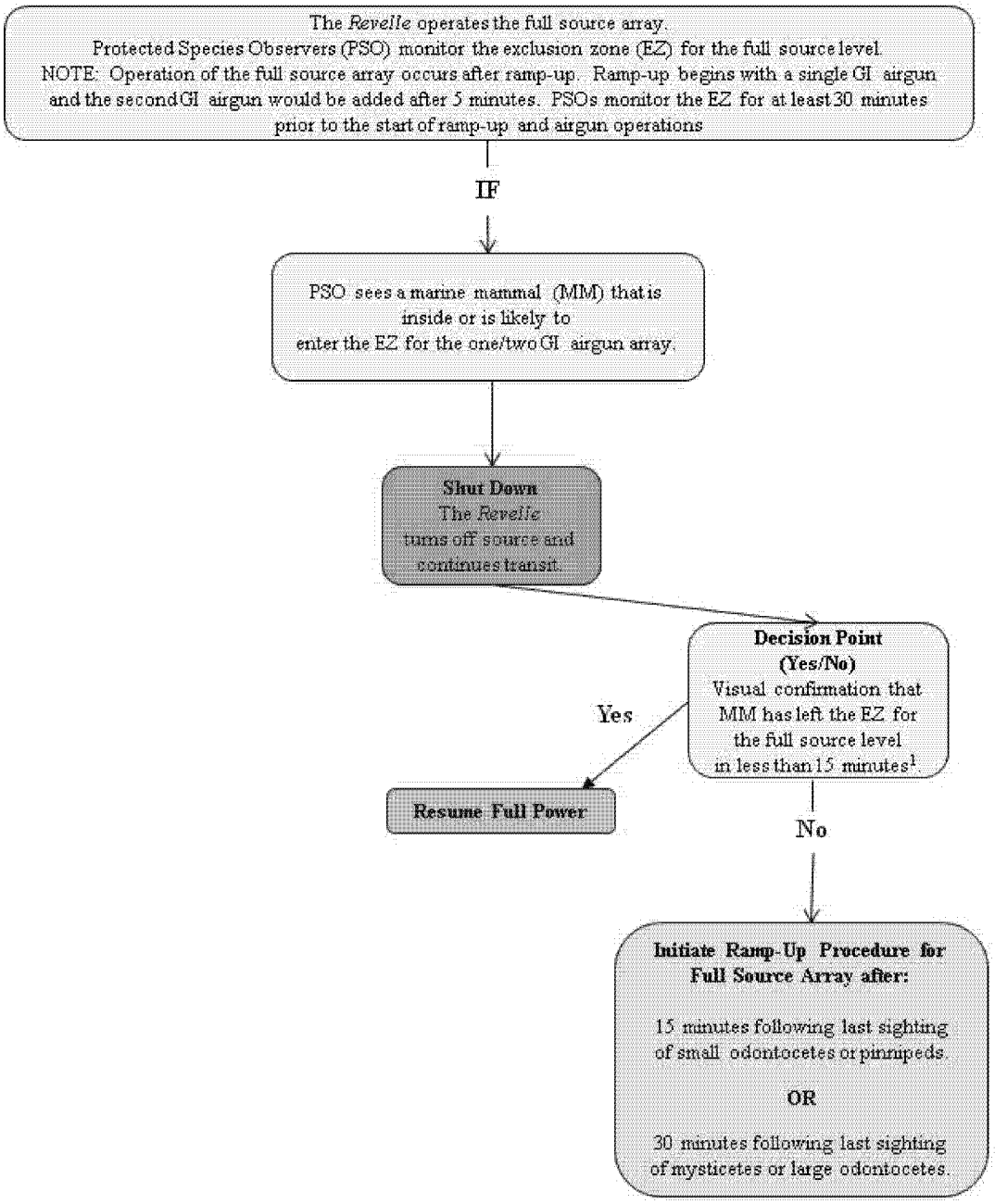
Although power-down procedures are often standard operating practice for seismic surveys, they will not be used during this planned low-energy seismic survey because powering-down from two airguns to one airgun will make only a small difference in the exclusion zone(s) that probably will not be enough to allow continued one-airgun operations if a marine mammal came within the exclusion zone for two airguns.

Ramp-up Procedures—Ramp-up of an airgun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of airguns firing until the full volume of the airgun array is achieved. The purpose of a ramp-up is to ''warn'' marine mammals in the vicinity of the airguns and to provide the time for them to leave the area, avoiding any potential injury or impairment of their hearing abilities. SIO will follow a ramp-up procedure when the airgun array begins operating after a specified period without airgun operations or when a shut-down has exceeded that period. For the present cruise, this period will be approximately 15 minutes. SIO, L–DEO, USGS, NSF, and ASC have used similar periods (approximately 15 minutes) during previous low-energy seismic surveys.

Ramp-up will begin with a single GI airgun (45 in^3). The second GI airgun (45 in^3) will be added after 5 minutes. During ramp-up, the PSOs will monitor the exclusion zone, and if marine mammals are sighted, a shut-down will be implemented as though both GI airguns were operational.

If the complete exclusion zone has not been visible for at least 30 minutes prior to the start of operations in either daylight or nighttime, SIO will not commence the ramp-up. Given these provisions, it is likely that the airgun array will not be ramped-up from a complete shut-down during low light conditions, at night, or in thick fog, (*i.e.,* poor visibility conditions) because the outer part of the exclusion zone for that array will not be visible during those conditions. If one airgun has been operating, ramp-up to full power will be permissible during low light, at night, or in poor visibility, on the assumption that marine mammals will be alerted to the approaching seismic vessel by the sounds from the single airgun and could move away if they choose. SIO will not initiate a ramp-up of the airguns if a marine mammal is sighted within or near the applicable exclusion zones during day or night. NMFS refers the reader to Figure 2, which presents a flowchart representing the ramp-up and shut-down protocols described in this notice.

Figure 2. Current mitigation procedures for low-energy seismic surveys.



[1] Ramp-Up Procedures
SIO has used similar periods (15 minutes) for previous low-energy seismic surveys. Ramp-up would not occur if a marine mammal has not cleared the exclusion zone for the full airgun array.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's mitigation measures and has considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. NMFS's evaluation of potential measures included consideration of the following factors in relation to one another:

(1) The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;

(2) The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and

(3) The practicability of the measure for applicant implementation including consideration of personnel safety, practicality of implementation, and

impact on the effectiveness of the activity.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

(1) Avoidance of minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).

(2) A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of airguns, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(3) A reduction in the number of time (total number or number at biologically important time or location) individuals would be exposed to received levels of airguns, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).

(4) A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of airguns, or other activities, or other activities expected to result in the take of marine mammals (this goal may contribute to a, above, or to reducing the severity of harassment takes only).

(5) Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.

(6) For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more effective implementation of the mitigation.

Based on NMFS's evaluation of the applicant's measures, as well as other measures considered by NMFS or recommended by the public, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking.'' The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for IHAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the action area. SIO submitted a marine mammal monitoring plan as part of the IHA application. It can be found in Section 13 of the IHA application. The plan has not been modified or supplemented between the notice of the proposed IHA (80 FR 15060, March 20, 2015) and this notice announcing the issuance of the IHA, as none of the comments or new information received from the public during the public comment period required a change to the plan.

Monitoring measures prescribed by NMFS should accomplish one or more of the following general goals:

(1) An increase in the probability of detecting marine mammals, both within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general to generate more data to contribute to the analyses mentioned below;

(2) An increase in our understanding of how many marine mammals are likely to be exposed to levels of sound (airguns) that we associate with specific adverse effects, such as behavioral harassment, TTS, or PTS;

(3) An increase in our understanding of how marine mammals respond to stimuli expected to result in take and how anticipated adverse effects on individuals (in different ways and to varying degrees) may impact the population, species, or stock (specifically through effects on annual rates of recruitment or survival) through any of the following methods:

- Behavioral observations in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information);
- Physiological measurements in the presence of stimuli compared to observations in the absence of stimuli (need to be able to accurately predict received level, distance from source, and other pertinent information); and
- Distribution and/or abundance comparisons in times or areas with concentrated stimuli versus times or areas without stimuli

(4) An increased knowledge of the affected species; and

(5) An increase in our understanding of the effectiveness of certain mitigation and monitoring measures.

Monitoring

SIO will conduct marine mammal monitoring during the low-energy seismic survey, in order to implement the mitigation measures that require real-time monitoring and to satisfy the monitoring requirements of the IHA. SIO's ''Monitoring Plan'' is described below this section. The monitoring work described here has been planned as a self-contained project independent of any other related monitoring projects that may be occurring simultaneously in the same regions. SIO is prepared to discuss coordination of their monitoring program with any related work that might be done by other groups insofar as this is practical and desirable.

Vessel-Based Visual Monitoring

SIO's PSOs will be based aboard the seismic source vessel and will watch for marine mammals near the vessel during daytime airgun operations and during any ramp-ups of the airguns at night. PSOs will also watch for marine mammals near the seismic vessel for at least 30 minutes prior to the start of airgun operations and after an extended shut-down (*i.e.,* greater than approximately 15 minutes for this low-energy seismic survey). When feasible, PSOs will conduct observations during daytime periods when the seismic system is not operating (such as during transits) for comparison of sighting rates and behavior with and without airgun operations and between acquisition periods. Based on PSO observations, the airguns will be shut-down when marine mammals are observed within or about to enter a designated exclusion zone.

During airgun operations in the Southwest Pacific Ocean, East of New Zealand, at least three PSOs will be based aboard the *Revelle.* At least one PSO will stand watch at all times while the *Revelle* is operating airguns during the low-energy seismic survey; this procedure would also be followed when the vessel is in transit. SIO will appoint the PSOs with NMFS's concurrence. The lead PSO will be experienced with marine mammal species in the Pacific Ocean and/or off the east coast of New Zealand, the second and third PSOs would receive additional specialized training from the lead PSO to ensure that they can identify marine mammal species commonly found in the Southwest Pacific Ocean. Observations will take place during ongoing daytime operations and ramp-ups of the airguns. During the majority of seismic operations, at least one PSO will be on

duty from observation platforms (*i.e.,* the best available vantage point on the source vessel) to monitor marine mammals near the seismic vessel. PSO(s) will be on duty in shifts no longer than 4 hours in duration. Other crew will also be instructed to assist in detecting marine mammals and implementing mitigation requirements (if practical). Before the start of the low-energy seismic survey, the crew will be given additional instruction on how to do so.

The *Revelle* is a suitable platform for marine mammal observations and will serve as the platform from which PSOs will watch for marine mammals before and during airgun operations. The *Revelle* has been used for marine mammal observations during the routine California Cooperative Oceanic Fisheries Investigations (CalCOFI). Two locations are likely as observation stations onboard the *Revelle*. Observing stations are located at the 02 level, with PSO eye level at approximately 10.4 m (34 ft) above the waterline and the PSO will have a good view around the entire vessel. At a forward-centered position on the 02 deck, the view is approximately 240° around the vessel; and one atop the aft hangar, with an aft-centered view includes the 100 m radius around the GI airguns. The PSO eye level on the bridge is approximately 15 m (49.2 ft) above sea level. PSOs will work on the enclosed bridge and adjoining aft steering station during any inclement weather.

Standard equipment for PSOs will be reticle binoculars and optical range finders. Night-vision equipment will be available at night and low-light conditions during the cruise. The PSOs will be in communication with ship's officers on the bridge and scientists in the vessel's operations laboratory, so they can advise promptly of the need for avoidance maneuvers or seismic source shut-down. During daylight, the PSO(s) will scan the area around the vessel systematically with reticle binoculars (*e.g.,* 7 × 50 Fujinon FMTRC–SX), Big-eye binoculars (*e.g.,* 25 × 150 Fujinon MT), optical range-finders (to assist with distance estimation), and the naked eye. These binoculars will have a built-in daylight compass. Estimating distances is done primarily with the reticles in the binoculars. The optical range-finders are useful in training PSOs to estimate distances visually, but are generally not useful in measuring distances to animals directly. At night, night-vision equipment will be available. The PSO(s) will be in direct (radio) wireless communication with ship's officers on the bridge and scientists in the vessel's operations laboratory during seismic operations, so they can advise the vessel operator, science support personnel, and the science party promptly of the need for avoidance maneuvers or a shut-down of the seismic source.

When a marine mammal is detected within or about to enter the designated exclusion zone, the airguns will immediately be shut-down, unless the vessel's speed and/or course can be changed to avoid having the animal enter the exclusion zone. The PSO(s) will continue to maintain watch to determine when the animal is outside the exclusion zone by visual confirmation. Airgun operations will not resume until the animal is confirmed to have left the exclusion zone, or is not observed after 15 minutes for species with shorter dive durations (small odontocetes and pinnipeds) or 30 minutes for species with longer dive durations (mysticetes and large odontocetes, including sperm, dwarf and pygmy sperm, killer, and beaked whales).

PSO Data and Documentation

PSOs will record data to estimate the numbers of marine mammals exposed to various received sound levels and to document apparent disturbance reactions or lack thereof. Data will be used to estimate numbers of animals potentially ''taken'' by harassment. They will also provide information needed to order a shut-down of the airguns when a marine mammal is within or near the exclusion zone. Observations will also be made during daylight periods when the *Revelle* is underway without seismic airgun operations (*i.e.,* transits to, from, and through the study area) to collect baseline biological data.

When a sighting is made, the following information about the sighting will be recorded:

1. Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from seismic vessel, sighting cue, apparent reaction to the seismic source or vessel (*e.g.,* none, avoidance, approach, paralleling, etc.), and behavioral pace.

2. Time, location, heading, speed, activity of the vessel (including number of airguns operating and whether in state of ramp-up or shut-down), sea state, wind force, visibility, cloud cover, and sun glare.

The data listed under (2) will also be recorded at the start and end of each observation watch, and during a watch whenever there is a change in one or more of the variables.

All observations, as well as information regarding ramp-ups or shut-downs, will be recorded in a standardized format. Data will be entered into an electronic database. The data accuracy will be verified by computerized data validity checks as the data are entered and by subsequent manual checking of the database by the PSOs at sea. These procedures will allow initial summaries of data to be prepared during and shortly after the field program, and will facilitate transfer of the data to statistical, graphical, and other programs for further processing and archiving.

Results from the vessel-based observations will provide the following information:

1. The basis for real-time mitigation (airgun shut-down).

2. Information needed to estimate the number of marine mammals potentially taken by harassment, which must be reported to NMFS.

3. Data on the occurrence, distribution, and activities of marine mammals in the area where the seismic study is conducted.

4. Information to compare the distance and distribution of marine mammals relative to the source vessel at times with and without airgun operations.

5. Data on the behavior and movement patterns of marine mammals seen at times with and without airgun operations.

Reporting

SIO will submit a comprehensive report to NMFS and NSF within 90 days after the end of the cruise. The report will describe the operations that were conducted and sightings of marine mammals near the operations. The report submitted to NMFS and NSF will provide full documentation of methods, results, and interpretation pertaining to all monitoring. The 90-day report would summarize the dates and locations of airgun operations and all marine mammal sightings (*i.e.,* dates, times, locations, activities, and associated seismic survey activities). The report will include, at a minimum:

- Summaries of monitoring effort—total hours, total distances, and distribution of marine mammals through the study period accounting for Beaufort sea state and other factors affecting visibility and detectability of marine mammals;
- Analyses of the effects of various factors influencing detectability of marine mammals including Beaufort sea state, number of PSOs, and fog/glare;
- Species composition, occurrence, and distribution of marine mammals sightings including date, water depth, numbers, age/size/gender, and group

sizes, and analyses of the effects of airgun operations;

- Sighting rates of marine mammals during periods with and without airgun operations (and other variables that could affect detectability);
- Initial sighting distances versus airgun operations state;
- Closest point of approach versus airgun operations state;
- Observed behaviors and types of movements versus airgun operations activity state;
- Numbers of sightings/individuals seen versus airgun operations state; and
- Distribution around the source vessel versus airgun operations state.

The report will also include estimates of the number and nature of exposures that could result in ''takes'' of marine mammals by harassment or in other ways. NMFS will review the draft report and provide any comments it may have, and SIO will incorporate NMFS's comments and prepare a final report. After the report is considered final, it would be publicly available on the NMFS Web site at: *http://www.nmfs.noaa.gov/pr/permits/incidental/*.

Reporting Prohibited Take—In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), SIO will immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov*. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with SIO to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. SIO may not resume their activities until notified by NMFS via letter or email, or telephone.

Reporting an Injured or Dead Marine Mammal with an Unknown Cause of Death—In the event that SIO discover an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition), SIO shall immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov*. The report must include the same information identified in the paragraph above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS shall work with SIO to determine whether modifications in the activities are appropriate.

Reporting an Injured or Dead Marine Mammal Not Related to the Activities—In the event that SIO discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate or advanced decomposition, or scavenger damage), SIO shall report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Howard.Goldstein@noaa.gov*, within 24 hours of discovery. SIO shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS. Activities may continue while NMFS reviews the circumstances of the incident.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

TABLE 4—NMFS'S CURRENT UNDERWATER ACOUSTIC EXPOSURE CRITERIA

[Impulsive (non-explosive) sound]

Criterion	Criterion definition	Threshold
Level A harassment (injury)	Permanent threshold shift (PTS) (Any level above that which is known to cause TTS).	180 dB re 1 μPa-m (root means square [rms]) (cetaceans). 190 dB re 1 μPa-m (rms) (pinnipeds).
Level B harassment	Behavioral disruption (for impulsive noise)	160 dB re 1 μPa-m (rms).
Level B harassment	Behavioral disruption (for continuous noise)	120 dB re 1 μPa-m (rms).

Level B harassment is anticipated and authorized as a result of the low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand. Acoustic stimuli (*i.e.,* increased underwater sound) generated during the operation of the seismic airgun array are expected to result in the behavioral disturbance of some marine mammals. NMFS's current underwater exposure criteria for impulsive sound are detailed in Table 4 (above). There is no evidence that the planned activities could result in injury, serious injury, or mortality. The required mitigation and monitoring measures will minimize any potential risk for injury, serious injury, or mortality.

The following sections describe SIO's methods to estimate take by incidental harassment and present the applicant's estimates of the numbers of marine mammals that could be affected. The estimates are based on a consideration of the number of marine mammals that could be harassed during the approximately 135 hours and 1,250 km of seismic airgun operations with the two GI airgun array to be used.

Density Data

There are no known systematic aircraft- or ship-based surveys conducted for marine mammals stock assessments and very limited population information available for marine mammals in offshore waters of the Southwest Pacific Ocean off the east coast of New Zealand. For most cetacean species, SIO and NMFS used densities from extensive NMFS Southwest Fisheries Science Center (SWFSC) cruises (Ferguson and Barlow, 2001, 2003; Barlow, 2003, 2010; Forney, 2007) in one province of Longhurst's (2006) pelagic biogeography, the California Current Province (CALC). That province is similar to the South Subtropical Convergence Province (SSTC) in which the proposed low-energy seismic survey is located, in that productivity is high and large pelagic fish such as tuna occur. Specifically, SIO and NMFS used the 1986 to 1996 data from blocks 35, 36, 47, 48, 59, and 60 of Ferguson and Barlow (2001, 2003), the 2001 data from Barlow (2003) for the Oregon, Washington, and California strata, and the 2005 and 2008 data from Forney (2007) and Barlow (2010), respectively, for the two strata combined. The densities used were effort-weighted means for the 10 locations (blocks or States). The surveys off California, Oregon, and Washington were conducted up to approximately 556 km (300.2 nmi) offshore, and most of those data were from offshore areas that overlap with the above blocks selected from Ferguson and Barlow (2001, 2003).

For pinnipeds, SIO and NMFS used the densities in Bonnell *et al.* (1992) of northern fur seals (*Callorhinus ursinus*) and northern elephant seals in offshore areas of the western U.S. (the only species regularly present in offshore areas there) to estimate the numbers of pinnipeds that might be present off New Zealand.

The marine mammal species that will be encountered during the low-energy seismic survey will be different from those sighted during surveys off the western U.S. and in the Eastern Tropical Pacific Ocean. However, the overall abundances of species groups with generally similar habitat requirements are expected to be roughly similar. Thus, SIO and NMFS used the data described above to estimate the group densities of beaked whales, delphinids, small whales, and mysticetes in the proposed study area. SIO and NMFS then estimated the relative abundance of individual southern species within the species groups using various surveys and other information from areas near the study area, and general information on species' distributions such as latitudinal ranges and group sizes. Group densities from northern species were multiplied by their estimated relative abundance off New Zealand divided by the relative abundance for all species in the species group to derive estimates for the southern species (see Table 3 of the IHA application).

Densities for several cetacean species are available for the Southern Ocean (Butterworth *et al.,* 1994), as follows: (1) For humpback, sei, fin, blue, sperm, killer, and pilot whales in Antarctic Management areas I to VI south of 60° South, based on the 1978/1979 to 1984 and 1985/1986 to 1990/1991 IWC/IDCR circumpolar sighting survey cruises, and (2) for humpback, sei, fin, blue, and sperm whales extrapolated to latitudes 30 to 40° South, 40 to 50° South, 50 to 60° South based on Japanese scouting vessel data from 1965/1966 to 1977/1978 and 1978/1979 to 1987/1988. SIO and NMFS calculated densities based on abundance and surface areas given in Butterworth *et al.* (1994) and used the weighted or mean density for the Regions V and/or VI (whichever is available) due to locations that represent foraging areas or distributions for animals that are likely to move past New Zealand during northerly migrations or breed in New Zealand waters.

The densities used for purposes of estimating potential take do not take into account the patchy distributions of marine mammals in an ecosystem, at least on the moderate to fine scales over which they are known to occur. Instead, animals are considered evenly distributed throughout the assessed study area and seasonal movement patterns are not taken into account, as none are available. Although there is some uncertainty about the representativeness of the data and the assumptions used in the calculations below, the approach used here is believed to be the best available approach, using the best available science.

TABLE 5—ESTIMATED DENSITIES AND NUMBERS OF MARINE MAMMAL SPECIES THAT MIGHT BE EXPOSED TO GREATER THAN OR EQUAL TO 160 dB (AIRGUN OPERATIONS) DURING SIO'S LOW-ENERGY SEISMIC SURVEY (APPROXIMATELY 1,250 KM OF TRACKLINES/APPROXIMATELY 1,154 KM^2 ENSONIFIED AREA FOR AIRGUN OPERATIONS) IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND, MAY TO JUNE 2015

Species	Density U.S. West Coast/Southern Ocean/estimate used (# of animals/1,000 km^2) [1]	Calculated take from seismic airgun operations (*i.e.,* estimated number of individuals exposed to sound levels ≥160 dB re 1 μPa) [2]	Authorized take [3]	Abundance [4]	Approximate percentage of population estimate (authorized take) [5]	Population trend [6]
Mysticetes						
Southern right whale	0.98/NA/0.98	1.13	2	8,000 to 15,000—Worldwide. 12,000—Southern Hemisphere. 2,700—Sub-Antarctic New Zealand.	0.03—Worldwide 0.02—Southern Hemisphere. 0.07—Sub-Antarctic New Zealand.	Increasing at 7 to 8% per year.
Pygmy right whale	0.39/NA/0.39	0.45	2	NA	NA	NA.
Humpback whale.	0.98/0.25/0.25	0.29	2	35,000 to 42,000—Southern Hemisphere.	<0.01—Southern Hemisphere.	Increasing.
Antarctic minke whale	0.59/NA/0.59	0.68	2	720,000 to 750,000—Southern Hemisphere.	<0.01—Southern Hemisphere.	Stable.
Minke whale (including dwarf minke whale sub-species).	0.59/NA/0.59	0.68	2	720,000 to 750,000—Southern Hemisphere.	<0.01—Southern Hemisphere.	NA.

TABLE 5—ESTIMATED DENSITIES AND NUMBERS OF MARINE MAMMAL SPECIES THAT MIGHT BE EXPOSED TO GREATER THAN OR EQUAL TO 160 dB (AIRGUN OPERATIONS) DURING SIO'S LOW-ENERGY SEISMIC SURVEY (APPROXIMATELY 1,250 KM OF TRACKLINES/APPROXIMATELY 1,154 KM^2 ENSONIFIED AREA FOR AIRGUN OPERATIONS) IN THE SOUTHWEST PACIFIC OCEAN, EAST OF NEW ZEALAND, MAY TO JUNE 2015—Continued

Species	Density U.S. West Coast/Southern Ocean/estimate used (# of animals/1,000 km^2) [1]	Calculated take from seismic airgun operations (*i.e.,* estimated number of individuals exposed to sound levels ≥160 dB re 1 μPa) [2]	Authorized take [3]	Abundance [4]	Approximate percentage of population estimate (authorized take) [5]	Population trend [6]
Bryde's whale	0.20/NA/0.20	0.23	2	At least 30,000 to 40,000—Worldwide. 21,000—Northwestern Pacific Ocean 48,109.	<0.01—Worldwide <0.01—Northwestern Pacific Ocean. <0.01	NA.
Sei whale	0.59/0.08/0.08	0.09	2	80,000—Worldwide 10,000—South of Antarctic Convergence.	<0.01—Worldwide 0.02—South of Antarctic Convergence.	NA.
Fin whale	0.59/0.13/0.13	0.15	2	140,000—Worldwide 15,000—South of Antarctic Convergence.	<0.01—Worldwide 0.01—South of Antarctic Convergence.	NA.
Blue whale	0.59/0.05/0.05	0.06	2	8,000 to 9,000—Worldwide. 2,300—True Southern Hemisphere. 1,500—Pygmy	0.03—Worldwide 0.09—True Southern Hemisphere. 0.13—Pygmy	NA.
Odontocetes						
Sperm whale	1.62/1.16/1.16	1.34	10	360,000—Worldwide 30,000—South of Antarctic Convergence.	<0.01—Worldwide 0.03—South of Antarctic Convergence.	NA.
Pygmy sperm whale	0.97/NA/0.97	1.12	5	NA	NA	NA.
Arnoux's beaked whale	NA/NA/NA	NA	8	NA	NA	NA.
Cuvier's beaked whale	0.69/NA/0.69	0.80	2	600,000	<0.01	NA.
Shepherd's beaked whale.	0.46/NA/0.46	0.53	3	600,000	<0.01	NA.
Southern bottlenose whale.	0.46/NA/0.46	0.53	2	50,000—South of Antarctic Convergence 600,000.	<0.01—South of Antarctic Convergence. <0.01	NA.
Andrew's beaked whale	0.46/NA/0.46	0.53	2	600,000	<0.01	NA.
Blainville's beaked whale.	0.23/NA/0.23	0.27	2	600,000	<0.01	NA.
Gray's beaked whale	0.92/NA0.92	1.06	2	600,000	<0.01	NA.
Hector's beaked whale	0.46/NA/0.46	0.53	2	600,000	<0.01	NA.
Pygmy beaked whale	NA/NA/NA	NA	3	NA	NA	NA.
Spade-toothed beaked whale.	0.23/NA/0.23	0.27	2	600,000	<0.01	NA.
Strap-toothed beaked whale.	0.69/NA/0.69	0.80	3	600,000	<0.01	NA.
Killer whale	0.45/5.70/5.70	6.58	12	80,000—South of Antarctic Convergence.	0.02—South of Antarctic Convergence.	NA.
False killer whale	0.27/NA/0.27	0.31	10	NA	NA	NA.
Long-finned pilot whale	0.27/6.41/6.41	7.40	20	200,000—South of Antarctic Convergence.	0.01—South of Antarctic Convergence.	NA.
Short-finned pilot whale	0.45/NA/0.45	0.52	20	At least 600,000—Worldwide.	<0.01—Worldwide	NA.
Bottlenose dolphin	81.55/NA/81.55	94.11	95	At least 614,000—Worldwide.	0.02—Worldwide	NA.
Dusky dolphin	81.55/NA/81.55	94.11	95	12,000 to 20,000—New Zealand.	0.79—New Zealand	NA.
Hector's dolphin	32.62/NA/32.62	37.64	38	7,400	0.51	Declining.
Hourglass dolphin	48.93/NA/48.93	56.47	57	144,000 to 150,000—South of Antarctic Convergence.	0.04—South of Antarctic Convergence.	NA.
Risso's dolphin	NA/NA/NA	NA	10	At least 330,000—Worldwide.	<0.01—Worldwide	NA.
Short-beaked common dolphin.	163.10/NA/163.10	188.22	189	At least 3,500,000—Worldwide.	<0.01—Worldwide	NA.
Southern right whale dolphin.	48.93/NA/48.93	56.46	57	NA	NA	NA.
Pinnipeds						
Southern elephant seal	5.11/NA/5.11	5.90	6	640,000 to 650,000—Worldwide. 470,000—South Georgia Island 607,000.	<0.01—Worldwide or South Georgia Island.	Increasing, decreasing, or stable depending on breeding population.
New Zealand fur seal	12.79/NA/12.79	14.76	15	135,000—Worldwide 50,000 to 100,000—New Zealand.	0.01—Worldwide 0.03—New Zealand.	Increasing.

NA = Not available or not assessed.

[1] Densities based on sightings from NMFS SWFSC, IWC, and Bonnell *et al.* (2012) data.
[2] Calculated take is estimated density multiplied by the area ensonified to 160 dB (rms) around the seismic tracklines, increased by 25% for contingency.
[3] Adjusted to account for average group size.
[4] See population estimates for marine mammal species in Table 3 (above).
[5] Total authorized takes expressed as percentages of the species or regional populations.
[6] Jefferson *et al.* (2008).

Calculation

As described above, numbers of marine mammals that might be present and potentially disturbed are estimated based on the available data about marine mammal distribution and densities in the U.S. west coast and Southern Ocean as a proxy for the planned study area off the east coast of New Zealand. SIO then estimated the number of different individuals that may be exposed to airgun sounds with received levels greater than or equal to 160 dB re 1 μPa (rms) for seismic airgun operations on one or more occasions by considering the total marine area that would be within the 160 dB radius around the operating airgun array on at least one occasion and the expected density of marine mammals in the area (in the absence of the low-energy seismic survey). The number of possible exposures can be estimated by considering the total marine area that would be within the 160 dB radius (the diameter is 400 m multiplied by 2 for deep water depths, the diameter is 600 m multiplied by 2 for intermediate water depths) around the operating airguns, including areas of overlap. The spacing of tracklines is 500 m (1,640.4 ft) in the smaller grids and 1,250 m (4,101.1 ft) in the larger grids. Overlap was measured using GIS and was minimal (area with overlap is equal to 1.13 multiplied by the area without overlap). The take estimates were calculated without overlap. The 160 dB radii are based on acoustic modeling data for the airguns that may be used during the planned action (see SIO's IHA application). During the low-energy seismic survey, the transect lines are widely spaced relative to the 160 dB distance. As summarized in Table 3 (see Table 1 and Figure 2 of the IHA application), the modeling results for the low-energy seismic airgun array indicate the received levels are dependent on water depth. Since the majority of the planned airgun operations would be conducted in waters 100 to 1,000 m deep or greater than 1,000 m deep, the buffer zone of 600 m or 400 m, respectively, for the two 45 in^3 GI airguns was used.

The number of different individuals potentially exposed to received levels greater than or equal to 160 dB re 1 μPa (rms) from seismic airgun operations was calculated by multiplying:

(1) The expected species density (in number/km^2), times.

(2) The anticipated area to be ensonified to that level during airgun operations (excluding overlap).

The area expected to be ensonified to 160 dB (rms) was determined by entering the planned tracklines into MapInfo GIS using the GIS to identify the relevant areas by ''drawing'' the applicable 160 dB (rms) isopleth around each trackline, and then calculating the total area within the isopleth. Applying the approach described above, approximately 1,153.6 km^2 (including the 25% contingency [approximately 923 km^2 without contingency]) will be ensonified within the 160 dB isopleth for seismic airgun operations on one or more occasions during the planned low-energy seismic survey. The total ensonified area (1,154 km^2 [336.5 nmi^2]) was calculated by adding 847 km^2 (246.9 nmi^2) in deep water, 76 km^2 (22.2 nmi^2), and 230.8 km^2 (67.3 nmi^2) for the 25% contingency.

The take calculations do not explicitly add animals to account for ''turnover,'' the fact that new animals not accounted for in the initial density snapshot could also approach and enter the area ensonified above 160 dB for seismic airgun operations. However, studies suggest that many marine mammals will avoid exposing themselves to sounds at this level, which suggests that there would not necessarily be a large number of new animals entering the area once the seismic survey started. Because this approach for calculating take estimates does not account for turnover in the marine mammal populations in the area during the course of the planned low-energy seismic survey, the actual number of individuals exposed may be underestimated. However, any underestimation is likely offset by the conservative (*i.e.,* probably overestimated) line-kilometer distances (including the 25% contingency) used to calculate the survey area, and the fact that the approach assumes no cetaceans or pinnipeds would move away from or toward the tracklines as the *Revelle* approaches in response to increasing sound levels before the levels reach 160 dB for seismic airgun operations, which is likely to occur and would decrease the density of marine mammals in the survey area. Another way of interpreting the estimates in Table 5 is that they represent the number of individuals that would be expected (in absence of a seismic program) to occur in the waters that would be exposed to greater than or equal to 160 dB (rms) for seismic airgun operations.

SIO's estimates of exposures to various sound levels assume that the planned low-energy seismic survey will be carried out in full; however, the ensonified areas calculated using the planned number of line-kilometers has been increased by 25% to accommodate lines that may need to be repeated, equipment testing, etc. As is typical during offshore seismic surveys, inclement weather and equipment malfunctions would be likely to cause delays and may limit the number of useful line-kilometers of airgun operations that can be undertaken. The estimates of the numbers of marine mammals potentially exposed to 160 dB (rms) received levels are precautionary and probably overestimate the actual numbers of marine mammals that could be involved. These estimates assume that there will be no weather, equipment, or mitigation delays that limit the airgun operations, which is highly unlikely.

Table 5 shows the estimates of the number of different individual marine mammals anticipated to be exposed to greater than or equal to 160 dB re 1 μPa (rms) for seismic airgun operations during the low-energy seismic survey if no animals moved away from the survey vessel. The total authorized take is presented in column 4 of Table 5.

Encouraging and Coordinating Research

SIO and NSF will coordinate the planned marine mammal monitoring program associated with the low-energy seismic survey with other parties that express interest in this activity and area. SIO and NSF will coordinate with applicable U.S. agencies (*e.g.,* NMFS) and the government of New Zealand, and will comply with their requirements. The planned low-energy seismic survey falls under Level 3 of the ''Code of Conduct for minimizing acoustic disturbance to marine mammals from seismic survey operations'' issued by New Zealand. Level 3 seismic surveys are exempt from the provisions of the Code of Conduct.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) of the MMPA also requires NMFS to determine that the authorization will not have an unmitigable adverse impact on the availability of marine mammal species or stocks for subsistence use. There are no relevant subsistence uses of marine mammals implicated by this action (in the Southwest Pacific Ocean, East of New Zealand study area). Therefore, NMFS has determined that the total taking of affected species or stocks will not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Analysis and Determinations

Negligible Impact

Negligible impact is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.) and the context of any responses (critical reproductive time or location, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

In making a negligible impact determination, NMFS evaluates factors such as:

(1) The number of anticipated serious injuries and or mortalities;

(2) The number and nature of anticipated injuries;

(3) The number, nature, intensity, and duration of takes by Level B harassment (all of which are relatively limited in this case);

(4) The context in which the takes occur (*e.g.,* impacts to areas of significance, impacts to local populations, and cumulative impacts when taking into account successive/contemporaneous actions when added to baseline data);

(5) The status of stock or species of marine mammals (*e.g.,* depleted, ESA-listed, decreasing, increasing, stable, impact relative to the size of the population);

(6) Impacts on habitat affecting rates of recruitment/survival; and

(7) The effectiveness of monitoring and mitigation measures.

To avoid repetition, the discussion of NMFS's analyses applies to all the species or stocks for which take is being authorized (listed in Table 5), given that the anticipated effects of this short duration low-energy seismic survey on marine mammals are expected to be relatively similar in nature in this case. Additionally, there is no information about the size, status, or structure of any species or stock that would lead to a different analysis for this activity. NMFS has determined that the specified activities associated with the low-energy seismic survey are not likely to cause long-term behavioral disturbance, PTS, or other (non-auditory) injury, serious injury, or death, based on the analysis contained in the notice of the proposed IHA (80 FR 15060, March 20, 2015). NMFS also considered the following factors:

(1) The anticipated impacts of SIO and NSF's low-energy seismic survey on marine mammals are temporary behavioral changes due to avoidance of the action area.

(2) The likelihood that marine mammals approaching the action area will be traveling through the area or opportunistically foraging within the vicinity, as no known breeding, calving, pupping, nursing areas, or haul-outs, overlap with the action area.

(3) The likelihood that, given sufficient notice through relatively slow ship speed, marine mammals are expected to move away from a noise source that is annoying prior to its becoming potentially injurious;

(4) The availability of alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the operation of the airgun(s) to avoid acoustic harassment;

(5) The expectation that the low-energy seismic survey would have not more than a temporary and minimal adverse effect on any fish or invertebrate species that serve as prey species for marine mammals, and therefore consider the potential impacts to marine mammal habitat minimal.

(6) The relatively low potential for temporary or permanent hearing impairment and the likelihood that it would avoided through the implementation of the required monitoring and mitigation measures (including shut-down measures); and

(7) The high likelihood that trained PSOs would detect marine mammals at close proximity to the vessel.

No injuries, serious injuries, or mortalities are anticipated to occur as a result of the SIO's planned low-energy seismic survey, and none are authorized by NMFS. NMFS anticipates only behavioral disturbance to occur primarily in the form of avoidance behavior to the sound source during the conduct of the low-energy seismic survey. Table 5 of this document outlines the number of authorized Level B harassment takes that are anticipated as a result of these activities. Due to the nature, degree, and context of Level B (behavioral) harassment anticipated and described in the notice of the proposed IHA (80 FR 15060, March 20, 2015 (see ''Potential Effects on Marine Mammals'' section above), NMFS does not expect Level B harassment to affect the ability of marine mammals to survive or reproduce. Additionally, the low-energy seismic survey will not adversely impact marine mammal habitat.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (*i.e.,* 24 hr cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). While airgun operations are anticipated to occur on consecutive days, the estimated duration of the survey would not last more than a total of approximately 27 operational days, with only a total of approximately 135 hours, meaning that the airgun operations will not be continuous for more than approximately 72 hours at time during the May to June 2015 time period. Additionally, the low-energy seismic survey will be increasing sound levels in the marine environment in a relatively small area surrounding the vessel (compared to the range of the animals), and constantly travelling over distances, so individual animals likely will only be exposed to and harassed by sound for less than a day.

As mentioned previously, NMFS estimates that 35 species of marine mammals under its jurisdiction could be potentially affected by Level B harassment over the course of the IHA. The population estimates for the marine mammal species that may be taken by Level B harassment were provided in Table 2 and 5 of this document. As shown in those tables, the authorized takes represent small proportions of the overall populations of these marine mammal species where abundance

estimates are available (*i.e.,* less than 1%).

Of the 35 marine mammal species under NMFS jurisdiction that may or are known to likely occur in the study area, six are listed as threatened or endangered under the ESA: Southern right, humpback, sei, fin, blue, and sperm whales. These species are also considered depleted under the MMPA. None of the other marine mammal species that may be taken are listed as depleted under the MMPA. Of the ESA-listed species, incidental take has been authorized for six species. As mitigation to reduce impacts to the affected species or stocks, SIO will be required to cease airgun operations if any marine mammal enters designated exclusion zones. No injury, serious injury, or mortality is expected to occur for any of these species, and due to the nature, degree, and context of the Level B harassment anticipated, and the activity is not expected to impact rates of recruitment or survival for any of these species.

NMFS has determined that, provided that the aforementioned mitigation and monitoring measures are implemented, the impact of conducting a low-energy marine seismic survey in the Southwest Pacific Ocean, May to June 2015, may result, at worst, in a modification in behavior and/or low-level physiological effects (Level B harassment) of certain species of marine mammals.

While behavioral modifications, including temporarily vacating the area during the operation of the airgun(s), may be made by these species to avoid the resultant acoustic disturbance, the availability of alternate areas for species to move to and the short and sporadic duration of the research activities, have led NMFS to determine that the taking by Level B harassment from the specified activity will have a negligible impact on the affected species in the specified geographic region. Due to the nature, degree, and context of Level B (behavioral) harassment anticipated and described (see ''Potential Effects on Marine Mammals'' section above) in this notice, the specified activity is not expected to impact rates of annual recruitment or survival for any affected species or stock, particularly given the required mitigation, monitoring, and reporting measures to minimize impacts. Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the required monitoring and mitigation measures, NMFS finds that the total marine mammal take from SIO's low-energy seismic survey will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers

As mentioned previously, NMFS estimates that 35 species of marine mammals under its jurisdiction could be potentially affected by Level B harassment over the course of the IHA. The population estimates for the marine mammal species that may be taken by Level B harassment were provided in Tables 2 and 5 of this document.

The estimated numbers of individual cetaceans and pinnipeds that could be exposed to seismic sounds with received levels greater than or equal to 160 dB re 1 μPa (rms) during the low-energy seismic survey (including a 25% contingency) are in Table 5 of this document. Of the cetaceans, 2 southern right, 2 pygmy right, 2 humpback, 2 Antarctic minke, 2 minke, 2 Bryde's, 2 sei, 2 fin, 2 blue, and 10 sperm whales could be taken by Level B harassment during the planned low-energy seismic survey, which would represent 0.03, unknown, 0.1, less than 0.01, less than 0.01, less than 0.01, less than 0.01, less than 0.01, 0.03, and 0.03% of the affected worldwide or regional populations, respectively. In addition, 5 pygmy sperm, 8 Arnoux's beaked, 2 Cuvier's beaked, 3 Shepherd's beaked, 2 southern bottlenose, 2 Andrew's beaked, 2 Blainville's beaked, 2 Gray's beaked, 2 Hector's beaked, 3 pygmy beaked, 2 spade-toothed beaked, and 3 strap-toothed beaked could be taken be Level B harassment during the planned low-energy seismic survey, which would represent unknown, unknown, less than 0.01, less than 0.01, less than 0.01, less than 0.01, less than 0.01, less than 0.01, less than 0.01, unknown, less than 0.01, and less than 0.01% of the affected worldwide or regional populations, respectively. Of the delphinids, 12 killer whales, 10 false killer whales, 20 long-finned pilot whales, 20 short-finned pilot whales, 95 bottlenose dolphins, 95 dusky dolphins, 38 Hector's dolphins, 57 hourglass dolphins, 10 Risso's dolphins, 189 short-beaked common dolphins, and 57 southern right whale dolphins could be taken by Level B harassment during the planned low-energy seismic survey, which would represent 0.02, unknown, 0.01, less than 0.01, 0.02, 0.79, 0.51, 0.04, less than 0.01, less than 0.01, and unknown of the affected worldwide or regional populations, respectively. Of the pinnipeds, 15 New Zealand fur seals and 6 southern elephant seals could be taken by Level B harassment during the planned low-energy seismic survey, which would represent 0.01 and less than 0.01 of the affected worldwide or regional population, respectively.

No known current worldwide or regional population estimates are available for 6 species under NMFS's jurisdiction that could potentially be affected by Level B harassment over the course of the IHA. These species are the pygmy right, pygmy sperm, Arnoux's beaked, pygmy beaked, and false killer whales and southern right whale dolphins. Pygmy right whales have a circumglobal distribution and occur throughout coastal and oceanic waters in the Southern Hemisphere (between 30 to 55° South) (Jefferson *et al.,* 2008). Pygmy sperm whales occur in deep waters on the outer continental shelf and slope in tropical to temperate waters of the Atlantic, Indian, and Pacific Oceans. Arnoux's beaked whales occur in deep, cold, temperate, and subpolar waters of the Southern Hemisphere (most south of 40° South) (Jefferson *et al.,* 2008). Pygmy beaked whales occur in deep waters beyond the continental shelf in tropical/warm temperate waters of the Pacific Ocean (between 28° North to 30° South) (Jefferson *et al.,* 2008). False killer whales generally occur in deep offshore tropical to temperate waters (between 50° North to 50° South) of the Atlantic, Indian, and Pacific Oceans (Jefferson *et al.,* 2008). Southern right whale dolphins have a circumpolar distribution and generally occur in deep temperate to sub-Antarctic waters in the Southern Hemisphere (between 30 to 65° South) (Jefferson *et al.,* 2008). Based on these broad distributions and preferences of these species relative to the area where the specified activity will occur, NMFS concludes that the authorized take of these species likely represent small numbers relative to the affected species' overall population sizes, even though we are unable to quantify the take numbers.

NMFS makes its small numbers determination based on the numbers or proportion of marine mammals that will be taken relative to the populations of the affected species or stocks. The authorized take estimates all represent small numbers relative to the affected species or stock size (*i.e.,* less than 1%), with the exception of the six species (*i.e.,* pygmy right, pygmy sperm, Arnoux's beaked, pygmy beaked, and false killer whales and southern right whale dolphins) for which a qualitative rationale was provided.

Endangered Species Act

Of the species of marine mammals that may occur in the planned survey area, six are listed as endangered under the ESA: The southern right, humpback,

sei, fin, blue, and sperm whales. Under section 7 of the ESA, NSF, on behalf of SIO, initiated formal consultation with the NMFS, Office of Protected Resources, Endangered Species Act Interagency Cooperation Division, on this low-energy seismic survey. NMFS's Office of Protected Resources, Permits and Conservation Division, initiated and engaged in formal consultation under section 7 of the ESA with NMFS's Office of Protected Resources, Endangered Species Act Interagency Cooperation Division, on the issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. These two consultations were consolidated and addressed in a single Biological Opinion addressing the direct and indirect effects of these independent actions. In May 2015, NMFS issued a Biological Opinion that concluded that the action is not likely to jeopardize the continued existence of the six listed cetaceans that may occur in the study area and included an Incidental Take Statement (ITS) incorporating the requirements of the IHA as Terms and Conditions of the ITS. Compliance with those Terms and Conditions is likewise a mandatory requirement of the IHA. The Biological Opinion also concluded that designated critical habitat of these species does not occur in the action area and would not be affected by the low-energy seismic survey.

National Environmental Policy Act

With SIO's complete IHA application, NSF and SIO provided NMFS an *Environmental Analysis of a Low-Energy Marine Geophysical Survey by the R/V Roger Revelle in the Southwest Pacific Ocean, East of New Zealand, May to June 2015,* (Environmental Analysis), prepared by LGL Limited, Environmental Research Associates, on behalf of NSF and SIO. The Environmental Analysis analyzes the direct, indirect, and cumulative environmental impacts of the planned specified activities on marine mammals, including those listed as threatened or endangered under the ESA. NMFS, after independently reviewing and evaluating the document for sufficiency and compliance with Council on Environmental Quality (CEQ) NEPA regulations and NOAA Administrative Order 216–6 § 5.09(d), conducted a separate NEPA analysis and prepared an *Environmental Assessment on the Issuance of an Incidental Harassment Authorization to the Scripps Institution of Oceanography to Take Marine Mammals by Harassment Incidental to a Low-Energy Marine Geophysical Survey in the Southwest Pacific Ocean, East of New Zealand, May to June 2015.* This process included a public review period. Following completion of our EA, NMFS has determined that the issuance of the IHA is not likely to result in significant impacts on the human environment and issued a Finding of No Significant Impact (FONSI).

Authorization

NMFS has issued an IHA to SIO for conducting a low-energy seismic survey in the Southwest Pacific Ocean, East of New Zealand, incorporating the previously mentioned mitigation, monitoring, and reporting requirements.

Dated: May 15, 2015.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–12531 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

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: Western Pacific Community Development Program Process.

OMB Control Number: 0648-0612.

Form Number(s): None.

Type of Request: Regular (revision and extension of a currently approved information collection).

Number of Respondents: 5.

Average Hours per Response: 6 hours.

Burden Hours: 30.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

The Federal regulations at 50 CFR part 665 authorize the Regional Administrator of the National Marine Fisheries Service (NMFS), Pacific Island Region to provide eligible western Pacific communities with access to fisheries that they have traditionally depended upon, but may not have the capabilities to support continued and substantial participation, possibly due to economic, regulatory, or other barriers. To be eligible to participate in the western Pacific community development program, a community must meet the criteria set forth in 50 CFR part 665.20, and submit a community development plan that describes the purposes and goals of the plan, the justification for proposed fishing activities, and the degree of involvement by the indigenous community members, including contact information.

This collection of information provides NMFS and the Western Pacific Fishery Management Council (Council) with data to determine whether a community that submits a community development plan meets the regulatory requirements for participation in the program, and whether the activities proposed under the plan are consistent with the intent of the program, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable laws. The information is also important for evaluating potential impacts of the proposed community development plan activities on fish stocks, endangered species, marine mammals, and other components of the affected environment for the purposes of compliance with the National Environmental Policy Act, the Endangered Species Act and other applicable laws.

Affected Public: Business or other for profit organizations; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

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* or fax to (202) 395–5806.

Dated: May 19, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–12460 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD957

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Monday, June 8, 2015 through Thursday, June 11, 2015. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at: Hilton Virginia Beach Oceanfront, 3001 Atlantic Avenue, Virginia Beach, VA 23451, telephone: (757) 213–3000.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D. Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's Web site when possible.)

Monday, June 8, 2015

9 a.m.

Council Convenes

9 a.m.–12 p.m.

Species Interactions Workshop

—A workshop to convene scientists and managers to discuss potential strategies to fully consider species interactions and climate drivers in the stock assessment process, determination of catch limits, and to build capacity within the region to conduct comprehensive management strategy evaluations (MSEs).

1:30 p.m.–4:30 p.m.

Species Interactions Workshop (continued)

Tuesday, June 9, 2015

9 a.m.–11 a.m.

Mackerel, Squid, Butterfish Committee, Meeting as a Committee of the Whole

—Review SSC, Advisory Panel, Monitoring Committee, and staff recommendations
—Develop Council preferred alternatives for:
- 2016 squid and butterfish specifications (only if changes are necessary)
- 2016–2018 mackerel specifications
- Associated mackerel, squid, butterfish management measures

11 a.m.–12 p.m.

Mackerel, Squid, Butterfish Committee, Meeting as a Committee of the Whole (continued)

—Review squid amendment scoping comments
—Provide guidance to staff regarding amendment development

1 p.m.–2 p.m.

River Herring and Shad Committee, Meeting as a Committee of the Whole

—Review and develop recommendations for the river herring and shad cap (2016–2018)
—Review progress on river herring and shad conservation

2 p.m.

Council Convenes

2 p.m.–3:30 p.m.

Surfclam and Ocean Quahog Specifications

—Review SSC, Advisory Panel, and staff recommendations for 2016 specifications
—Recommend any changes if necessary

3:30 p.m.–4 p.m.

National Standard 1, 3, 7 Guidelines

—Review draft comment letter on proposed revisions

4 p.m.–4:30 p.m.

Commercial Fishery Mapping in support of Regional Ocean planning: Northeast Regional Ocean Council—George Lapointe

4:30 p.m.–5:30 p.m.

Listening Session—Proposed Rule To Revise Listing Status of Humpback Whales—David Gouveia

Wednesday, June 10, 2015

9 a.m.

Council Convenes

9 a.m.–12 p.m.

Deep Sea Corals Amendment

—Summary of April Deep Sea Corals Workshop
—Select preferred alternatives for submission to NMFS

1 p.m.–3 p.m.

Deep Sea Coral Amendment (continued)

3 p.m.–4 p.m.

Unmanaged Forage Fish Action

—Update on progress
—Review and approve scoping document

4 p.m.–5 p.m.

Framework 9 to Monkfish

—Approve Framework 9 to the Monkfish Fishery Management Plan

Thursday, June 11, 2015

9 a.m.

Council Convenes

9 a.m.–9:30 a.m.

Cooperative Research

—Review and discuss Cooperative Research Committee Report

9:30 a.m.–10 a.m.

Guidelines for SAW Working Group Formation and Participation—Jim Weinberg

10 a.m.–10:30 a.m.

Trawl Survey Advisory Panel Formation—Bill Karp

10 a.m.–1 p.m.

Business Session

Organization Reports

—NMFS Greater Atlantic Regional Office
—NMFS Northeast Fisheries Science Center
—NOAA Office of General Counsel
—NOAA Office of Law Enforcement
—U.S. Coast Guard
—Atlantic States Marine Fisheries Commission
—Liaison Reports
- New England Council
- South Atlantic Council

—Executive Director's Report, *Chris Moore*
—Science Report, *Rich Seagraves*
—Committee Reports
- SSC Report

—Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities.

Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12494 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD896

Magnuson-Stevens Fishery Conservation and Management Act; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permit

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

ACTION: Notice; request for comments.

SUMMARY: The Regional Administrator, NMFS West Coast Region, has determined that four applications for exempted fishing permits (EFPs) warrant further consideration, and requests public comment on the applications. The applications request 2-year exemptions from various prohibitions under the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species (HMS FMP) to test the effects and efficacy of using deep-set buoy gear and longline gear to fish for swordfish and other highly migratory species (HMS) off the West Coast.

DATES: Comments must be submitted in writing by June 22, 2015.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0063, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0063,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments. EFP applications will be available under Relevant Documents through the same link.
- *Mail:* Attn: Chris Fanning, NMFS West Coast Region, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2015–0063'' in the comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Chris Fanning, NMFS, West Coast Region, 562–980–4198.

SUPPLEMENTARY INFORMATION: On July 2, 2014, the Pacific Fishery Management Council (Council) solicited EFP proposals to test alternative gears and/or new approaches or methods for the California large-mesh drift gillnet fishery to target swordfish and other HMS. Applications for EFPs were submitted on February 9, 2015, to the Council for consideration during the March 2015 meeting (Agenda H.3, *http://www.pcouncil.org/resources/archives/briefing-books/march-2015-briefing-book/#hmsMar2015*). On March 20, 2015, the Council made recommendations to NMFS to consider issuing EFPs for three proposals to use deep-set buoy gear (DSBG—multiple hooks deployed relatively deep in the water column, using one or more weighted mainlines which are suspended with one or more buoys floating on the ocean surface) and a single proposal to use deep-set and shallow-set longline gear in the exclusive economic zone (EEZ) off of the West Coast of the United States. If approved, the EFPs would exempt a limited number of federally permitted commercial fishing vessels from requirements of the HMS FMP pertaining to non-authorized gear types and areas currently closed to longline fishing. The EFPs would authorize up to 11 DSBG vessels and one longline vessel to fish year-round in areas within the Federal U.S. EEZ off of the West Coast. Aside from the exemptions described above (*e.g.,* allowing non-authorized gear types to fish and allowing longline gear within the EEZ to target swordfish), vessels fishing under an EFP would be subject to all other regulations implementing the HMS FMP, including measures to protect sea turtles, marine mammals, and seabirds. The EFP applications request issuance for 2 fishing seasons or 2 calendar years.

The Council suggested NMFS impose the following additional conditions on these EFPs (originally outlined here: *http://www.pcouncil.org/wpcontent/uploads/2015/03/0315decisions.pdf*):

(1) 100 percent observer coverage;

(2) prohibit fishing in waters north of the Washington/Oregon border, and in the first year prohibit fishing in waters north of the Oregon/California border;

(3) close fishing for the remainder of the year if the number of Endangered Species Act (ESA) listed species taken in the fishery is the lower of either double the amount of incidental take estimated in an ESA biological opinion prepared for that activity, or 10 animals;

(4) for those EFPs testing buoy gear, permit fishing only in Federal waters;

(5) for the EFP testing longline gear, prohibit fishing within 50 miles of the mainland shore and islands; and

(6) for the EFP testing longline gear, develop and impose an annual incidental catch limit for striped marlin. NMFS is seeking public comment on the EFP applications and the Council's recommended conditions.

In accordance with NOAA Administrative Order 216–6, appropriate National Environmental Policy Act documents will be completed prior to the issuance of the EFPs. Additionally, NMFS will consider all applicable laws, including Section 7(a)(2) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*), to determine if the proposed action is likely to jeopardize the continued existence and recovery of any endangered or threatened species or result in the destruction or adverse modification of critical habitat.

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

Dated: May 18, 2015.

Alan D. Risenhoover,

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

[FR Doc. 2015–12411 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD950

Western Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of its Social Science Planning Committee (SSPC) in Honolulu, HI.

DATES: The SSPC meeting will be held on Monday, June 8, 2015, from 9 a.m. to 12 p.m.

ADDRESSES: The teleconference will be conducted by telephone and by web. The teleconference numbers are: U.S. toll-free: 1–888–482–3560 or International Access: +1 647 723–3959, and Access Code: 5228220. The webconference can be accessed at *https://wprfmc.webex.com/join/info.wpcouncilnoaa.gov*.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: A public comment period will be provided. The order in which agenda items are addressed may change. The Committee will meet as late as necessary to complete scheduled business.

Agenda

9 a.m., Monday, June 8, 2015

1. Introductions
2. Approval of Agenda
3. Status of June 2014 Meeting Recommendations
4. Update on Recent WPFMC Human Dimensions Activities
5. New WPRFMC Annual Fishery Report Contents and Process
6. Status of WPFMC Human Communities Priorities
7. Current Pacific Islands Region Human Dimensions Research
   A. Non-commercial Knowledge, Attitudes, and Perceptions Survey
   B. MRIP Boat-Based Intercept Pilot
   C. Guam Fishing Conflict
   D. Yellowfin Commercial Size Limit—Social and Economic Impacts
   E. Other
8. Social Scientists in Regional Fisheries Management Working Group Meeting Key Conclusions
9. Other Business
10. Public Comment
11. Committee Recommendations
12. Next Social Science Planning Committee Meeting
    A. Date
    B. Agenda items

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: May 19, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–12496 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products from the Procurement List previously furnished by such agencies.

DATES: Effective date: June 22, 2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 3/6/2015 (80 FR 12156), 3/20/2015 (80 FR 14973), and 3/27/2015 (80 FR 16363–16364), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and service and impact of the additions on the current or most recent contractors, the Committee has determined that the products and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.
2. The action will result in authorizing small entities to furnish the products and service to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and service are added to the Procurement List:

Products

Product Name/NSN(s): Easy Storage Box, 14 3/4″ x 12″ x 9 1/2″, White 8115–00–NSH–0338
Mandatory Purchase for: Total Government Requirement
Mandatory Source of Supply: ReadyOne Industries, Inc., El Paso, TX
Contracting Activity: General Services Administration
Distribution: A-List

Product Name/NSN(s): Shaker, Salad Dressing/MR 342, Mandoline Slicer, Handheld/MR 338
Mandatory Purchase for: Requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency
Mandatory Source of Supply: Cincinnati Association for the Blind, Cincinnati, OH
Contracting Activity: Defense Commissary Agency, Fort Lee, VA
Distribution: C-List

Product Name/NSN(s): Neck Lanyard:
8455–00–NIB–0040—Cord Style, J-Hook, Black, 36″ x .25″
8455–00–NIB–0041—Strap Style, J-Hook, Black, 36″ x .75″
8455–00–NIB–0042—Strap Style, J-Hook, Tan, 36″ x .75″
8455–00–NIB–0043—Cord Style, J-Hook, Tan, 36″ x .25″
8455–00–NIB–0046—Clip Adapter Strap, 100 PK
8455–00–NIB–0047—Holder, Identification, Smart Card, RFID Shielded, Opaque, Bulk PK
Mandatory Purchase for: Total Government Requirement
Mandatory Source of Supply: West Texas Lighthouse for the Blind, San Angelo, TX
Contracting Activity: General Services Administration
Distribution: A-List

Service

Service Type: Base Operations and Administrative Service
Mandatory Purchase for: Marine Corps Base Hawaii (MCB), Camp Smith, Halawa, HI and Kaneohe Bay, HI
Mandatory Source of Supply: PRIDE

Industries, Roseville, CA
Contracting Activity: Dept of the Navy, HQBN, Marine Corps Base Hawaii, Kaneohe Bay, HI

Deletions

On 4/17/2015 (80 FR 21223), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Product Name/NSN(s): Rain Gauge, 4″/6660–00–920–3722
Mandatory Source of Supply: Productive Alternatives, Inc., Fergus Falls, MN
Contracting Activity: Dept of Comm/Office of the Secretary, Kansas City, MO

Product Name/NSN(s): Brassard, Military Police
8455–00–818–8826
8455–01–236–1174
Mandatory Source of Supply: Unknown
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Product Name/NSN(s): Vest, Load Bearing Equipment
8465–01–440–3690—Rappel Seat, Assembly
PART NO 3505–06–203—strap, Leg
PART NO 3505–06–205—Strap, Waist
8465–01–440–5883—Harness, SPIE, Assembly
Mandatory Source of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY
Contracting Activity: Dept of the Navy, Commander, Quantico, VA

Barry S. Lineback,
Director, Business Operations.
[FR Doc. 2015–12490 Filed 5–21–15; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by the nonprofit agency employing persons who are blind or have other severe disabilities.

Comments Must be Received on Or Before: 6/22/2015

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agency listed:

Products

Product Name/NSN(s): Bag, Insulated, Thermal, Reusable
MR 408—Small
MR 409—Large
Mandatory Purchase for: Requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency
Mandatory Source of Supply: Industries for the Blind, Inc., West Allis, WI
Contracting Activity: Defense Commissary Agency, Fort Lee, VA
Distribution: C-List

Barry S. Lineback,
Director, Business Operations.
[FR Doc. 2015–12489 Filed 5–21–15; 8:45 am]
BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11:00 a.m., Wednesday, May 27, 2015.

PLACE: Three Lafayette Centre, 1155 21st Street NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance, enforcement, and examinations matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Christopher J. Kirkpatrick,
Secretary of the Commission.
[FR Doc. 2015–12585 Filed 5–20–15; 11:15 am]
BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Reserve Forces Policy Board; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Secretary of Defense, Reserve Forces Policy Board, DoD.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the Reserve Forces Policy Board (RFPB) will take place.

DATES: Tuesday, June 9, 2015 from 9:05 a.m. to 4:05 p.m.

ADDRESSES: The address is the Pentagon, Room 3E863, Arlington, VA.

FOR FURTHER INFORMATION CONTACT: Mr. Alex Sabol, Designated Federal Officer, (703) 681–0577 (Voice), (703) 681–0002 (Facsimile), Email—*Alexander.J.Sabol.Civ@Mail.Mil.* Mailing address is Reserve Forces Policy Board, 5113 Leesburg Pike, Suite 601,

Falls Church, VA 22041. Web site: *http://rfpb.defense.gov/.* The most up-to-date changes to the meeting agenda can be found on the RFPB's Web site.

SUPPLEMENTARY INFORMATION: This meeting notice is being published under the provisions of the Federal Advisory Committee Act of 1972 (FACA) (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to obtain, review and evaluate information related to strategies, policies, and practices designed to improve and enhance the capabilities, efficiency, and effectiveness of the Reserve Components.

Agenda: The RFPB will hold a meeting from 9:05 a.m. to 4:05 p.m. The meeting will be closed to the public and will consist of remarks to the RFPB from invited speakers that include Secretary of Defense; Acting Under Secretary of Defense (Personnel & Readiness); The Reserve Chiefs: Chief, National Guard Bureau; Chief, Navy Reserve; Commander, Marine Forces Reserve; Coast Guard, Director, Reserve and Military Personnel; Director, Air National Guard; Chief, Air Force Reserve; Director, Army National Guard; and Chief, Army Reserve; and RFPB member, MajGen Burke W. Whitman, USMCR. The Secretary of Defense will address future strategies for use of the Reserve Components, highlighting his thoughts on issues impacting reserve organizations, the right balance of Active and Reserve Component forces, and the cost to maintain a strong Reserve Component. The Acting Under Secretary of Defense (Personnel & Readiness) will present his thoughts and recommendations on Reserve Component cost, force mix, and future strategies for Reserve Component use given the national security challenges in a constrained fiscal environment. The Reserve Chiefs: Chief, National Guard Bureau; Chief, Navy Reserve; Commander, Marine Forces Reserve; Coast Guard, Director, Reserve and Military Personnel; Director, Air National Guard; Chief, Air Force Reserve; Director, Army National Guard; and Chief, Army Reserve will discuss their views on the continued relevance and use of the ''Operational Reserve'' concept in the current and future resource environment. As a part of the discussion, they will comment on anticipated resourcing positions and implications on future force structure/end strength; use of mob-to-dwell ratios to size and shape the force; current and anticipated readiness states and areas of greatest concern; and planned (FY15/16) use of forces/personnel in contingency and other operations. MajGen, Burke W. Whitman, USMCR will brief his observations on his recent deployment to Afghanistan.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, the closed meeting is from 9:05 a.m. to 4:05 p.m. and will not be accessible to the public. In accordance with section 10(d) of the FACA, 5 U.S.C. 552b, and 41 CFR 102–3.155, the Department of Defense has determined that this meeting scheduled to occur from 9:05 a.m. to 4:05 p.m. will be closed to the public. Specifically, the Acting Under Secretary of Defense (Personnel and Readiness), in coordination with the DoD FACA Attorney, has determined in writing that this meeting, in its entirety, will be closed to the public because it is likely to disclose classified matters covered by 5 U.S.C. 552b(c)(1).

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, interested persons may submit written statements to the RFPB about its approved agenda or at any time on the RFPB's mission. Written statements should be submitted to the RFPB's Designated Federal Officer at the address or facsimile number listed in the **FOR FURTHER INFORMATION CONTACT** section. If statements pertain to a specific topic being discussed at the planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to or considered by the RFPB until its next meeting. The Designated Federal Officer will review all timely submitted written statements and provide copies to all the committee members before the meeting that is the subject of this notice. Please note that since the RFPB operates under the provisions of the FACA, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the RFPB's Web site.

Dated: May 19, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–12478 Filed 5–21–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2015–ICCD–0025]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Migrant Student Information Exchange (MSIX) User Guide and Application Form

AGENCY: Department of Education (ED), Office of Elementary and Secondary Education (OESE).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before June 22, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0025 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will only accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E115, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Pat Meyertholen, 202.260.1394.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection

requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Migrant Student Information Exchange (MSIX) User Guide and Application Form.

OMB Control Number: 1810–0686.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 1,598.

Total Estimated Number of Annual Burden Hours: 799.

Abstract: The Department of Education is requesting approval to extend the 1810–0686 information collection that supports statutory requirements for data collection under Title I, Part C MEP. The purpose of the Migrant Student Information Exchange (MSIX) User Guide and Application is to collect data to verify the identity of users in order to grant them access to the MSIX system for the purpose of transferring migrant student data.

Dated: May 18, 2015.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2015–12426 Filed 5–21–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Electricity Advisory Committee Meeting

AGENCY: Office of Electricity Delivery and Energy Reliability, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Electricity Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES:

Monday, June 29, 2015—12:00 p.m.–5:30 p.m.

Tuesday, June 30, 2015—8:30 a.m.–12:15 p.m.

ADDRESSES: National Rural Electric Cooperative Association, 4301 Wilson Boulevard, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Matthew Rosenbaum, Office of Electricity Delivery and Energy Reliability, U.S. Department of Energy, Forrestal Building, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (202) 586–1060 or Email: *matthew.rosenbaum@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Electricity Advisory Committee (EAC) was re-established in July 2010, in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. 2, to provide advice to the U.S. Department of Energy (DOE) in implementing the Energy Policy Act of 2005, executing the Energy Independence and Security Act of 2007, and modernizing the nation's electricity delivery infrastructure. The EAC is composed of individuals of diverse background selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to electricity.

Tentative Agenda: The meeting of the EAC is expected to include an update on the programs and initiatives of DOE's Office of Electricity Delivery and Energy Reliability, the DOE Quadrennial Energy Review and Technical Review, and the DOE Grid Consortium effort. The meeting is also expected to include panel discussions on the value of volt-ampere reactive (VAr) power and the current and future development of microgrids, as well as a discussion on cyber security strategies. Additionally, the meeting is expected to include a discussion of the plans and activities of the Cyber Security Working Group, the Power Delivery Subcommittee, the Smart Grid Subcommittee, and the Energy Storage Subcommittee.

Tentative Agenda: June 29, 2015

12:00 p.m.–1:00 p.m.—EAC Leadership Committee Meeting
12:00 p.m.–1:00 p.m.—Registration
1:00 p.m.–1:15 p.m.—Welcome, Introductions, Developments since the March 2015 Meeting
1:15 p.m.–1:45 p.m.—Update on the DOE Office of Electricity Delivery and Energy Reliability's Programs and Initiatives
1:45 p.m.–2:05 p.m.—Update on the DOE Quadrennial Energy Review
2:05 p.m.–2:25 p.m.—Update on the DOE Quadrennial Technical Review
2:25 p.m.–2:45 p.m.—Update on the DOE Grid Consortium Effort
2:45 p.m.–3:00 p.m.—Break
3:00 p.m.–3:30 p.m.—Value of a VAr Panel
3:30 p.m.–3:50 p.m.—EAC Discussion of Value of a VAr
3:50 p.m.–4:10 p.m.—EAC Power Delivery Subcommittee Activities and Plans
4:10 p.m.–4:25 p.m.—EAC Member Discussion of Power Delivery Subcommittee
4:25 p.m.–4:55 p.m.—EAC Smart Grid Subcommittee Activities and Plans
4:55 p.m.–5:15 p.m.—EAC Member Discussion of Smart Grid Subcommittee Plans
5:15 p.m.–5:30 p.m.—Wrap-up and Adjourn Day One of June 2015 Meeting of the EAC

Tentative Agenda: June 30, 2015

8:30 a.m.–10:00 a.m.—Microgrid Current and Future Development Panel
10:00 a.m.–10:20 a.m.—EAC Discussion of Microgrids
10:20 a.m.–10:40 a.m.—Cyber Security Strategies
10:40 a.m.–11:00 a.m.—EAC Member Discussion of Cyber Security Working Group Plans
11:00 a.m.–11:30 a.m.—EAC Energy Storage Subcommittee Activities and Plans
11:30 a.m.–11:45 a.m.—EAC Member Discussion of Energy Storage Subcommittee Plans
11:45 a.m.–12:00 p.m.—Public Comments
12:00 p.m.–12:15 p.m.—Wrap-up and Adjourn June 2015 Meeting of the EAC

The meeting agenda may change to accommodate EAC business. For EAC agenda updates, see the EAC Web site at: *http://energy.gov/oe/services/electricity-advisory-committee-eac.*

Public Participation: The EAC welcomes the attendance of the public at its meetings. Individuals who wish to offer public comments at the EAC meeting may do so on Tuesday, June 30, 2015, but must register at the registration table in advance. Approximately 10 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but is not expected to exceed three minutes.

Anyone who is not able to attend the meeting, or for whom the allotted public comments time is insufficient to address pertinent issues with the EAC, is invited to send a written statement to Mr. Matthew Rosenbaum.

You may submit comments, identified by ''Electricity Advisory Committee Open Meeting,'' by any of the following methods:

- *Mail/Hand Delivery/Courier:* Matthew Rosenbaum, Office of Electricity Delivery and Energy Reliability, U.S. Department of Energy, Forrestal Building, Room 8G–017, 1000 Independence Avenue SW., Washington, DC 20585.
- *Email: matthew.rosenbaum@hq.doe.gov.* Include ''Electricity Advisory Committee Open Meeting'' in the subject line of the message.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. *Instructions:* All submissions received must include the agency name and identifier. All comments received will be posted without change to *http://energy.gov/oe/services/electricity-advisory-committee-eac,* including any personal information provided.
- *Docket:* For access to the docket, to read background documents or comments received, go to *http://energy.gov/oe/services/electricity-advisory-committee-eac.*

The following electronic file formats are acceptable: Microsoft Word (.doc), Corel Word Perfect (.wpd), Adobe Acrobat (.pdf), Rich Text Format (.rtf), plain text (.txt), Microsoft Excel (.xls), and Microsoft PowerPoint (.ppt). If you submit information that you believe to be exempt by law from public disclosure, you must submit one complete copy, as well as one copy from which the information claimed to be exempt by law from public disclosure has been deleted. You must also explain the reasons why you believe the deleted information is exempt from disclosure.

DOE is responsible for the final determination concerning disclosure or nondisclosure of the information and for treating it in accordance with the DOE's Freedom of Information regulations (10 CFR 1004.11).

Note: Delivery of the U.S. Postal Service mail to DOE may be delayed by several weeks due to security screening. DOE, therefore, encourages those wishing to comment to submit comments electronically by email. If comments are submitted by regular mail, the Department requests that they be accompanied by a CD or diskette containing electronic files of the submission.

Minutes: The minutes of the EAC meeting will be posted on the EAC Web page at *http://energy.gov/oe/services/electricity-advisory-committee-eac.* They can also be obtained by contacting Mr. Matthew Rosenbaum at the address above.

Issued in Washington, DC, on May 18, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–12458 Filed 5–21–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, June 10, 2015—6:00 p.m.

ADDRESSES: Department of Energy Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37830.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Federal Coordinator, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM–90, Oak Ridge, TN 37831. Phone (865) 241–3315; Fax (865) 576–0956 or email: *noemp@emor.doe.gov* or check the Web site at *http://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Public Comment Period
- Presentation on Groundwater Strategic Plan for the Oak Ridge Reservation
- Additions/Approval of Agenda
- Motions/Approval of May 13, 2015 Meeting Minutes
- Status of Recommendations with DOE
- Committee Reports
- Federal Coordinator Report
- Adjourn

Public Participation: The EM SSAB, Oak Ridge, 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 Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda item should contact Melyssa P. Noe at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following Web site: *http://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board.*

Issued at Washington, DC, on May 18, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–12457 Filed 5–21–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3030–019]

Antrim County; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 Code of Federal Regulations Part 380 (Order No. 486, 52 FR 47879), the Office of Energy Projects has reviewed Antrim County's application for a subsequent license for the Elk Rapids Hydroelectric Project (FERC No. 3030), located on the Elk

River in the Village of Elk Rapids in Antrim, Grand Traverse, and Kalkaska Counties, Michigan, and prepared an environmental assessment (EA).

In the EA, Commission staff analyze the potential environmental effects of relicensing the project, and conclude that issuing a subsequent license for the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *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 number at 1–866–208–3676, or for TTY, 202–502–8659.

You may also register online at *www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file the requested information using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–3030–019.

For further information, please contact Patrick Ely by telephone at (202) 502–8570 or by email at *Patrick..ly@ferc.gov.*

Dated: May 15, 2015.

Kimberly D. Bose,

Secretary.

Environmental Assessment for Hydropower License

Elk Rapids Hydroelectric Project, FERC Project No. 3030–019, Michigan

Federal Energy Regulatory Commission, Office of Energy Projects, Division of Hydropower Licensing, 888 First Street NE., Washington, DC 20426

May 2015

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Acronyms and Abbreviations

APE area of potential effects
cfs cubic feet per second
chain-of-lakes Elk River Chain of Lakes
Commission Federal Energy Regulatory Commission
Consumers Energy Consumers Energy Company
CWA Clean Water Act
CZMA Coastal Zone Management Act
dam gage datum Elk Rapids dam gage datum
DO dissolved oxygen
EA environmental assessment
Elk Rapids Hydro Elk Rapids Hydroelectric Power, LLC
Elk Rapids Project or project Elk Rapids Hydroelectric Project
EPA U.S. Environmental Protection Agency
ESA Endangered Species Act
°F degrees Fahrenheit
FERC Federal Energy Regulatory Commission
FPA Federal Power Act
FWS U.S. Fish and Wildlife Service
Interior U.S. Department of Interior
Lakes Association Three Lakes Association
mg/l milligrams per liter
Michigan DEQ Michigan Department of Environmental Quality
Michigan DNR Michigan Department of Natural Resources
Michigan SHPO Michigan State Historic Preservation Officer
MISO Midcontinent Independent System Operator, Inc.
MiSWIMS Michigan Surface Water Information Management System
MW megawatt
MWh megawatt-hour
National Register National Register of Historic Places
NERC North American Electric Reliability Corporation
NHPA National Historic Preservation Act
NPDES National Pollution Discharge Elimination System
RFC ReliabilityFirst Corporation
USGS United States Geological Survey
Watershed Council Tipp of the Mitt Watershed Council
WQC Water Quality Certification

EXECUTIVE SUMMARY

Proposed Action

On December 21, 2012, Antrim County filed an application with the Federal Energy Regulatory Commission (Commission) for a new license for the continued operation and maintenance its Elk Rapids Hydroelectric Project No. 3030–019 (Elk Rapids Project or project).[1] The 0.700 megawatt (MW) project is located on the Elk River in the Village of Elk Rapids in Antrim, Grand Traverse, and Kalkaska Counties, Michigan. Antrim County does not propose any increase in the project's generating capacity or any new construction. The project does not occupy any federal land.

Project Description

The Elk Rapids Project consists of the following existing facilities: (1) A reservoir that includes the 2,560-acre Skegemog Lake and the 7,730-acre Elk Lake; (2) a 121-foot-long, 52-foot-high, 26-foot-wide powerhouse that spans the north channel of the Elk River, with an approximate operating head of 10.5 feet; (3) intake trashracks having a 1.75-inch clear bar spacing; (4) four intake bays, each 22 feet wide with sliding head gates; (5) two 525 horsepower Francis turbines, each coupled to a generator with an installed capacity of 0.350 MW, for a total installed capacity of 0.700 MW; (6) two turbine gate cases used to spill excess water through the two intake bays that do not contain turbines and generators; (7) a 14-foot-wide overflow spillway located about 400 feet south of the powerhouse on the south channel of the Elk River; (8) a 4.16-kilovolt (kV) transmission line that extends about 30 feet from the powerhouse to a 20-foot by 30-foot substation enclosure; (9) a 50-foot-long underground 12.5-kV transmission line;

[1] The project is owned by Antrim County and is manually operated by Elk Rapids Hydroelectric Power, LLC.

and (10) appurtenant facilities. Recreation facilities at the project include an angler walkway that is attached to the tailrace side of the powerhouse and a parking lot adjacent to the powerhouse. The average annual generation is about 2,422 megawatt-hours.

Antrim County operates the project in a modified run-of-river mode.[2] The water surface elevation of the project reservoir (measured as Elk Rapids dam gage datum (dam gage datum) is maintained at 590.8 feet dam gage datum from April 15 through November 1 and at 590.2 feet dam gage datum from November 1 through April 15.[3] Flows greater than the capacities of the project's two operating turbine/generator units are passed through one or both of the two overflow turbine gate cases. When flows in the Elk River are too low to operate one turbine/generator unit, the overflow turbine gate case is used with decreased gate openings to maintain a modified run-of-river mode of operation.

Proposed Environmental Measures

Antrim County proposes to continue operating the project in a modified run-of-river mode to maintain existing seasonal lake levels. Antrim County also proposes to continue to operate and maintain the existing angler walkway and associated parking lot. No other environmental measures are proposed.

Public Involvement

Before filing its license application, Antrim County conducted pre-filing consultation under the Commission's Traditional Licensing Process. The intent of the Commission's pre-filing process is to initiate public involvement early in the project planning process and to encourage citizens, governmental entities, tribes, and other interested parties to identify and resolve issues prior to an application being formally filed with the Commission.

Before preparing this environmental assessment (EA), staff conducted scoping to determine what issues and alternatives should be addressed. A scoping document was distributed to interested parties on August 29, 2013, which solicited comments, recommendations, and information on the project. Two scoping meetings were held on September 19, 2013, in Elk Rapids, Michigan. On December 26, 2013, staff issued a ready for environmental analysis notice, requesting comments, recommendations, terms and conditions, and prescriptions.

Alternatives Considered

This EA considers the following alternatives: (1) Antrim County's proposal; (2) Antrim County's proposal with staff modifications (staff alternative); and (3) no action, meaning the project would continue to be operated as it presently with no changes. The staff alternative includes Antrim County's proposed measures with some additions as described below. Staff's recommended additional environmental measures include, or are based on, recommendations made by federal and state resource agencies that have an interest in resources that may be affected by operation of the proposed project.

The staff alternative includes the following additional measures:

(1) An operation compliance monitoring plan that includes a description of project operation and the equipment and procedures necessary to maintain and monitor compliance with the operational mode required in any license issued;

(2) posting signage that describes proper boat maintenance techniques to reduce the spread of invasive plant and mussel species; and

(3) if archaeological resources are discovered during project operation or other project-related activities, cease all activities related to the disturbance and discovery area, and consult with the Michigan State Historic Preservation Officer (Michigan SHPO) to determine appropriate treatment.

Under the no-action alternative, the project would continue to operate and the terms of the existing license. No new environmental protection, mitigation, or enhancement measures would be implemented.

Environmental Impacts and Measures of the Staff Alternative

The primary issue associated with relicensing the Elk Rapids Project is the regulation of the reservoir elevation, invasive species, and recreational opportunities. Below we summarize the environmental effects associated with staff's alternative and the measures recommended to address those effects.

Aquatic Resources

Operating the project in a modified run-of-river mode would enable the project to continue to maintain seasonal lake levels in Elk and Skegemong Lakes. Because the project currently operates in a modified run-of-river mode, minimal changes to aquatic habitat are expected in the reservoir, bypassed reach, and within the project tailrace by continuing this mode of operation.

An operation compliance monitoring plan that includes a description of project operation and the equipment and procedures that would be used by Antrim County to monitor project operation would provide a means to verify compliance with the operational requirements of any license issued for the project. Verifying compliance would, in turn, prevent possible misunderstandings of project operation and reduce the likelihood of noncompliance.

Invasive curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels, which are all primarily transferred to other waterbodies by boat, are found within and adjacent to the project boundary and are present in the Elk River Chain of Lakes (chain-of-lakes) watershed.[4] Zebra mussels are so pervasive throughout the chain-of-lakes, Michigan DEQ has no plan to control or eradicate the in the chain-of-lakes watershed. Posting signage that describes proper boat maintenance techniques to reduce the spread of curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels would limit the spread of these invasive species to other waterbodies, benefiting native species.

Terrestrial Resources

Current project operation and the presence of the project powerhouse have been successful in preventing invasive fish species in Lake Michigan from passing upstream of project into the chain-of-lakes. Antrim County's proposal to continue current project operation would ensure that invasive fish species are blocked from passing upstream of the powerhouse.

Threatened and Endangered Species

Kirtland's warbler, Rufa red knot, Pitcher's thistle, Houghton's goldenrod, and northern long-eared bat are known to occur in Antrim, Grand Traverse, and/or Kalkaska Counties, Michigan; however, no federally listed threatened

[2] The project is operated in a modified run-of-river mode, whereby the flows through the powerhouse and bypassed spillway approximately equals inflow of the Elk River, but are modified so as to maintain the seasonal water levels of Elk and Skegemog Lakes, as required by the order approving settlement and amending license. *See* 88 FERC ¶ 62, 158 (1999).

[3] The elevations 590.80 and 590.20 feet dam gage datum are equivalent to 588.26 and 587.66 feet International Great Lakes Datum of 1955, respectively.

[4] The chain-of-lakes watershed is a 75-mile-long waterway consisting of 14 lakes (including Elk and Skegemog Lakes) and connecting rivers that discharge to empty into Grand Traverse Bay, Lake Michigan.

or endangered species are known to occur within the project affected area. Continued operation of the project would not affect the federally listed Kirtland's warbler, Rufa red knot, Pitcher's thistle, and Houghton's goldenrod because each species requires specialized habitat that does not exist within the project boundary or in areas potentially affected by the project.

Continued operation of the project would not affect the federally listed northern long-eared bat. The project is located in an area that does not contain habitat needed for winter hibernation. Also, although a limited amount of dispersed riparian and wetland habitat in the project boundary could be used by northern long-eared bats for roosting, foraging, and breeding, this habitat would not be affected because there would be no changes to project operation, no new construction, and there would be no changes to seasonal water levels. Also, any maintenance activities would be restricted to areas around the powerhouse and transmission lines, which do not contain habitat for the northern long-ear bat.

Recreation, Land Use, and Aesthetics

There are 38 public access points and three marinas around the project reservoir or downstream of the project. In addition, Antrim County owns and operates an existing angler walkway and parking lot. Antrim County proposes to continue to operate and maintain the existing angler walkway and parking lot, and does not propose any changes to current project operation. The project would have no effect on existing recreational use because there would be no change in existing lake levels, recreational opportunities, or access.

Cultural Resources

The project would not affect any known properties eligible for, or listed on, the National Register of Historic Places. However, there is a possibility that unknown archaeological resources may be discovered during project operation or project-related activities. To ensure proper treatment of any such unknown archaeological resources that may be discovered, Antrim County would cease all land-disturbing activities and notify the Michigan SHPO of any unknown archaeological resources that are discovered, and follow the Michigan SHPO's guidance regarding the evaluation of the archaeological resource and, if necessary, ways to avoid, lessen, or mitigate for any adverse effects.

Conclusions

Based on our analysis, we recommend licensing the project as proposed by Antrim County, with staff modifications and additional measures.

In section 4.2 of the EA, *Comparison of Alternatives,* we estimate the likely cost of alternative power for each of the alternatives identified above. Our analysis shows that during the first year of operation under the no-action alternative, project power would cost $50,378, or $20.80/megawatt hour (MWh), more than the likely alternative cost of power. Under Antrim County's proposal, project power would cost $50,644, or $20.91/MWh, more than the likely alternative cost of power. Under the staff alternative, project power would cost $51,346, or $21.20/MWh, more than the likely alternative cost of power.

Based on our independent review of agency comments filed on this project and our review of the environmental and economic effects of the proposed project and its alternatives, we selected the staff alternative, as the preferred option. The staff alternative includes the applicant's proposal with additional staff-recommended measures.

We chose the staff alternative as the preferred alternative because: (1) The project would continue to provide a dependable source of electrical energy for the local area; (2) the 0.700 MW of electric capacity comes from a renewable resource that does not contribute to atmospheric pollution, including greenhouse gases; and (3) the environmental measures proposed by Antrim County, as modified by staff, would adequately protect and enhance environmental resources affected by the project. The overall benefits of the staff alternative would be worth the cost of the recommended environmental measures.

We conclude that issuing a subsequent license for the project, with the environmental measures we recommend, would not be a major federal action significantly affecting the quality of the human environment.

Environmental Assessment

Federal Energy Regulatory Commission, Office of Energy Projects, Division of Hydropower Licensing, Washington, DC

Elk Rapids Hydroelectric Project, FERC Project No. 3030–019—Michigan

1.0 INTRODUCTION

1.1 APPLICATION

On December 21, 2012, Antrim County (or applicant) filed an application with the Federal Energy Regulatory Commission (Commission) for a subsequent license for the existing Elk Rapids Hydroelectric Project (Elk Rapids Project or project).[5] The 0.700 megawatt (MW) project is located on the Elk River in the Village of Elk Rapids in Antrim, Grand Traverse, and Kalkaska Counties, Michigan (figure 1). The project does not occupy any federal lands. The project generates an average of about 2,422 megawatt-hours (MWh) of energy annually. Antrim County is not proposing any change in operation, new construction, or new generating capacity.

1.2 PURPOSE OF ACTION AND NEED FOR POWER

1.2.1 Purpose of Action

The purpose of the Elk Rapids Project is to continue to provide a source of hydroelectric power to meet the region's power needs. Therefore, under the provisions of the Federal Power Act (FPA), the Commission must decide whether to issue a license to Antrim County for the Elk Rapids Project and what conditions should be placed on any license issued. In deciding whether to issue a license for a hydroelectric project, the Commission must determine that the project will be best adapted to a comprehensive plan for improving or developing a waterway. In addition to the power and developmental purposes for which licenses are issued (such as flood control, irrigation, or water supply), the Commission must give equal consideration to the purposes of: (1) Energy conservation; (2) the protection of, mitigation of damage to, and enhancement of fish and wildlife resources; (3) the protection of recreational opportunities; and (4) the preservation of other aspects of environmental quality.

Issuing a subsequent license for the project would allow Antrim County to generate electricity at the project for the term of a subsequent license, making electric power from a renewable resource available for sale to Consumers Energy Company (Consumers Energy).

In this environmental assessment (EA), we assess the environmental and economic effects of continuing to operate the project: (1) As proposed by Antrim County; and (2) with staff's recommended measures (staff alternative). We also consider the effects of the no-action alternative. Important issues that are addressed include the project's effects on aquatic, terrestrial, threatened and endangered species, and recreation resources.

[5] The project is owned by Antrim County and is manually operated by Elk Rapids Hydroelectric Power, LLC (Elk Rapids Hydro).

1.2.2 Need for Power

The Elk Rapids Project would provide hydroelectric generation to meet part of the region's power requirements, resource diversity, and capacity needs. The project would have an installed capacity of 0.700 MW and generate approximately 2,422 MWh per year.

The North American Electric Reliability Corporation (NERC) annually forecasts electrical supply and demand nationally and regionally for a 10-year period. The Elk Rapids Project is located in the ReliabilityFirst Corporation (RFC) regional entity of NERC. However, the NERC assessment was performed on the Midcontinent Independent System Operator, Inc. (MISO) area although the Elk Rapids Project belongs to the RFC regional entity. These assessment boundaries were intended to more accurately reflect the planning and operational properties of the bulk power system. MISO anticipates a system-wide growth rate of approximately 0.72 percent, causing Total Internal Demands of 96,879 MW and 103,056 MW in 2014 and 2023, respectively. The MISO summer Adjusted Potential Planning Reserve Margin [6] is forecasted to range from 24.55 percent in 2014 to 20.28 percent in 2023. The MISO winter Adjusted Potential Planning Reserve Margin is forecasted to range from 50.81 percent in 2014/2015 to 44.70 percent in 2023/2024. Throughout the assessment period, neither the summer nor the winter Adjusted Planning Potential Reserve Margins are forecasted to fall below the Reference Margin Level of 14.20 percent. However, the MISO summer Anticipated Planning Reserve Margin is forecasted to range from 18.28 percent in 2014 to 3.44 percent in 2023. The MISO winter Anticipated Planning Reserve Margin is forecasted to range from 43.22 percent in 2014/2015 to 24.44 percent in 2023/2024. Based on MISO's current awareness of projected retirements and the resource plans of its membership, Planning Reserve Margins would erode over the course of the next couple of years and would not meet the 14.2 percent Reference Margin Level. The impacts of environmental regulations and economic factors contribute to a potential shortfall of 6,750 MW, or a 7.0 percent Anticipated Planning Reserve Margin (7.2 percentage points below the Reference Margin Level) by summer 2016. Accordingly, Existing-Certain resources are projected to be reduced by 10,382 MW because of retirement and suspended operation. At a 7.0 percent Anticipated Reserve Margin in 2016, MISO does not have enough Planning Resources to effectively manage risk associated with load uncertainty and system outages and has an 87.0 percent chance of shedding firm load on 2016 peak (NERC, 2013).

We conclude that power from the Elk Rapids Project would help meet a need for power in the MISO area in both the short and long-term. The project provides low-cost power that displaces generation from non-renewable sources. Displacing the operation of non-renewable facilities may avoid some power plant emissions, thus creating an environmental benefit.

[6] Planning Reserve Margin is approximately equivalent to the following: [(Capacity minus demand) divided by demand]. Planning Reserve Margin replaced Capacity Margin for NERC assessments in 2009.

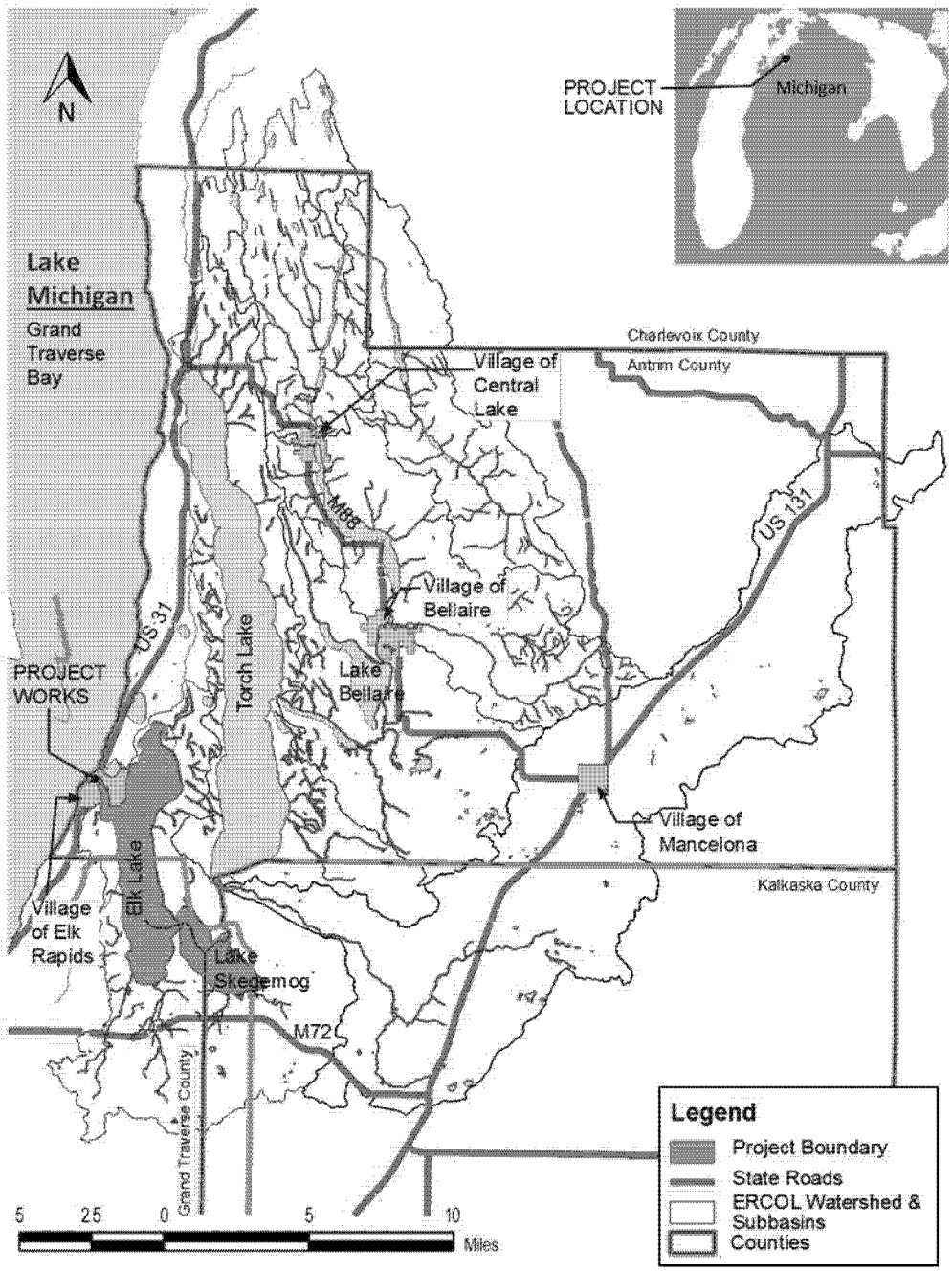

Figure 1. Location of the Elk Rapids Hydroelectric Project, Michigan (Source: Antrim County, 2012; as modified by staff).

1.2 STATUTORY AND REGULATORY REQUIREMENTS

A subsequent license for the Elk Rapids Project would be subject to numerous requirements under the FPA and other applicable statutes. The major regulatory and statutory requirements are described below.

1.2.1 Federal Power Act

1.2.1.1 Section 18 Fishway Prescriptions

Section 18 of the FPA states that the Commission is to require the construction, operation, and maintenance by a licensee of such fishways as may be prescribed by the Secretaries of Commerce or the U.S. Department of the Interior. No fishway prescriptions or requests for reservation of authority to prescribe fishways were filed under section 18 of the FPA.

1.2.1.2 Section 10(j) Recommendations

Under section 10(j) of the FPA, each hydroelectric license issued by the Commission must include conditions based on recommendations provided by federal and state fish and wildlife agencies for the protection, mitigation, or enhancement of fish and wildlife resources affected by the project. The Commission is required to include these conditions unless it determines that they are inconsistent with the purposes and requirements of the FPA or other applicable law. Before rejecting or modifying an agency recommendation, the Commission is required to attempt to resolve any such inconsistency with the agency, giving due weight to the recommendations, expertise, and

statutory responsibilities of such agency. No recommendations were filed pursuant to section 10(j) of the FPA.

1.2.2 Clean Water Act

Under section 401 of the Clean Water Act (CWA), a license applicant must obtain certification from the appropriate state pollution control agency verifying compliance with the CWA. On September 21, 2009, Antrim County applied to the Michigan Department of Environmental Quality (Michigan DEQ) for a section 401 water quality certification (WQC) for the Elk Rapids Project. Michigan DEQ issued the WQC for the Elk Rapids Project on June 26, 2012; however, because Michigan DEQ did not act on the request within 1 year from receipt of the request, the WQC is considered waived.[7]

1.2.3 Endangered Species Act

Section 7 of the Endangered Species Act (ESA) requires federal agencies to ensure their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species.

Review of U.S. Fish and Wildlife Service (FWS) records in April 2015 indicate that one federally listed endangered species, the Kirtland's warbler (Setophaga kirtlandii), and 4 federally listed threatened species: (1) The Northern long-eared bat (Myotis septentrionalis); (2) Rufa red knot (Calidris canutus rufa); (3) Pitcher's thistle (Cirsium pitcher); (4) and Houghton's goldenrod (Solidago houghtonii) are listed as occurring within one or more of the counties where the Elk Rapids Project exists.[8] There is no designated critical habitat for these species.

The types of habitats needed for the Kirtland's warbler, Rufa red knot, Pitcher's thistle, and Houghton's goldenrod are not present at the project. Although a limited amount of dispersed riparian and wetland habitat in the project boundary could be used for foraging, roosting, and breeding by northern long-eared bats, this habitat would not be affected because there would be no changes to project operation, no new construction, and no trees would be removed as part of the proposed relicensing of the project. Also, maintenance activities would be restricted to areas around the powerhouse and transmission lines, which do not contain habitat for the northern long-ear bat. We conclude that licensing the Elk Rapids Project, as proposed by Antrim County and with staff recommended measures, would not affect listed species and no further consultation under section 7 is needed.

1.2.4 Coastal Zone Management Act

Under section 307(c)(3)(A) of the Coastal Zone Management Act (CZMA), 16 United States Code [U.S.C.] 1456(3)(A), the Commission cannot issue a license for a project within or affecting a state's coastal zone unless the state CZMA agency concurs with the license applicant's WQC of consistency with the state's CZMA program, or the agency's concurrence is conclusively presumed by its failure to act within 180 days of its receipt of the applicant's WQC.

By letter dated September 28, 2012, and filed with the license application, Michigan DEQ stated that the project is located within the state-designated coastal management boundary. However, Michigan DEQ determined that if the Commission's license requirements would be implemented, there would be no adverse effects to coastal resources from the relicensing of the project. Michigan DEQ concluded that the project would be considered consistent with the CZMA.

1.2.5 National Historic Preservation Act

Section 106 of the National Historic Preservation Act (NHPA)[9] requires that every federal agency ''take into account'' how each of its undertakings could affect historic properties. Historic properties are districts, sites, buildings, structures, traditional cultural properties, and objects significant in American history, architecture, engineering, and culture that are eligible for inclusion in the National Register of Historic Places (National Register).

By letter dated October 28, 2010, and filed with the license application, the Michigan State Historic Preservation Officer (Michigan SHPO) determined that there are no historic properties within the project's area of potential effects (APE). We have determined that there are no historic properties within the project's APE and that the project would not affect historic properties. Therefore, the Commission's regulatory requirements pertaining to section 106 of the NHPA have been satisfied.

1.3 PUBLIC REVIEW AND COMMENT

The Commission's regulations (18 CFR 4.38) require that applicants consult with appropriate resource agencies, tribes, and other entities before filing an application for a license. This consultation is the first step in complying with the Fish and Wildlife Coordination Act, ESA, NHPA, and other federal statutes. Pre-filing consultation must be complete and documented according to the Commission's regulations.

1.3.1 Scoping

Before preparing this EA, we conducted scoping to determine what issues and alternatives should be addressed in the EA. A scoping document was distributed to interested agencies and other stakeholders on August 29, 2013. The scoping meeting was noticed in the **Federal Register** on September 6, 2013. Two scoping meetings were held on September 19, 2013, in Elk Rapids, Michigan, to request oral comments on the project. A court reporter recorded all comments and statements made at the scoping meetings, and these are part of the Commission's public record for the project.

1.3.2 Interventions

On December 26, 2013, the Commission issued a notice accepting Antrim County's application to license the Elk Rapids Project and soliciting protests and motions to intervene. This notice set February 24, 2013, as the deadline for filing protests and motions to intervene. In response to the notice, Michigan DNR filed a timely motion to intervene on February 14, 2013.

1.3.3 Comments on the Application

A notice requesting terms, conditions, prescriptions, and recommendations was issued on December 26, 2013. The notice also stated that the application was ready for environmental analysis. No entities filed comments.

2.0 PROPOSED ACTION AND ALTERNATIVES

2.1 NO-ACTION ALTERNATIVE

Under the no-action alternative, the project would continue to operate under the terms and conditions of the existing license, and no new environmental protection, mitigation, or enhancement measures would be implemented. We use this alternative to establish the baseline environmental conditions for comparison with other alternatives.

[7] Although the 401 WQC issued by Michigan DEQ is considered waived, relevant conditions of the 401 WQC have been analyzed in this EA as recommendations pursuant to section 10(a) of the FPA.

[8] Except for the federally threatened Houghton's goldenrod, which is only listed in Kalkaska County, all of the other federally listed species are listed as occurring in Antrim, Grand Traverse, and Kalkaska Counties.

[9] 54 U.S.C. 306108 (2014).

2.1.1 Existing Project Facilities

The Elk Rapids Project consists of the following existing facilities: (1) A project reservoir that includes the 2,560-acre Skegemog Lake and the 7,730-acre Elk Lake; (2) a 121-foot-long, 52-foot-high, 26-foot-wide powerhouse that spans the north channel of the Elk River, with an approximate operating head of 10.5 feet; (3) intake trashracks having a 1.75-inch clear bar spacing; (4) four intake bays, each 22 feet wide with sliding head gates; (5) two 525 horsepower Francis turbines, each coupled to a generator with an installed capacity of 0.350 MW, for a total installed capacity of 0.700 MW; (6) two turbine gate cases used to spill excess water through the two intake bays that do not contain turbines and generators; (7) a 14-foot-wide overflow spillway located about 400 feet south of the powerhouse on the south channel of the Elk River, which consists of two adjacent concrete drop structures, each with a 7-foot-long stop log to control the lake level, with each drop structure leading to a 62.5-foot-long by 4.5-foot-diameter culvert that passes under Dexter Street; (8) a 4.16-kilovolt (kV) transmission line that extends about 30 feet from the powerhouse to a 20-foot by 30-foot substation enclosure; (9) a 50-foot-long underground 12.5-kV transmission line to connect the project substation to Consumers Energy Company's distribution lines; (10) an angler walkway that is attached to the tailrace side of the powerhouse and a parking lot adjacent to the powerhouse; and (11) appurtenant facilities.

The proposed project boundary would fully enclose all permanent project features, including the powerhouse, overflow spillway, and the project reservoir, which consists of Skegemog Lake, Elk Lake, and the upper Elk River (*i.e.,* the portion of Elk River upstream of the project's powerhouse).

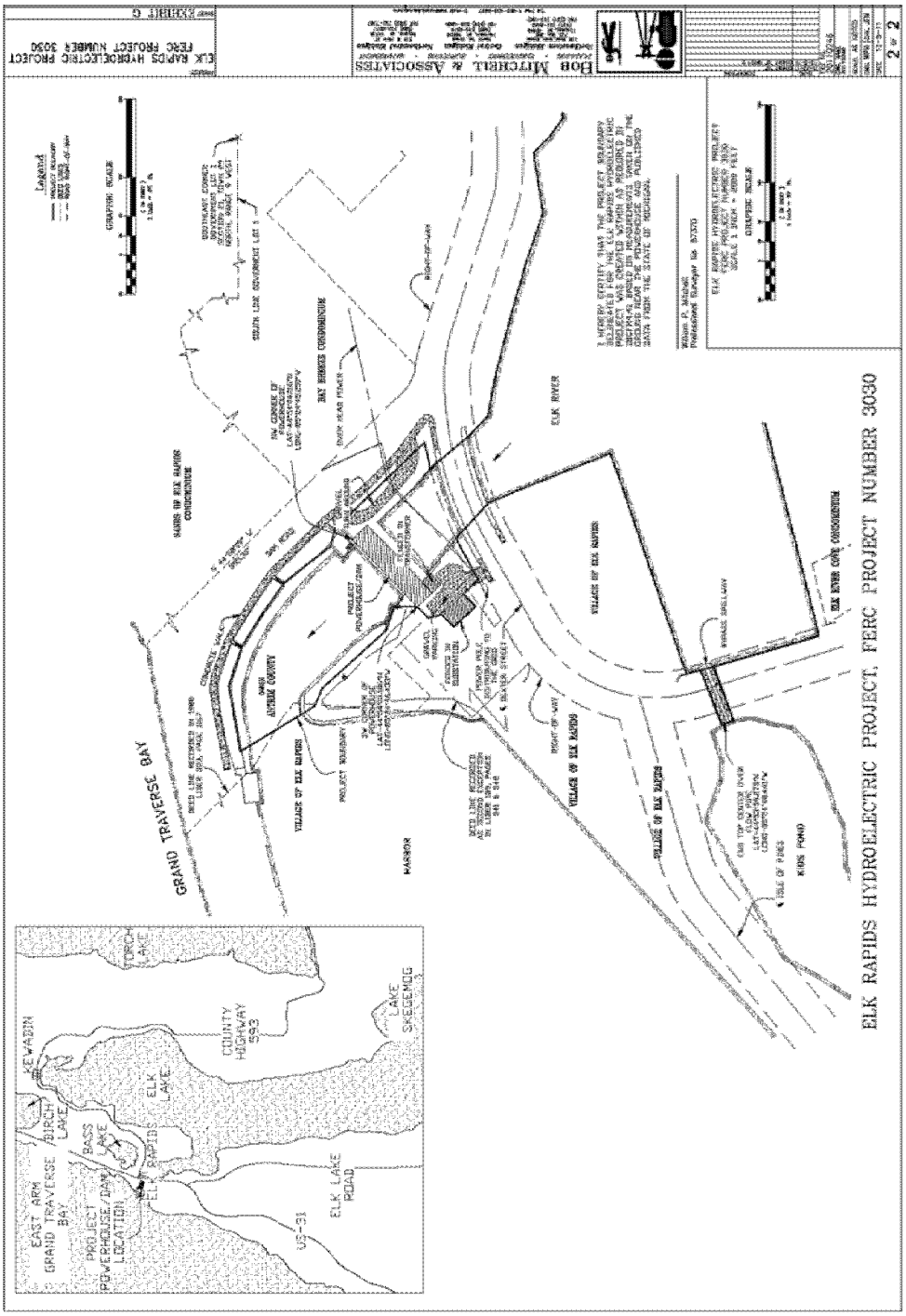

Figure 2. Project facilities for the Elk Rapids Project (Source: Antrim County, 2012).

2.1.2 Project Safety

The project has been operating for more than 33 years under the existing license and during this time Commission staff has conducted operational inspections focusing on the continued safety of the structures, identification of unauthorized modifications, efficiency and safety of operations, compliance with the terms of the license, and proper maintenance. As part of the relicensing process, the Commission staff would evaluate the continued adequacy of the proposed project facilities under a subsequent license. Special articles would be included in any license issued, as appropriate. Commission staff would continue to inspect the project during the subsequent license term to assure continued adherence to Commission-approved plans and specifications, special license articles relating to construction (if any), operation and maintenance, and accepted engineering practices and procedures.

2.1.3 Existing Project Operation

The Elk Rapids Project is operated as a modified run-of-river facility.[10] The project is manually operated by Elk Rapids Hydro's personnel. The powerhouse operation is checked by Elk

[10] The project is operated in a modified run-of-river mode, whereby the flows through the powerhouse and bypassed spillway approximately equals inflow of the Elk River and are modified so as to maintain the seasonal water levels of Elk and Skegemog Lakes, as required by the order approving settlement and amending license. *See* 88 FERC ¶ 62, 158 (1999).

Rapids Hydro two to three times each day, seven days a week.

Water flows to the project facilities by way of the Elk River Chain of Lakes (chain-of-lakes) [11] from the Torch River into Skegemog Lake, then to Elk Lake and then into the Elk River located immediately upstream of the project. Skegemog Lake is connected to Elk Lake through a 0.25-mile-long, 0.25-mile-wide, 5-foot-deep section of water known as the Narrows. The Narrows does not restrict flow between Skegemog and Elk Lakes, and therefore does not cause a surface level difference between the lakes. Elk and Skegemog Lakes have seasonal lake levels required by a court order issued in 1973 by the Circuit Court in Antrim County, Michigan.[12] The court order requires lake levels for the period from November 1 to April 15 to be maintained at 590.2 feet dam gage datum and 590.8 feet dam gage datum from April 15 (or the breakup of ice, whichever date is later) through November 1.[13] During the semi-annual lake level change (every April and November), generation and water flow through the project is adjusted gradually over a period of two weeks to achieve the required lake level. The project is responsible for maintaining the court ordered lake levels through its normal operations.

The project's normal operating head is about 10.5 feet. On the intake side of the powerhouse, the reservoir level is dictated by the required seasonal lake levels for Elk and Skegemog Lakes. At the powerhouse, the two north bays contain the operating turbines and generator units, and the two south bays, which don't have turbines or generating units, are used to spill excess water and provide flows when one or both of the generating units in the north bays are out of service for maintenance, when the grid goes down, or as needed to maintain the modified run-of-river operation. The project tailrace is directly connected to Grand Traverse Bay, Lake Michigan. As a result, the water levels in the tailrace are the same as water levels in Lake Michigan, and the project's net head varies as water levels in Lake Michigan rise and fall.

The two turbines, located in bays #3 and #4 at the north end of the powerhouse, each have a maximum hydraulic capacity of 504 cubic feet per second (cfs). The spill control gate case at bay #1, the southernmost bay, has a maximum hydraulic capacity of 239 cfs. The spill control gate case at bay #2 has a maximum hydraulic capacity of 442 cfs. The maximum hydraulic capacity of all four units in the powerhouse flowing at the same time is 1,620 cfs, which is less than the sum of the individual units because of flow interference between individual units. For the period from April 15 (or ice breakup on Elk and Skegemog Lakes, whichever occurs later) to November 1 the minimum flow increases because of the 0.6-foot higher lake level. Therefore, the project has a maximum hydraulic capacity of 1,675 cfs during the warmer months and 1,655 cfs during the colder months. Although the 1 percent flood is 1,800 cfs, the project can pass this flood because of the attenuation from significant storage in Elk and Skegemog Lakes.

About 400 feet adjacent (south) of the powerhouse, the upper Elk River's south channel diverts into a 14-foot-wide overflow spillway pond that is stop log controlled with two 5-foot-diameter culverts. During the winter, when the lake level is 590.2 feet dam gage datum, the south channel spillway provides a minimum flow of 35 cfs. During the summer, when the lake level is raised to 590.8 feet dam gage datum, the south channel spillway provides a minimum flow of 55 cfs. Flows over the spillway enter the Kids' Fishing Pond then continue as a small stream and discharge directly into Grand Traverse Bay.

When flows are too low to operate one turbine/generator with a minimum of efficiency and stability of operation, bays #1 and/or #2 are used at smaller gate openings to maintain modified run-of-the-river operation. This minimum level of operation and increasing instability occurs at about 0.070 MW, which corresponds to a flow value of about 280 cfs.

Because of actively flowing water at the intakes, ice generally does not form in the project forebay area; however, during very cold weather, ice sheets can form in the forebay and sometimes these ice sheets break and become submerged and block flows through the trashracks. When sheet ice prevents project operation, different units are opened/started and/or closed/shut down simultaneously to shift the ice within the forebay so it becomes fractured, disperses among the four intake bays, and melts the flowing water.

The project's average annual energy produced during the period from 2001 to 2011 ranged from 2,162 MWh to 2,711 MWh, with an estimated average annual generation of 2,422 MWh.

2.2 APPLICANT'S PROPOSAL

2.2.1 Proposed Project Facilities

Antrim County does not propose to construct any new facilities or modify any existing project facilities.

2.2.2 Proposed Project Operation

Antrim County proposes to operate the project as it has been operated under the existing license.

2.2.3 Proposed Environmental Measures

Antrim County proposes to operate and maintain the existing angler walkway, which is attached to the tailrace side of the powerhouse, and associated parking lot.

2.3 STAFF ALTERNATIVE

Under the staff alternative, the project would include Antrim County's proposed measures and the following modifications and additional measures:

- An operation compliance monitoring plan that includes a description of project operation and the equipment and procedures necessary to maintain and monitor compliance with the operational mode required in any license issued;
- posting signage that describes proper boat maintenance techniques to reduce the spread of invasive plant and mussel species; and
- if archaeological resources are discovered during project operation or other project-related activities, cease all activities related to the disturbance and discovery area, and consult with the Michigan SHPO to determine appropriate treatment.

2.4 ALTERNATIVES CONSIDERED BUT ELIMINATED FROM DETAILED STUDY

We considered several alternatives to the applicant's proposal, but eliminated them from further analysis because they are not reasonable in the circumstances of this case. They are: (1) Issuing a non-power license; (2) Federal Government takeover of the project; and (3) retiring the project.

2.4.1 Issuing a Non-Power License

A non-power license is a temporary license the Commission would terminate whenever it determines that another governmental agency will assume regulatory authority and

[11] The chain-of-lakes watershed is a 75 mile-long waterway consisting of 14 lakes and connecting rivers that discharge to empty into Grand Traverse Bay on Lake Michigan.

[12] Circuit Court for the County of Antrim, dated September 25, 1973, in the Matter of the Petition of the Antrim County Board of Commissioners for a Determination of the Normal Height and Level of the Waters of Elk and Skegemog Lakes situated in the County (sic) of Antrim, Grand Traverse and Kalkaska, Michigan file #962–CZ.

[13] The elevations 590.2 and 590.8 feet dam gage datum are equivalent to 587.66 and 588.26 feet International Great Lakes Datum of 1955, respectively.

supervision over the lands and facilities covered by the non-power license. At this time, no agency has suggested a willingness or ability to do so. No party has sought a non-power license, and we have no basis for concluding that the project should no longer be used to produce power. Thus, we do not consider issuing a non-power license a realistic alternative to relicensing the project in this circumstance.

2.4.2 Federal Government Takeover of the Project

We do not consider federal takeover to be a reasonable alternative. Federal takeover and operation of the project would require Congressional approval. Although that fact alone would not preclude further consideration of this alternative, there is no evidence to indicate that federal takeover should be recommended to Congress. No party has suggested federal takeover would be appropriate, and no federal agency has expressed an interest in operating the project.

2.4.3 Retiring the Project

Project retirement could be accomplished with or without the removal of the powerhouse or overflow spillway. Either alternative would involve denial of the license application and surrender or termination of the existing license with appropriate conditions. No participant has suggested that the removal of the powerhouse or overflow spillway would be appropriate in this case, and we have no basis for recommending it. The project reservoir (*i.e.,* Elk and Skegemog Lakes) formed by the powerhouse and overflow spillway serve other important purposes, such as use for recreational activities and in providing water for irrigation. Thus, removal of the powerhouse and overflow spillway is not a reasonable alternative to relicensing the project with appropriate protection, mitigation, and enhancement measures.

The second project retirement alternative would involve retaining the powerhouse and overflow spillway, and disabling or removing equipment used to generate power. Project works would remain in place and could be used for historic or other purposes. This alternative would require us to identify another government agency with authority to assume regulatory control and supervision of the remaining facilities. No agency has stepped forward, no participant has advocated this alternative, nor have we any basis for recommending it. Because the power supplied by the project is needed, a source of replacement power would have to be identified. In these circumstances, we do not consider removal of the electric generating equipment to be a reasonable alternative.

3.0 ENVIRONMENTAL ANALYSIS

In this section, we present: (1) A general description of the project vicinity; (2) an explanation of the scope of our cumulative effects analysis; and (3) our analysis of the proposed action and other recommended environmental measures. Sections are organized by resource area (aquatic, recreation, etc.). Under each resource area, historic and current conditions are first described. The existing condition is the baseline against which the environmental effects of the proposed action and alternatives are compared, including an assessment of the effects of proposed mitigation, protection, and enhancement measures, and any potential cumulative effects of the proposed action and alternatives. Staff conclusions and recommended measures are discussed in section 5.1, *Comprehensive Development and Recommended Alternative* of the EA.[14]

3.1 GENERAL DESCRIPTION OF THE RIVER BASIN

The chain-of-lakes watershed is a 75-mile-long waterway consisting of fourteen lakes (including Elk Lake and Skegemog Lake) and connecting rivers in the northwestern section of the Lower Peninsula of the state of Michigan, which empties into Lake Michigan. The total drainage area of the entire chain-of-lakes covers about 512 square miles across five counties (Antrim, Grand Traverse, Kalkaska, Charlevoix and Otsego) in northwestern Michigan.

The project is located within the Elk-Skegemog subwatershed of the chain-of-lakes (figure 3). The total drainage area of the Elk-Skegemog subwatershed is about 214 square miles. Within the Elk-Skegemog subwatershed, water flows from the Torch River into Skegemog Lake, which is the meeting point of Antrim, Grand Traverse, and Kalkaska Counties. Skegemog Lake then connects to Elk Lake, and flows from Elk Lake into the Elk River upstream of the project (*i.e.,* upper Elk River). Flows from the upper Elk River are then released into the section of the Elk River downstream of the project (*i.e.,* lower Elk River) or over an overflow spillway through the Kids' Fishing Pond, and then into the east arm of Grand Traverse Bay, Lake Michigan (figure 3).

[14] Unless otherwise indicated, our information is taken from the application for license filed by Antrim County on December 21, 2012, and the response to deficiencies and requests for additional information filed on October 16, 2013.

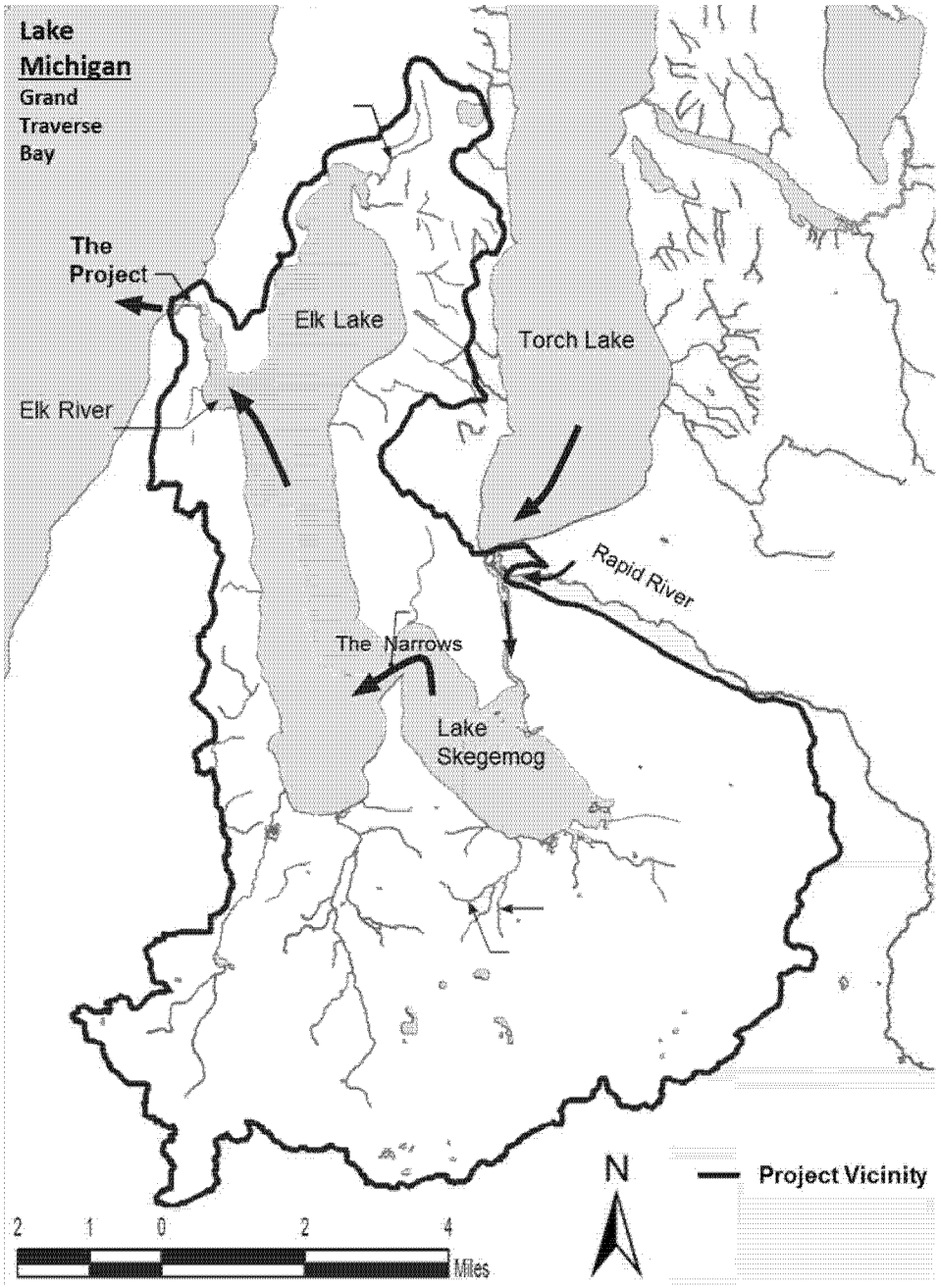

Figure 3. Elk Rapids Project vicinity and direction of water flow through the chain-of-lakes (Source: Antrim County, 2012; as modified by staff).

The project is located on the Elk River in the Village of Elk Rapids in Antrim, Grand Traverse, and Kalkaska Counties, Michigan. The project powerhouse is located approximately 1,000 feet upstream from the confluence of the lower Elk River with Grand Traverse Bay, Lake Michigan. The project's physical structures are located on a 3.7-acre parcel of land owned by Antrim County, which extends from the west edge of Dexter Road to Grand Traverse Bay (Lake Michigan) and includes a narrow strip of land on both sides of the Elk River. Dam Road borders the north side of the project. The project occupies about 0.46 acres of the land parcel, and the remainder of the parcel is leased to the Village of Elk Rapids under a 99-year lease for use as public open space and recreational use.

3.2 SCOPE OF CUMULATIVE EFFECTS ANALYSIS

According to the Council on Environmental Quality's regulations for implementing the National Environmental Policy Act (40 CFR 1508.7), a cumulative effect is the impact on the environment that results from the incremental impact of the action when added to other past, present and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such actions. Cumulative effects can result from individually minor but collectively significant actions taking place over a period of time, including hydropower and other land and water developmental activities.

Based on our review of the license application and agency and public comments, we have determined that no

resources would be cumulatively affected by the continued operation of the project. The project is located in a where there is no proposed future hydropower development other than the Elk Rapid Project.

3.3 PROPOSED ACTION AND ACTION ALTERNATIVES

Only resources that would be affected, or about which comments have been received, are addressed in detail in this EA and discussed in this section. We have not identified any substantive issues related to soils and geology or socioeconomics associated with the proposed action; therefore, we do not assess environmental effects on these resources in this EA. We present our recommendations in section 5.1, *Comprehensive Development and Recommended Alternative* section.

3.3.1 Aquatic Resources

3.3.1.1 Affected Environment

Water Quantity

Project Reservoir

Skegemog Lake, Elk Lake, and the upper Elk River have the same water surface elevation and constitute the project reservoir. Waterways upstream of the reservoir (*e.g.,* Torch Lake) are not included in the project boundary because their surface water levels do not influence the surface levels of Elk and Skegemog Lakes.[15]

Skegemog Lake has a surface area of four square miles (2,560 acres) and a volume of 30,700 acre-feet, with a flushing rate of 24 days. Skegemog Lake has a maximum depth of about 29 feet and an average depth of about 12 feet. Skegemog Lake's shoreline is approximately 11 miles.

Elk Lake, which is the last lake in the chain-of-lakes, has a surface area of 12 square miles (7,730 acres) and a volume of 548,830 acre-feet, with a flushing rate of 365 days. Elk Lake has a maximum depth of about 192 feet and an average depth of about 71 feet. Elk Lake's shoreline is approximately 26 miles.

Water flows to the project by way of the reservoir. Skegemog Lake is connected to Elk Lake via a 0.25-mile-long, 0.25-mile-wide, 5-foot-deep section of water known as the Narrows (figure 3). The Narrows does not restrict flow between the lakes and therefore does not cause a surface level difference between the lakes. As discussed in section 2.1.3, *Existing Project Operation,* Elk and Skegemog Lakes have the same seasonal, legally established lake levels. The lake level for the period from November 1 to April 15 are maintained at 590.2 feet dam gage datum and 590.8 feet dam gage datum from April 15 (or the breakup of ice, whichever date is later) through November 1. During the semi-annual lake level change (every April and November), power generation and water flow through the project is adjusted gradually over a period of two weeks to achieve the required lake levels. The project is responsible for maintaining the court ordered lake levels through its normal operations.

The project's normal operating head is about 10.5 feet. On the intake side of the powerhouse, the reservoir level is dictated by the court ordered lake levels for Elk and Skegemog Lakes. At the powerhouse, the two north bays contain the operating turbines and generator units, and the two south bays, which don't have turbines or generating units, are used to spill excess water and provide flows into the lower Elk River when one or both of the generating units in the north bays are out of service for maintenance. The project tailrace is directly connected to Grand Traverse Bay, Lake Michigan. As a result, the water levels in the tailrace are the same as water levels in Lake Michigan, and the project's net head varies as water levels in Lake Michigan rise and fall.

Project Outflow

Historical generation data was used to calculate a continuous record of accurate outflow for the Elk River drainage basin from 2001–2011. Generation data from the project was gathered from Consumers Energy. The generation data was converted into daily flow values using the United States Geological Survey's (USGS) calibrated turbine rating curves. Historic operation logs from the previous plant operator, Traverse City Light and Power,[16] were used to modify the resulting data for bypassed flows that were encountered during repairs or down time of the generating units. Further adjustments were made to the data twice annually to offset the effects of raising and lowering the Elk Lake level during the legally mandated spring and fall seasons. A final adjustment was made by adding the flow through the spillway located on south channel of the Elk River. The results showed that the highest mean monthly flow on record is 720 cfs for the month of May and the lowest is 412 cfs for September, while the maximum monthly flow on record is 1,049 cfs for June and the minimum monthly flow is 247 cfs for September (table 1).

TABLE 1—CALCULATED MONTHLY FLOWS AT THE ELK RAPIDS PROJECT INTAKE FROM 2001–2011.

[Source: Michigan DNR, 2011; Antrim County, 2011; as modified by staff]

Month	Max (cfs)	Mean (cfs)	Min (cfs)
January	933	663	369
February	805	656	391
March	857	644	375
April	1,044	714	370
May	1,016	720	396
June	1,049	661	386
July	792	497	349
August	753	454	308
September	904	412	247
October	871	537	301
November	951	651	363
December	823	636	355

About 400 feet adjacent (south) of the powerhouse, the upper Elk River's south channel spillway diverts into a 14-foot-wide overflow spillway pond (*i.e.,* Kids' Fishing Pond) that is stop log controlled with two 5 foot diameter culverts. During the winter, when the lake level is 590.2 feet dam gage datum, the south channel spillway provides a minimum flow of 35 cfs. During the summer, when the lake level is raised to 590.8 feet dam gage datum, the south channel spillway provides a minimum flow of 55 cfs. The flows then continue unimpeded after leaving the Kids' Fishing Pond as a small stream that discharges directly into Grand Traverse Bay.

Water Use

The project was originally constructed to produce hydropower. Presently, the project continues to generate hydropower and provides recreational opportunities (*e.g.,* fishing, boating, and wildlife viewing) to the area. The Village of Elk Rapids withdraws surface water for fire protection and for limited irrigation of parks and public properties at four locations, two upstream of the project and two downstream.[17] In addition, riparian landowners and golf courses are permitted to withdraw surface water for irrigation; some riparian landowners also have seasonal pumps that they use for irrigating their lawns and gardens.

[15] The Torch River, which connects Torch Lake with Skegemog Lake (see figure 1), has a flow restriction that creates a surface level difference between Torch Lake and Skegemog Lake.

[16] The project was operated under contract on Antrim County's behalf by Traverse City Light and Power until 2007 when Antrim County entered into the current operating agreement with Elk Rapids Hydro.

[17] Upstream of the project, water is withdrawn from the north channel of the Elk River off the west side of U.S. 31 south of Dexter Street and at a location east of U.S. 31. Along the south channel of the Elk River, water is withdrawn downstream of the project at Memorial Park and on Dexter Street near the Kids' Fishing Pond.

There are two National Pollution Discharge Elimination System (NPDES) permits for discharges within the project, all of which are monitored by Michigan DEQ (table 2). The outfall pipe for the Village of Elk Rapids Water Treatment Plant (NPDES Permit MIG570208) is located immediately downstream of the powerhouse and discharges into the tailrace. The outfall for Burnette Foods is an unnamed tributary downstream of the south channel bypass of the Elk River.

TABLE 2—NPDES PERMITS WITHIN THE ELK RAPIDS PROJECT VICINITY

[Source: U.S. Environmental Protection Agency (EPA), 2012a]

Location	Permit holder	NPDES
Elk River	Village of Elk Rapids Wastewater	MIG570208
Elk River	Burnette Foods, Inc	MI0000485

Water Quality

The Michigan DEQ sets surface water quality standards based on specified designated uses. State water quality standards specify which uses (such as industrial or aquatic life use) individual waters should support (EPA, 2010). According to the Michigan Surface Water Information Management System (MiSWIMS) database (MiSWIMS, 2014), and the EPA (EPA, 2013 and 2014), the surface waters in the project boundary have been recently assessed for the following designated uses:

- Agriculture
- Public water supply
- Navigation
- Coldwater fishery

Results show that the overall status of the project reservoir is considered ''good'', meaning that the reservoir is meeting its attainment goals for Cold Water Fishery, Agriculture, Public Water Supply, and Navigation (table 3) (EPA, 2013 and 2014; MiSWIMS, 2014).

TABLE 3—EPA AND STATE OF MICHIGAN ATTAINMENT GOALS AT THE ELK RAPIDS PROJECT RESERVOIR FOR COLD WATER FISHERY, AGRICULTURE, PUBLIC WATER SUPPLY, AND NAVIGATION

[Source: Staff]

Designated use *	Designated use group **	Project reservoir
Agriculture	Agricultural	Good.
Cold Water Fishery	Fish, Shellfish, and Wildlife Protection and Propagation	Good.
Public Water Supply	Industrial	Good.
Navigation	Other	Good.

* State water quality standards specify which uses individual waters should support.
** The parent designated use represents an EPA-assigned, general categorization for the specific, state-reported designated use.

Michigan DEQ administers federal and state surface water quality standards for wastewater, non-point source pollution, seepage and NPDES permits. State water quality standards for temperature and dissolved oxygen (DO) applicable to the project area are summarized in table 4.[18]

TABLE 4—SUMMARY OF STATE WATER QUALITY STANDARDS FOR DO AND WATER TEMPERATURE APPLICABLE TO THE ELK RAPIDS PROJECT BOUNDARY

[Source: State of Michigan, 1994, as modified by staff]

Parameter	Application	Standard
Dissolved Oxygen	All surface waters of the State.	Min. 7 milligrams per liter (mg/L) in designated coldwater fisheries; Min. 5 mg/L in designated warmwater fisheries.
Temperature	Inland Lakes	No receipt of a heat load is permitted that will increase the receiving water's temperature more than 3 °Fahrenheit (°F) above the existing natural water temperature. No receipt of a head load is permitted that will increase the temperature of the hypolimnion (the dense, cooler layer of water at the bottom of a lake) or decrease its volume.
	Great Lakes and connecting waters.	(1) No receipt of a heat load is permitted that will increase the receiving water's temperature more than 3 °F above the existing natural water temperature. (2) No receipt of a heat load is permitted that will increase the receiving water's temperature more than the following monthly maximum temperature (°F):

Jan.	Feb.	March	April	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
38	38	48	54	65	68	68	68	63	56	48	40

[18] Michigan water quality standards are described in detail in *Part 4 Rules of Part 31 of the Water Resources Protection Act 451 of 1994.*

The Tip of the Mitt Watershed Council (Watershed Council) has been collecting water quality data in the project boundary since 1992, and is currently the primary source for water quality information for Elk River, Elk Lake, and Skegemog Lake. Other general water quality data comes from Michigan DEQ who periodically collects data from Elk and Skegemong Lakes. The Michigan DEQ last collected water quality data from Elk Lake in 1985 and from Skegemog Lake in 2003. Overall, the data indicates that water quality within the project reservoir have remained relatively consistent over the past 10–20 years and typically meets state water quality standards.

Elk and Skegemog Lakes experience thermal stratification [19] during summer. Results from a 2007 water quality study at Elk Lake (Watershed Council, 2008), demonstrates that water temperatures are similar throughout the water column during the spring, meaning that Elk Lake is unstratified (*i.e.*, completely mixed). By late June, Elk Lake is completely stratified, and surface water temperatures throughout the summer (*i.e.*, late June through August) can occasionally exceed the state standard for temperature of 20 °C (*i.e.*, 68 °F). Results from previous water quality studies conducted in Elk Lake during 1985 and 1993 support these recent findings, where water surface temperatures ranged from 21.0 to 24.3 °C (*i.e.*, 69.8 to 75.7 °F) during July and August (Weiss, 1995; Antrim County, 2012).

Elk Lake is classified as an oligotrophic lake, which are characteristically deep, clear, nutrient poor (*i.e.*, low algal biomass), and with abundant levels of DO. Low algal biomass in the lake allows deeper light penetration into the lake resulting in less decomposition of vegetative material, which decreases DO levels. Because oxygen is more soluble in colder water, DO concentrations may therefore increase with depth below the thermocline [20] in Elk Lake.

According to the Watershed Council (2008), results from monitoring Elk Lake from 1998 through 2006 show that high DO concentrations persist in the deeper waters of the lake throughout the most of the summer, and only slightly decline in the deepest potions of the lake toward the end of summer. The Watershed Council (2008) also states that during the course of the 2007 water quality study, DO levels in Elk Lake throughout the water column were consistently around 8 mg/l, and have only been recorded below the state standard of 7 mg/l on one occasion in late summer at the very bottom of the lake (*i.e.*, around 192 feet deep). Results from previous water quality studies conducted in Elk Lake during 1985 and 1993 support these findings, where bottom DO levels in the lake ranged from 8.9 to 10.2 mg/l and surface DO levels in the lake ranged from 8.1 to 9.6 mg/l during July and August (Weiss, 1995; Antrim County, 2012).

Fishery Resources

Fish Community

Skegemog Lake supports a mixed warmwater/coolwater fishery. Typical fish species found in Skegemog Lake include largemouth bass, northern pike, smallmouth bass, sucker species, sunfish, walleye, rock bass, muskellunge, and yellow perch (Michigan DNR, 2014).

Elk Lake, the last lake in the chain-of-lakes, is classified as a coldwater fishery. Because of its cold, deep, and well oxygenated waters, Elk Lake is managed by the Michigan DNR for coldwater species and supports populations of lake trout, lake whitefish, lake herring (*i.e.,* cisco), burbot, and deepwater sculpin. Coolwater species (*e.g.,* smallmouth bass, rock bass, muskellunge, walleye) can be found throughout both Elk and Skegemog Lakes, but tend to concentrate around the Narrows.

The most recent fish survey in the project reservoir (*i.e.,* Elk and Skegemog Lakes) was conducted by Michigan DNR (2011) from April 2008 through March 2009. During the 2008–2009 survey, a total of 21 species were captured using netting and electrofishing techniques; the most abundant species was rock bass, followed by white sucker, yellow perch, and smallmouth bass.

The less than 0.5-mile-long Elk River is a mixed warmwater/coolwater/coldwater fishery. Coldwater species from Lake Michigan, including steelhead trout and other salmonids, are present in the lower Elk River downstream of the project. The south channel bypass pond (Kids' Fishing Pond) is about three acres and also provides a mixed warmwater/coolwater/coldwater fishery; species in the Kids' Fishing Pond include bullhead, largemouth Bass, rainbow trout, suckers, sunfish, and yellow perch (Michigan DNR, 2013).

Aquatic Habitat

Unlike Skegemog Lake, which has an abundance of submerged woody debris along its shoreline (Diana et al., 2014), naturally occurring fish cover (*e.g.,* woody debris) in Elk Lake is limited as a result of shoreline development. In an effort to improve fish habitat by adding structural cover in Elk Lake and other lakes within the chain-of-lakes, a five year collaborative program headed by the Three Lakes Association (Lakes Association), which started in 2012, is currently underway in which man-made fish shelters (*e.g.,* crates, slab trees, and tree stumps) are being deployed in areas devoid of natural habitat (Varga, 2012). At present, 15 fish shelters have been deployed in Elk Lake (Lakes Association, 2014).

The addition of these types of cover structures into Elk Lake and other water bodies is an accepted practice and is a suitable form of habitat enhancement, particularly in areas where cover is limiting fish production (Roni *et al.*, 2005). Researchers have shown that the addition of physical habitat may increase juvenile fish survival in lakes where cover is limited (Bolding *et al.* 2004). For example, Tugend *et al.* (2002) referenced two studies that showed increases in production of age-0 fish (*i.e.,* young-of-the year fish) as a result of habitat improvement efforts.

Invasive Aquatic Plants

According to Antrim County, Eurasian watermilfoil and curly-leaf pondweed are present in the chain-of-lakes and within and adjacent to the project boundary.

Invasive Mussels

Zebra Mussels are an invasive species that were introduced into the Great Lakes in the late 1980s and-have invaded most water bodies in the chain-of-lakes, including Elk Lake and Skegemog Lake. There is no plan to control or eradicate the zebra mussel in the chain-of-lakes watershed because it is so pervasive (Michigan DEQ, 2002).

Invasive Fish Species

Sea lamprey, round goby, alewife, common carp, and white perch are all invasive fish species that are currently known to inhabit Lake Michigan. At present, none of these species have been detected within the project boundary or upstream of the project (*i.e.,* within the chain-of-lakes watershed).

[19] Thermal stratification is a seasonal phenomenon that refers to a change in water temperatures at different depths in a lake. This phenomenon is caused by the seasonal changes of water temperatures that result in changes in water density (*i.e.,* cold water sinks because it is denser than warm water). Because of this density-temperature relationship, a lake can stratify, that is, separate into distinct layers within the water column.

[20] A thermocline is the transition layer between the mixed layer at the surface and the deep water layer.

3.3.1.2 Environmental Effects

Project Operation

Antrim County proposes to continue to operate the project as currently operated. The project would operate in a modified run-of-river mode, whereby outflows from the powerhouse and overflow spillway approximately equals inflow from the chain-of-lakes and are modified to maintain a seasonal reservoir water surface elevations of 590.2 feet dam gage datum from November 1 through April 15 and 590.8 feet dam gage datum from April 15 (or the breakup of ice, whichever date is later) through November 1. Also, the project would continue to meet the lake levels by gradually adjusting the project's water surface levels over a two-week period during each seasonal changeover period (*i.e.,* every April and November).

Michigan DEQ recommends that during adverse conditions, when the operational requirements specified in the 1973 court order cannot be met, Antrim County should consult with the Supervisor for Michigan DEQ, Water Resources Division, regarding emergency actions taken or proposed measures that are planned to meet project operation. Michigan DEQ additionally recommends that when operational requirements specified in the court order are temporarily suspended for maintenance activities, inspections, or dam safety related issues, Antrim County should provide prior notice of these actions to the Supervisor for Michigan DEQ, Water Resources Division.

Our Analysis

Operating the project in a modified run-of-river mode, as proposed by Antrim County, would enable existing project operation to continue to meet the seasonal lake levels. Because the project currently operates in a modified run-of-river mode, minimal changes to aquatic habitat are expected in the reservoir, bypassed reach, and within the project tailrace by continuing this mode of operation.

Scheduled maintenance activities and dam safety inspections have the potential to create situations whereby Antrim County may deviate from its modified run-of-river operation requirements. Also, adverse conditions or emergency situations may create situations whereby Antrim County is unable to comply with its modified run-of-river operation. However, providing notification to not only the Michigan DEQ, but also to the Michigan DNR before or after such incidents and consulting with both agencies until normal project operation can resume, would allow for the state resource agencies to be promptly alerted to these non-compliance events which could potentially affect resources under their respective jurisdictions. Additionally, providing such notification to the Commission that details the cause of the deviation would assist the Commission with administering compliance directives for any license issued for the project.

Developing a compliance monitoring operation plan, after consultation with Michigan DEQ and Michigan DNR, would be beneficial in that it would document the procedures Antrim County would employ to demonstrate compliance with any license requirements for operating the project, including but not limited to, operating in a modified run-of-river mode, maintaining lake level requirements, and meeting reservoir drawdown and refill protocols. A detailed description of the equipment and procedures necessary to maintain, monitor, and report compliance would prevent possible misunderstandings of project operation and reduce the likelihood of complaints regarding project operation.

Water Quality and Monitoring

Michigan DEQ recommends that Antrim County operate the project in such a manner as to adhere to state water quality standards (for temperature and DO) in the Elk River downstream of the powerhouse. Specifically, Michigan DEQ recommends that project operation not cause the waters of the Elk River downstream of the powerhouse to exceed the following state standard monthly average temperatures (shown in °F):

Jan.	Feb.	March	April	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
38	38	48	54	65	68	68	68	63	56	48	40

However, Michigan DEQ states that deviations from these water temperature standards would be acceptable when natural temperatures of Elk Lake, as measured in the Elk River upstream of the project, exceed these specified monthly average temperature values. Michigan DEQ also recommends that project operation does not cause DO concentrations to be less than the state standard of 7.0 mg/L in the Elk River downstream of the powerhouse at any time.

To verify project-related effects on water quality, Michigan DEQ recommends that Antrim County monitor temperature and DO concentrations in the Elk River downstream of the project on an hourly basis from July 1 through August 31 beginning the first year after license issuance, for a minimum of one year.

Our Analysis

Recent and previous water quality studies demonstrate that surface water temperatures of Elk Lake occasionally exceed state standards (Weiss, 1995; Watershed Council, 2008; Antrim County, 2012), usually in late summer, in shallow, nearshore areas as a result of the effects of the thermocline, a naturally occurring phenomenon. Michigan DEQ states that deviations from the state water quality standards for temperature would be acceptable when natural temperatures of Elk Lake, as measured in the Elk River upstream of the project, exceed the specified monthly average temperature values.

Monitoring water temperature downstream of the project would only reflect water temperatures that are entering the project, which typically meeting state standards and any deviations in water temperatures would be caused by natural phenomena and not project operation; therefore, monitoring water temperature downstream of the project would not provide any additional benefits.

According to a condition of the 1999 settlement agreement, the project is required to operate in such a manner as to be in compliance with state water quality standards. Water quality assessments of Skegemog Lake, Elk Lake, and Elk River have demonstrated that temperature and DO levels within the reservoir have remained relatively consistent over the past 10 to 20 years and that water surface DO concentrations are typically at or above 8 mg/L throughout the summer months. Additionally, a recent study by Rediske *et al.* (2010) showed that DO levels within Grand Traverse Bay, near the project, were at or above 10 mg/l during July and August. Given that downstream of the project, the less than 0.5-mile-long Elk River flows directly into Grand Traverse Bay, any temporary decreases

in DO levels that may occur in the tailrace would be quickly mitigated by the high DO levels occurring in the bay. Therefore, continued operations of the project in the same mode of operation it has used in the past, would have little effect on water quality in the Elk River downstream of the powerhouse and that the state DO standard of 7 mg/L would continue to be met and monitoring DO downstream of the project would not be necessary.

Fish Impingement and Entrainment

The operation of the project has the potential to result in some fish impingement on the project trashracks and fish entrainment through the project turbines. Antrim County does not propose any additional measures to minimize fish mortality related to entrainment and impingement.

Our Analysis

The level of fish entrainment and impingement at the project is dependent upon many factors; including age, swim speeds, size, and the seasonality of entrainment and impingement patterns of fish present at the site (EPRI, 1992). Although turbine passage mortality rate estimates can be relatively variable, some trends have been recognized. For example, certain species typically dominate entrainment collections, and the dominant fishes entrained usually represent those species that are highly abundant (FERC, 1995) and are usually fish species that are very fecund (*i.e.,* high reproductive rates). However, fish size rather than species is usually the critical factor influencing the rates of turbine-related mortality. In general, most fish entrained at hydroelectric projects tend to be smaller fish less than 4 to 5 inches long and are often juvenile fish or species such as minnows that never exceed a length of 3 or 4 inches (FERC, 1995; EPRI, 1997).

The velocity of water surrounding a hydroelectric water intake is also an important component in determining the level of potential fish entrainment and impingement. At the project, when the turbines are operated at full gate, the intake velocity in front of the trashrack is 2.0 feet/sec; however, because the project operates at 90 percent of full gate whenever possible (about 98 percent of the time), the intake velocity is typically 1.8 feet/sec. Research has shown that a fish can swim about 8 to 12 body lengths per second in a burst mode that can last up to 20 seconds (Bell, 1986; Videler and Wardle, 1991; Aadland, 2010). For example, a four-inch long fish would have a burst speed of around 2.7 to 4.0 feet/sec. Therefore, most fish species greater than 4 inches in length exposed to the 1.8–2.0 feet/sec velocity at the project intake are likely to escape impingement and entrainment.

Although impingement and turbine entrainment at the project likely causes some losses of resident fish, these losses do not approach a magnitude that adversely affects fish populations. Evidence supporting this conclusion is that the reservoir is currently meeting its designated use attainment goal as a Coldwater Fishery. Also, there is no evidence that existing levels of fish impingement, entrainment, and related mortality, are adversely affecting fish communities in the project area. Therefore, continued operation of the project in the same mode of operation it has used in the past, would likely have little to no adverse effect on the overall fish community in the project reservoir.

Aquatic Invasive Plant and Mussel Species

Aquatic invasive species compete with native species for food and habitat, and can directly or indirectly kill or displace native species, degrade habitat and alter food webs. Eurasian milfoil and curly-leaf pondweed are present in the chain-of-lakes and within and adjacent to the project boundary. Also, the zebra mussel invaded the chain-of-lakes in the 1980s and is still present in the watershed, including in Elk Lake and Skegemog Lake. Antrim County does not propose any measures to address invasive species within the project boundary.

Our Analysis

Dense growth of curlyleaf pondweed and Eurasian watermilfoil reduces populations of native submersed plant species and alters the ecosystem so that it is inhospitable to fish and other fauna (Wolf, 2009; Madsen, 2009). Because curlyleaf pondweed and Eurasian watermilfoil can each form dense mats on the water's surface in May and June, they can inhibit fishing, boating, and other types of water recreation (Madsen, 2009).

Because curlyleaf pondweed and Eurasian watermilifoil may become tangled on the nets, ropes, and propellers of recreational boats, the spread of these species into new waters is often the result from overland dispersal by recreational boaters (Leung et al., 2006).

The zebra mussel, based on its ecological and economic effects, is considered the most aggressive freshwater invaders in the Northern hemisphere (Nalepa and Schloesser, 1993; Karatayev et al., 2014). The zebra mussel is a prolific filter feeder, removing substantial amounts of phytoplankton and suspended particulates from the host water body adversely affecting aquatic ecosystems by altering food webs (USGS, 2013). Zebra mussels have high reproductive potential, planktonic free-swimming larvae called veligers, and an attached benthic adult stage. This life history facilitates their success as invaders, allowing it to spread rapidly across landscapes, and become extremely abundant when introduced into a new waterbody (Karatayev et al., 2014). Because zebra mussels can attach to the hulls of boats, and their veligers (*i.e.,* planktonic larvae) may be taken up and carried in the bilge water of recreational vessels, the majority of new invasions result from overland dispersal by recreational boaters (Leung et al., 2006).

Curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels are all transferred to other waterbodies primarily by boats. While there is no plan to control or eradicate the zebra mussel in the chain-of-lakes watershed because it is so pervasive, public education may reduce the transfer of the invasive mussel to other water bodies. Also, public education on how to minimize transfer of curlyleaf pondweed and Eurasian watermilifoil could reduce the likelihood of further invasions of project waters and other waterbodies. As discussed in section 3.3.4.1, *Regional Recreation Resources,* the project's recreation site is near a marina. Developing signage, in consultation with the Michigan DNR and Michigan DEQ, regarding cleaning and drying of boats between launches, and posting the signage at the project recreation site, would help inform the public of proper management techniques to reduce the spread of curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels.

Invasive Fish Species

Invasive fish species are known to spread quickly and out-compete native fish for food and habitat, which can cause a decline in the diversity of aquatic ecosystems. Sea lamprey, round goby, alewife, common carp, and white perch are all invasive fish species that are currently known to inhabit Lake Michigan. At present, none of these species have been detected upstream of the project powerhouse (*i.e.,* within the chain-of-lakes watershed). Once established in a water body (*e.g.,* Lake Michigan), invasive fish species primarily spread to new water bodies (*e.g.,* inland lakes) by way of direct hydrologic connection.

Our Analysis

To date, project operation and the presence of the project powerhouse have been successful in preventing the invasive fish species identified above from passing upstream into the reservoir. No invasive fish species have been collected upstream of the project powerhouse during the surveys conducted by Michigan DNR in 1990, 1996, and 2011. Therefore, continuing to operate the project in a modified run-of-river mode, and maintaining the project powerhouse, as proposed by Antrim County, would likely continue to block invasive fish species from passing upstream of the project.

3.3.2. Terrestrial Resources

3.3.2.1 Affected Environment

Botanical Resources

The chain-of-lakes watershed is classified as a flat lake plain with well-drained sand, dominated by northern hardwoods in the uplands, conifer swamps in the lowlands and American beech/hemlock forests in between (Michigan Natural Features Inventory, 1999). The Northern Hardwood forest community is the northernmost deciduous forest community in eastern North America. In general, this community is dominated by three deciduous tree species: yellow birch, sugar maple, and American beech. Two coniferous species, eastern hemlock and white pine, are also typically found in abundance in this forest community.

Wetland acreage within the project vicinity totals about 4,090 acres; of those, about 3,155 acres are classified as forested, 560 acres as emergent, and 376 as scrub-shrub. The Watershed Council classifies many of the wetlands within the project vicinity as ''high quality''. They define high quality wetlands as wetlands that are large, contiguous wetlands on a major lake or stream, approximately 50 acres or greater in size, and identified on a USGS topographic map.

The riparian zone in the project vicinity is about 80 percent developed. Preliminary estimates indicate that the Skegemog Lake shoreline is 80 percent developed, with patches of wetlands located on 74 percent of the shoreline parcels. Elk Lake is estimated to be 78 percent developed with patches of wetlands on 50 percent of the shoreline parcels (Fuller, 2001). Over 80 percent of the Elk River's shoreline has been armored with seawall and riprap.

Wildlife Resources

The upland habitat supports a variety of bird species such as songbirds and woodpeckers, raptors (hawks, bald eagle), and upland game birds (wild turkey, ruffed grouse). Larger species such as black bear, bobcat, coyotes, and white-tailed deer are also found in the uplands of the project vicinity. Habitat for populations of songbirds, waterfowl, shorebirds, muskrat, mink, and raccoon are provided by the wetlands and lakeshores. The predominant small mammal species found near the project are squirrel, fox, raccoon, mink, muskrat, skunk, and rabbit (Village of Elk Rapids, 2013).

3.3.2.1 Environmental Effects

Antrim County does not propose any changes to project operation, and does not propose any new construction.

Our Analysis

Based on the fact there would be no changes to project operation, and there would be no changes to seasonal water levels in the reservoir, the project would not affect wildlife resources and their habitats.

3.3.3 Threatened and Endangered Species

3.3.3.1 Affected Environment

FWS records indicate that that one federally listed endangered species, the Kirtland's warbler (Setophaga kirtlandii), and 4 federally listed threatened species: (1) The Northern long-eared bat (Myotis septentrionalis); (2) Rufa red knot (Calidris canutus rufa); (3) Pitcher's thistle (Cirsium pitcher); (4) and Houghton's goldenrod (Oligoneuron houghtonii) are listed as occurring within one or more of the counties where the Elk Rapids Project exists.[21]

Kirtland's Warbler

The Kirtland's warbler is federally listed as endangered. The bird species primarily breeds in Michigan's Upper and Lower Peninsulas, but have also been documented nesting in Wisconsin and Canada since 2007 (FWS, 2012). The Kirtland's warbler nests only in young jack pine forests of 80 acres or larger that grow on a special type of sandy soil and contain numerous small, grassy openings (FWS, 2015a). The species is also migratory, and winters throughout the Bahama Islands. Factors limiting Kirtland's Warbler populations include their highly specialized habitat requirements, narrow geographic range, and cowbird nest parasitism.[22] No critical habitat has been designated for the Kirtland's warbler.

Rufa Red Knot

The Rufa red knot is federally listed as threatened. The bird species is a regular, low-density spring migrant that uses the shores of the Great Lakes as stopover areas to rest and forage between wintering and breeding areas (FWS, 2013 and 2014a). Some Rufa red knots fly more than 9,300 miles from south to north every spring and repeat the trip in reverse every autumn, making this bird one of the longest-distance migrants (FWS, 2013). The Rufa red knot is imperiled due to losses of both breeding and nonbreeding habitat, as well as a reduction in its primary prey, horseshoe crab eggs. No critical habitat has been designated for the Rufa red knot.

Northern Long-Eared Bat

The northern long-eared bat is federally listed as threatened. The range of the northern long-eared bat includes much of the eastern and north central United States, as well as the southern and central provinces of Canada. The species hibernates in caves and mines during winter months, and typically prefers those with large passages and entrances, constant temperatures, and high humidity. In the summer, northern long-eared bats roost singularly or in colonies underneath bark, in cavities, or in crevices of both live and dead trees (FWS, 2015b). Males and non-reproductive females may also roost in cooler places, like caves and mines, and foraging primarily occurs within forested hillsides and ridgelines with moths, flies, and other insects serving as the main food source. White-nose syndrome, a fungal disease known to affect only bats, is the largest threat to the northern long-eared bat, and according to the FWS (2015c), the species would likely not be imperiled were it not for this disease. No critical habitat has been designated for the northern long-eared bat.

Houghton's Goldenrod

The Houghton's goldenrod is federally listed as threatened. The plant species occurs primarily in the northernmost regions of Lakes Huron and Michigan. Habitat of the Houghton's goldenrod is restricted to calcareous beach sands, cobble and rocky shores, beach flats, and most commonly the shallow, trough-like interdunal wetlands that parallel shoreline areas (Penskar et al., 2000). Fluctuating water levels of the

[21] Except for the federally threatened Houghton's goldenrod, which is only listed in Kalkaska County, all of the other federally listed species are known to occur in Antrim, Grand Traverse, and Kalkaska Counties.

[22] Cowbirds lay one or more eggs in a Kirtland's warbler nest and their young typically hatch first and overpower the smaller Kirtland's nestlings (Mayfield, 1992).

Great Lakes play a role in maintaining the species. During high water years, colonies of Houghton's Goldenrod may be submerged; when water levels recede some plants survive the inundation and new seedlings establish on the moist sand (Michigan DNR, 2015). The species is threatened by habitat loss or modification caused by residential development and recreational activities, particularly off-road vehicles. No critical habitat has been designated for the Houghton's goldenrod.

Pitcher's Thistle

Pitcher's thistle is federally listed as threatened. The range of the plant species is primarily within Michigan's borders, occurring along the entire shoreline of Lake Michigan, with localities along the more limited dunes of Lake Huron and a few sites along the shores of Lake Superior. Pitcher's thistle is most commonly found on large, intact, active dunes of the Great Lakes; the species requires sand dune habitat that is subject to natural disturbance processes to maintain its early successional habitat (Higman and Penskar, 2000). The plant's survival is threatened by shoreline development, dune stabilization, recreation, and invasive non-native plants and insects. No critical habitat has been designated for Pitcher's thistle.

3.3.3.1.1 Environmental Effects

Antrim County does not propose any changes to project operation, and does not propose any new construction. No comments regarding these species were provided by any resource agency or interested party.

Our Analysis

The Kirtland's warbler nests only in young jack pine forests growing on a special type of sandy soil that are about 80 acres or larger with numerous small, grassy openings. Because this type of habitat is not present at the project, we conclude that continued operation of the project would have no effect on this species.

The Rufa red knot and Pitcher's thistle each require specialized coastal shoreline habitat of the Great Lakes that does not exist within the project boundary and are not affected by project operations. Furthermore, no new construction is proposed for the project. Therefore, we conclude that continued operation of the project would have no effect on these species.

The Houghton's goldenrod is restricted to specialized coastal habitat primarily consisting of interdunal wetlands and its ability to reproduce is dependent on the natural fluctuating water levels of the Great Lakes. There are no interdunal wetlands within the project boundary. Furthermore, because outflow from the project has no effect on water levels in Lake Michigan, continued operation of the project would have no effect on this species.

Northern long-eared bats could potentially occur in any area with forested habitat in any county in Michigan; however, the project boundary is highly developed. According to the FWS (2014b),[23] trees found in developed urban areas, such as the lands located around the project powerhouse, are extremely unlikely to be suitable habitat for northern long-ear bats. Additionally, the project is not located in an area that contains kart geologic features (Gillespie et al., 2008), which can support cave and mine habitat needed for hibernation and roosting. Although a limited amount of dispersed riparian and wetland habitat in the project area could be used for foraging, roosting, and breeding by northern long-eared bats, this habitat would not be affected because there would be no changes to project operation and therefore no changes to seasonal water levels. Moreover, Antrim County does not propose any new construction and no trees would be removed as part of the proposed relicensing of the project. Also, maintenance activities would be restricted to areas around the powerhouse and transmission lines, which do not contain habitat or trees at or nearby the facilities. Therefore, we conclude that continuing to operate the project would have no effect on this species.

3.3.4 Recreation, Land Use, and Aesthetic Resources

3.3.4.1 Affected Environment

Regional Recreation Resources

Regional recreation resources in Antrim County include opportunities for camping, hiking, biking, hunting, fishing, boating, swimming, picnicking, wildlife viewing and nature photography, ice skating, skiing, snowmobiling, and parks and fields for a variety of playground and sport activities. Within the county, outdoor recreation abounds with the availability of parks, trails, ponds, lakes, trails, natural areas, and nature preserves. Battle Creek and Kewadin Wetlands natural areas, along with Palustra-Holm Nature Preserve surround Elk Lake. Around Lake Skegemog are North Skegemog Nature Preserve and Skegemog Lake Wildlife Area. Cumulatively, these sites provide 3,300 acres of habitat and wildlife view surrounding both lakes.

Elk River, Elk Lake, and Lake Skegemog constitute the project's water bodies. Together, the lakes have a surface area of 16 square miles and a shoreline length of 37 miles. Elk River is less than a half mile long. There are 38 public access points and three marinas around the reservoir or downstream of the project. The public access points consist of paved boat launches, street ends, beaches, parks, overlooks, and walking trails. Table 5 identifies all public water access sites and marinas around Elk Lake and Lake Skegemog, while figure 4 provides a map of marinas and water access sites around Elk Lake and Lake Skegemog, and figure 5 provides a detailed map of the same facilities near the powerhouse.

TABLE 5—PUBLIC WATER ACCESS SITES AT THE ELK RAPIDS PROJECT

[Source: Staff]

Access site	Manager	Facilities
Elk Lake		
Bussa Road Extension	Antrim County	Launch, beach.
Chippewa Trail Extension	Antrim County	Launch, beach, swimming.
Easly Road Extension	Antrim County	Launch, parking.
East Elk Lake Drive/Schweitzer Lane Addition.	Antrim County	Launch, parking.

[23] [Online] URL: *http://www.fws.gov/northeast/virginiafield/pdf/NLEBinterimGuidance6Jan2014.pdf.* Accessed May 7, 2015.

TABLE 5—PUBLIC WATER ACCESS SITES AT THE ELK RAPIDS PROJECT—Continued

[Source: Staff]

Access site	Manager	Facilities
Elk Lake Access	Antrim County	Launch, swimming, picnic area, seasonal floating pier and slip, parking.
Elk Lake Access—East 3rd	Village of Elk Rapids	Launch, parking.
Elk Rest Drive	Milton Township	Beach, parking.
Hoopfer Road Extension	Antrim County	Overlook.
Kewadin Access	Milton Township	Paved launch, parking.
Milton Township Beach	Milton Township	Beach, swimming, volleyball, nature trail, parking.
Milton Township Park Annex—East Elk Lake Drive.	Milton Township	Pavilions, picnic area, parking.
Quail Street Extension	Antrim County	Paved launch, parking.
Rex Terrace Extension	Antrim County	Launch, parking.
Ringler Road Park—Site #38	Milton Township	Beach, parking.
Rotary Park	Village of Elk Rapids	Pavilions, picnic area, parking.
Schweitzer Lane	Michigan DNR	Launch, beach, restrooms, parking.
Terrace Avenue Extension	Antrim County	Launch.
Townline Road Extension	Antrim County	Beach, picnic area, swimming, volleyball, parking.
Wahboos Road Extension	Antrim County	Launch, parking.
Whitewater Township Park	Whitewater Township	Paved launch, beach, fishing, swimming, pavilions, picnic area, electric campsites, restrooms and showers, volleyball, parking.
Williams Drive	Milton Township	Launch, beach, fishing, swimming, parking.
Elk River		
Bridge Street Access	Village of Elk Rapids	Paved launch, parking.
Dexter Street Walkway	Village of Elk Rapids	Walkway, picnic area.
Elk Rapids Dam Fishing Park	Village of Elk Rapids	Fishing, restrooms, parking.
Elk Rapids Upper Harbor	Village of Elk Rapids	Marina, slips and docks, picnic area, restrooms, parking.
Elk River Access—East 3rd	Village of Elk Rapids	Launch, parking.
Elk River Access—US31	Village of Elk Rapids	Paved launch, parking.
Elk River Boardwalk	Village of Elk Rapids	Boardwalk, seasonal floating slips.
Elk River Marina	Private	Marina, slips, seasonal boat storage and dry docks, restrooms, boat rentals, customer parking.
4th Street	Village of Elk Rapids	Launch, parking.
Millers Park Road North	Village of Elk Rapids	Access.
Millers Park Road South	Village of Elk Rapids	Access, parking.
West Meguzee Point Road	Village of Elk Rapids	Launch.
Elk River Spillway		
Kids' Fishing Pond	Village of Elk Rapids	Fishing, picnic area, parking.
Grand Traverse Bay		
Dam Beach	Village of Elk Rapids	Beach, swimming, picnic area, restrooms, volleyball, parking.
Elk Rapids Lower Harbor	Village of Elk Rapids	Marina, paved launch, slips, beach, fishing, pavilions, picnic area, restrooms, parking.
Lake Skegemog		
Baggs Landing	Michigan DNR	Paved launch, restrooms, parking.
Fairmont Drive—Site #48	Milton Township	Launch.
Hoiles Drive NW	Clearwater Township	Launch, parking.
Skegemog Lake Wildlife Area Viewing Platform.	Michigan DNR	Viewing platform, nature trail, parking.
Skegemog Swamp Pathway	Michigan DNR	Nature trail, parking.

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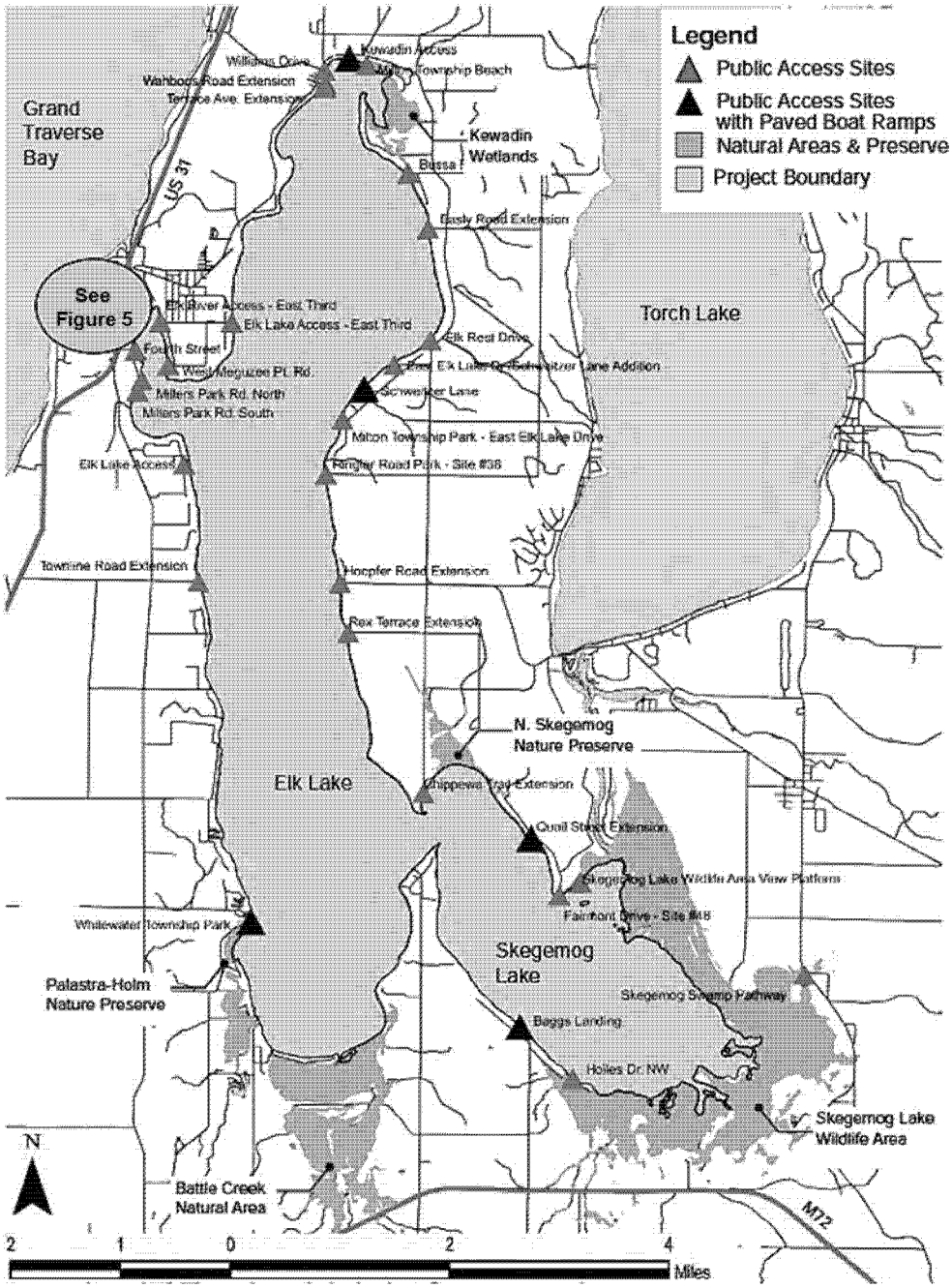

Figure 4. Public access sites around the Elk Rapids Project reservoir (Source: Antrim County, 2012; as modified by staff).

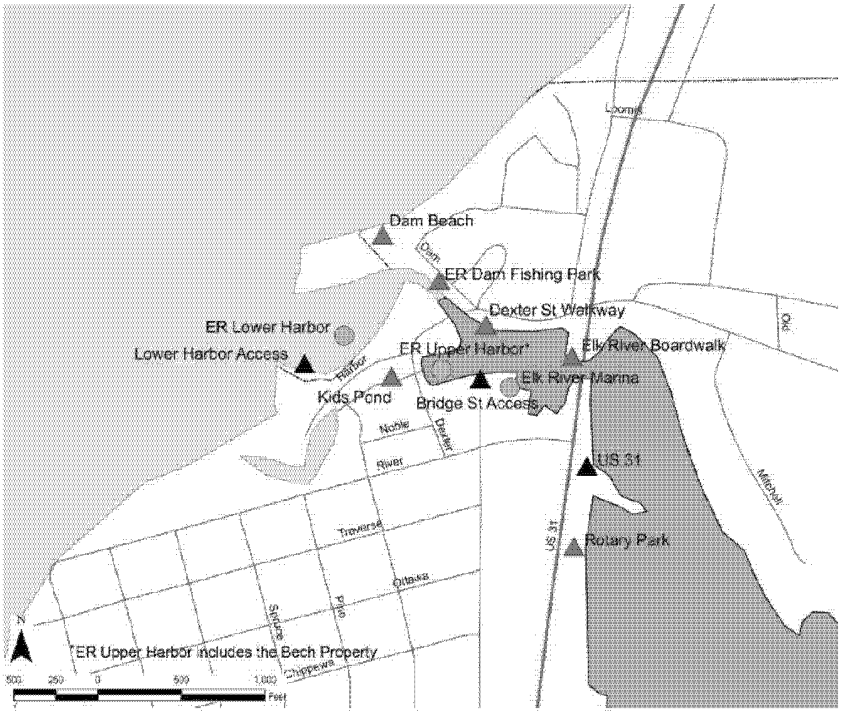

Figure 5. Recreation facilities in the Elk Rapids Project boundary (Source: Antrim County, 2012).

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Existing Project Recreation Facilities

Within the project boundary, Antrim County owns and maintains an angler's walkway, attached to the tailrace side of the powerhouse, which anglers use to access the tailrace for fishing. Antrim County also owns and maintains the project's parking lot, located adjacent to the powerhouse, which is where anglers can park their vehicles to access the walkway.

Recreation Use

The reservoir is located in the Village of Elk Rapids and the Elk Rapids, Milton, Clearwater, and Whitewater Townships. These communities all have small residential populations that nearly double during the summer when seasonal residents and tourists arrive. Many of the area's seasonal homes are converting to permanent homes as people retire, and there is a general demographic shift towards an older permanent population. A site inventory and field survey were conducted on August 28, 2011, and reported all marinas, access sites, and recreation sites to be in good to excellent condition.

Land Use

Land use on the reservoir's shorelines is 80 percent developed, with primary uses being residential, commercial, and parks/open space. Seawall and riprap cover over 80 percent of the Elk River's shoreline to protect the lawns of restaurants, condominiums, and other residential development along the river.

3.3.4.1 Environmental Effects

Antrim County does not propose any construction or changes to current project operation or recreation enhancements. Antrim County proposes to continue operation and maintenance of angler's walkway, attached to the tailrace side of the powerhouse, and the project's adjacent parking lot, which is where anglers can park their vehicles.

Our Analysis

The continued operation of the angler's walkway and the adjacent parking lot would ensure that anglers have access to fishing in the tailrace of the project. In addition, the project's proposed operation would not change; therefore, the existing recreational access sites would remain accessible at current water elevations.

Numerous opportunities for public recreation and access to the project reservoir exist, which are owned, operated, and maintained by either Antrim County; the Village of Elk Rapids; the Elk Rapids, Milton, Clearwater, or Whitewater townships; or the Michigan DNR.

Antrim County reviewed the most current relevant state, county, and local planning documents to assess whether the existing recreation along the reservoir are sufficient to meet current and future needs. Following document review, Antrim County conducted interviews with county and local officials to determine: (1) Whether county and local plans and priorities had changed since the publication of the most recent plan; (2) whether additional recreational needs had since been identified; and (3) if the local officials anticipated any changes in recreational access needs in the future.

Based on the aforementioned document review and interviews, Antrim County determined that existing water access to the reservoir would be sufficient to meet current and future recreational needs. No quantitative information was used to aid in this determination; however, local jurisdictions stated that the facilities are adequate, and no additional recreation or access points are needed to accommodate current and future recreation needs.

By 2020, the population for the towns and villages adjacent to the project is estimated to grow between 3 to 6 percent. The existing recreational access and facilities around the project's reservoir should be sufficient for future recreation needs. However, if existing recreation access or facilities were to reach or exceed capacity, the FERC Form 80—Licensed Hydropower Development Recreation Report, which requires a licensee to collect recreation

use data every 6 years, would provide a forum for adding additional recreation facilities.

3.3.5 Cultural Resources

3.3.5.1 Affected Environment

Area of Potential Effect

Under section 106 of the NHPA of 1966, as amended, the Commission must take into account whether any historic property within project's APE could be affected by the project and allow the Advisory Council on Historic Preservation a reasonable opportunity to comment if any adverse effects on historic properties [24] are identified within the project's APE. The APE is defined as the geographic area or areas in which an undertaking may directly or indirectly cause alterations in the character or use of historic properties, if any such properties exist. In this case, the APE for the project is the lands enclosed by the project boundary.

Regional History

The Village of Elk Rapids was established in the 1850s, among many other ''boom towns,'' that sprang up along the mouths of northern Michigan's rivers to ship the area's natural resources, like semi-finished iron and lumber, to larger cities further south. The Dexter-Noble Company, later known as the Elk Rapids Iron Company, bought land and timber rights in the area and merged with the Elk Rapids Iron Company, monopolizing all commerce and industry within the village. The Elk Rapids Iron Company set up an industrial park on the east side of Elk River, which consisted of a chemical works, charcoal kilns, and a pig iron blast furnace. Today, the only surviving evidence is part of the furnace's brick hearth and a Michigan State Historic Marker stating that the furnace was ''one of the nation's greatest producers of charcoal iron.''

The first water-powered sawmill was installed in the early 1850s on the site of the project's current spillway, but by 1871, the Elk Rapids Iron Company had also constructed a water-powered, 4-story gristmill and wooden powerhouse at the site. The saw mill went through a number of renovations and upgrades before being relocated to the site of the current powerhouse. During its period of operation, the sawmill produced 15 million board feet of lumber annually until the facility was razed in 1915, along with the powerhouse and gristmill, as a result of the depletion of Northern Michigan white pine.

The project's powerhouse was constructed in 1916 with a brick superstructure and housed two generation units in the two south bays. Equipment for Bay #2 was installed in 1918 and, in 1920, the turbine from the Elk Rapids Iron Company's old wooden powerhouse was installed in Bay #1. Bay #3 received a wooden superstructure and a turbine-generating unit in 1923. Between 1929 and 1930, the brick and wood superstructure was removed and the current building was built to cover all four bays. In preparation for the project's 1981 license application, the Michigan SHPO determined that the building was not eligible for the National Register.

3.3.5.2 Environmental Effects

Antrim County does not propose any changes to project operation or any new construction. In a letter dated October 28, 2010, and filed with the license application, the Michigan SHPO stated that based on the information provided for their review, no known historic properties would be affected by the project.

Our Analysis

The Elk Rapids Project would not affect any known historic properties; however, there is always a possibility that unknown archaeological resources may be discovered in the future as a result of the project's operation or project-related activities. To ensure the proper treatment of any archaeological resource that may be discovered, a provision should be included in any license issued to notify the Michigan SHPO of any such unanticipated discovery, follow the Michigan SHPO's guidance regarding an evaluation of the discovery, and, if the resource would be eligible for the National Register and adversely affected, implement ways to avoid, lessen, or mitigate for any adverse effects.

3.4 NO-ACTION ALTERNATIVE

Under the no-action alternative, the project would continue to operate as it has in the past. None of the applicant's proposed measures or the resource agencies' recommendations would be required. No new environmental protection, mitigation, or enhancement measures would be implemented.

4.0 DEVELOPMENTAL ANALYSIS

In this section, we look at the project's use of the Elk River for hydropower purposes to see what effect various environmental measures would have on the project's costs and power generation. Under the Commission's approach to evaluating the economics of hydropower projects, as articulated in *Mead Corp.*,[25] the Commission compares the current project cost to an estimate of the cost of obtaining the same amount of energy and capacity using a likely alternative source of power for the region (cost of alternative power). In keeping with Commission policy as described in *Mead Corp*, our economic analysis is based on current electric power cost conditions and does not consider future escalation of fuel prices in valuing the hydropower project's power benefits.

For each of the licensing alternatives, our analysis includes an estimate of: (1) The cost of individual measures considered in the EA for the protection, mitigation, and enhancement of environmental resources affected by the project; (2) the cost of alternative power; (3) the total project cost (*i.e.*, for continued operation of the project and environmental measures); and (4) the difference between the cost of alternative power and total project cost. If the difference between the cost of alternative power and total project cost is positive, the project produces power for less than the cost of alternative power. If the difference between the cost of alternative power and total project cost is negative, the project produces power for more than the cost of alternative power. This estimate helps to support an informed decision concerning what is in the public interest with respect to a proposed license. However, project economics is only one of many public interest factors the Commission considers in determining whether, and under what conditions, to issue a license.

4.1 POWER AND ECONOMIC BENEFITS OF THE PROJECT

Table 6 summarizes the assumptions and economic information we use in our analysis. This information, except as noted, was provided by Antrim County in its license application filed with the Commission on December 21, 2012, and in deficiency and additional information request responses filed on October 16, 2013. We find that the values provided are reasonable for the purposes of our analysis. Cost items common to all alternatives include: (1) Taxes and insurance costs; (2) estimated future capital investment required to maintain and extend the life of plant

[24] Historic properties are defined as any district, site, building, structure, or object that is included in or eligible for inclusion in the National Register.

[25] See Mead Corporation, Publishing Paper Division, 72 FERC ¶ 61,027 (July 13, 1995). In most cases, electricity from hydropower would displace some form of fossil-fueled generation, in which fuel cost is the largest component of the cost of electricity production.

equipment and facilities; (3) licensing costs; and (4) normal operation and maintenance cost. Because the project is operated by a municipality, no federal or local taxes were considered. Pursuant to 18 Code of Federal Regulations 11.1 (a)(1) a hydropower project's authorized installed capacity must be above 1.5 MW to be assessed annual charges. Therefore, no Commission fees are assessed. All dollars are year 2015.

TABLE 6—PARAMETERS FOR THE ECONOMIC ANALYSIS OF THE ELK RAPIDS PROJECT

[Source: Antrim County, 2012; as modified by staff]

Economic parameter	Value	Source
Installed capacity (MW)	0.700	Applicant.
Average annual generation (MWh)	2,422	Applicant.
Annual O&M cost	$110,497 [a]	Applicant.
Cost to prepare license application	$179,046 [a]	Applicant.
Undepreciated net investment	$511,560 [a]	Applicant.
Period of economic analysis	30 years	Staff.
Term of financing	20 years	Staff.
Cost of capital (Long-term interest rate) (%)	8.00	Staff.
Short-term interest rate (during construction) (%)	8.00	Staff.
Insurance rate (%)	0.25	Staff.
Energy rate ($/MWh) [b]	32.37	Staff.
Capacity rate ($/kilowatt-year)	162.00	Staff.

[a] Cost was provided by Antrim County in the application in $2012. Cost was indexed to $2015 using rates obtained from *http://www.usinflationcalculator.com/inflation/current-inflation-rates.*

[b] Source: Energy Information Administration using rates obtained from *Annual Energy Outlook 2014 at http://www.eia.gov/forecasts/aeo/index.cfm.*

4.2 COMPARISON OF ALTERNATIVES

Table 7 summarizes the installed capacity, annual generation, cost of alternative power, estimated total project cost, and the difference between the cost of alternative power and total project cost for each of the action alternatives considered in this EA: (1) No-action; (2) Antrim County's proposal; and (3) the staff-recommended alternative.

TABLE 7—SUMMARY OF ANNUAL COST OF ALTERNATIVE POWER AND ANNUAL PROJECT COST FOR THE ACTION ALTERNATIVES FOR THE ELK RAPIDS PROJECT

[Source: Antrim County, 2012; as modified by staff staff]

	No-action alternative	Antrim county's proposal	Staff-recommended alternative
Installed capacity (MW)	0.700	0.700	0.700
Annual generation (MWh)	2,422	2,422	2,422
Annual cost of alternative power ($/MWh)	50.86	50.86	50.86
Annual project cost ($/MWh)	71.66	71.77	72.06
Difference between the cost of alternative power and project cost ($/MWh) [a]	(20.80)	(20.91)	(21.20)

[a] A number in parentheses denotes that the difference between the cost of alternative power and project cost is negative, thus the total project cost is greater than the cost of alternative power.

4.2.1 No-Action Alternative

Under the no-action alternative, Antrim County would continue to operate the project in its current mode of operation. The project would have an installed capacity of 0.700 MW and generate an average of 2,422 MWh of electricity annually. The average annual cost of alternative power would be $123,183 or about $50.86/MWh. The average annual project cost would be $175,280 or $71.66/MWh. Overall, the project would produce power at a cost that is $50,378 or $20.80/MWh, more than the cost of alternative power.

4.2.2 Applicant's Proposal

Under the applicant's proposal, the project would continue to operate in its current mode with an installed capacity of 0.700 MW and generate an average of 2,422 MWh of electricity annually. The average annual cost of alternative power would be $123,183 or about $50.86/MWh. The average annual project cost would be $173,827, or about $71.77/MWh. Overall, the project would produce power at a cost that is $50,644 or $20.91/MWh more than the cost of alternative power.

4.2.3 Staff Alternative

Under the staff alternative, the project would have an installed capacity of 0.700 MW, and generate an average of 2,422 MWh of electricity annually. Table 8 shows the staff-recommended additions and modifications to Antrim County's proposed environmental protection and enhancement measures and the estimated cost of each.

Based on an installed capacity of 0.700 MW and an average annual generation of 2,422 MWh, the cost of alternative power would be $123,183 or $50.86/MWh. The average annual cost of project power would be $182,473 or $72.06/MWh. Overall, the project would produce power at a cost which is $51,346 or $21.20/MWh, more than the cost of alternative power.

4.3 COST OF ENVIRONMENTAL MEASURES

Table 8 gives the cost of each of the environmental enhancement measure considered in our analysis. We convert all costs to equal annual (levelized) values over a 30-year period of analysis to give a uniform basis for comparing the benefits of a measure to its cost.

TABLE 8—COST OF ENVIRONMENTAL MITIGATION AND ENHANCEMENT MEASURES CONSIDERED IN ASSESSING THE ENVIRONMENTAL EFFECTS OF CONTINUED OPERATION OF THE ELK RAPIDS PROJECT

[Source: Staff]

Enhancement/mitigation measure	Entities	Capital cost (2015 $)	Annual cost (2015 $)	Levelized cost (2015 $) [1]	Notes
Project Operations:					
Operate the project in a modified run-of river mode, except as necessary to seasonally drawdown or refill the project reservoir.	Antrim County, Staff	$0	$0	$0	a, b
Maintain the water surface elevation of the project reservoir at 590.8 feet dam gage datum April 15 to November 1 and 590.2 feet dam gage datum from November 1 to April 15, except as necessary to seasonally drawdown or refill the reservoir.	Antrim County, Staff	0	0	0	a, b
Develop an operation compliance monitoring plan in consultation with the Michigan DNR and Michigan DEQ.	Staff	2,000	325	508	a
Aquatic Resources:					
Monitor water temperature and DO downstream of the project from July 1 through August 31 on an annual basis, unless upon Michigan DEQ approval, results indicate the monitoring requirements may be relaxed.	Michigan DEQ	1,500	250	158	a, f
Ensure project operation does not cause water temperatures or DO concentrations downstream of the project to exceed state water quality standards.	Michigan DEQ	0	0	0	a, e
Consult with Michigan DEQ in the event of adverse conditions which prevent Antrim County from complying with operational requirements.	Michigan DEQ	0	0	0	a
Consult with the Commission, Michigan DEQ, and Michigan DNR in the event of adverse conditions which prevent Antrim County from complying with operational requirements.	Staff	0	0	0	a
Post signage that describes proper boat maintenance techniques to reduce the spread of curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels.	Staff	1,000	100	191	a
Recreation Resources:					
Operate and maintain the existing angler walkway, which is attached to the tailrace side of the powerhouse, and parking lot.	Antrim County, Staff	0	252	252	d
Cultural Resources:					
Cease project activities should archaeological resources be identified during project operation or other project-related activities and consult with the Michigan SHPO to determine appropriate treatment.	Staff	0	0	0	a, c

[1] Costs were rounded to the nearest dollar.
[a] Cost estimated by staff.
[b] This measure represents a continuation of existing conditions, so there would be no additional cost to implement this measure.
[c] Staff estimates that the cost to implement this measure would be negligible.
[d] Cost provided by Antrim County in its Additional Information Response filed on October 16, 2013.
[e] Staff was unable to assign a cost for this measure, because the project currently has no ability to control water temperature.
[f] The monitoring cost is $250 for the first year only, which equates to an annualized cost of 21.

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 COMPREHENSIVE DEVELOPMENT AND RECOMMENDED ALTERNATIVE

Sections 4(e) and 10(a) of the FPA require the Commission to give equal consideration to the power development purposes and to the purposes of energy conservation; the protection, mitigation of damage to, and enhancement of fish and wildlife; the protection of recreational opportunities; and the preservation of other aspects of environmental quality. Any licenses issued shall be such as in the Commission's judgment will be best adapted to a comprehensive plan for improving or developing waterway or waterways for all beneficial public uses. This section contains the basis for, and a summary of, our recommendations for the relicensing of the Elk Rapids Project. We weigh the costs and benefits of our recommended alternative against other proposed measures.

A. Recommended Alternative

Based on our independent review of agency comments filed on these projects and our review the environmental and economic effects of the proposed project and economic effects of the project and its alternatives, we selected the staff alternative as the preferred alternative. We recommend the staff alternative because: (1) Issuance of a new

hydropower license by the Commission would allow Antrim County to continue operating the project as a dependable source of electrical energy; (2) the 0.700 MW of electric capacity comes from a renewable resource that does not contribute to atmospheric pollution; (3) the public benefits of the staff alternative would exceed those of the no-action alternative; and (4) the proposed measures would protect and enhance aquatic and recreation resources.

In the following sections, we make recommendations as to which environmental measures recommended by agencies or other entities should be included in any license issued for the project. We also recommend additional staff-recommended environmental measures to be included in any license issued for the project and discuss which measures we do not recommend including in the license.

5.1.1 Measures Proposed by Antrim County

Based on our environmental analysis of Antrim County's proposal discussed in section 3 and the costs discussed in section 4, we conclude that the following environmental measure proposed by Antrim County would protect and enhance environmental resources and would be worth the cost. Therefore, we recommend including these measures in any license issued for the project:

• Operate and maintain the existing angler walkway, which is attached to the tailrace side of the powerhouse, and associated parking lot.

5.1.2 Additional Measures Recommended by Staff

In addition to Antrim County's proposed measure noted above, we recommend including the following measures in any license issued for Antrim County:

• An operation compliance monitoring plan that includes a description of project operation and the equipment and procedures necessary to maintain and monitor compliance with the operational mode required in any license issued;

• posting signage that describes proper boat maintenance techniques to reduce the spread of invasive plant and mussel species; and

• if archaeological resources are discovered during project operation or other project-related activities, cease all activities related to the disturbance and discovery area, and consult with the Michigan SHPO to determine appropriate treatment.

Below, we discuss the basis for our additional staff-recommended measures.

Operation Compliance Monitoring Plan

Developing an operation compliance monitoring plan would provide a means to verify compliance with the operational requirements of any license issued for the project. An operation compliance monitoring plan would include a description of project operation and any mechanisms or structures that would be used to by Antrim County to monitor project operation. Therefore, we recommend that Antrim County develop, in consultation with Michigan DEQ and Michigan DNR, an operation compliance monitoring plan. Antrim County should file the plan for Commission approval, documenting consultation with these agencies, including any comments received on the plan and responses to those comments. The plan should also provide a detailed description of the protocols Antrim County would implement during scheduled and unscheduled project shutdowns, reservoir drawdown and refills, and a provision to file an annual report of the operational data with the Commission. Based on our review and analysis contained in section 3.3.1, *Aquatic Resources,* we find that the benefits of ensuring an adequate means by which the Commission could track compliance with the operations terms of any license issued for the project would be worth the estimated levelized annual cost of $508.

Invasive Species Prevention

Aquatic invasive species compete with native species for food and habitat, and can directly or indirectly kill or displace native species, degrade habitat, and alter food webs. As discussed in section 3.3.1, *Aquatic Resources,* zebra mussels are found within the project boundary and throughout the chain-of-lakes watershed. Additionally, Eurasian milfoil and curly-leaf pondweed are within and adjacent to the project boundary and present in the chain-of-lakes.

Curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels are all transferred to other waterbodies primarily by boats. Zebra mussels are so pervasive throughout the chain-of-lakes that Michigan DEQ has no plan to control or eradicate them in the chain-of-lakes watershed. However, public education may help to minimize, and could reduce the likelihood of, transferring zebra mussels to other water bodies. Also, public education on how to minimize the transfer of curlyleaf pondweed and Eurasian watermilifoil could reduce the likelihood of further invasions of project waters. Therefore, we recommend that Antrim County develop signage, in consultation with the Michigan DNR and Michigan DEQ, which contains information on proper cleaning and drying of boats between launches to reduce the spread of curlyleaf pondweed, Eurasian watermilifoil, and zebra mussels. The project's recreation site is near a marina; therefore, we recommend posting the signage at the project recreation site to help inform the public of proper management techniques to reduce the spread of these invasive species.

We estimate that the levelized annual cost of the measure would be $191, and conclude that the benefits of the measure would outweigh the costs.

Cultural Resources

As discussed in section 3.3.5, *Cultural Resources,* no historic properties would be affected by the Elk Rapids Project; however, there is a possibility that unknown archaeological resources may be discovered during project operation or project-related activities. To ensure proper treatment if any unknown archaeological resource may be discovered, we recommend that Antrim County notify and consult with the Michigan SHPO: (1) To determine if a discovered archaeological resource is eligible for the National Register; (2) if the resource is eligible, determine if the proposed project would adversely affect the historic property; and (3) if the historic property would be adversely affected, obtain guidance from the Michigan SHPO on how to avoid, lessen, or mitigate for any adverse effects.

5.1.3 Measures Not Recommended by Staff

Some of the measures recommended by Michigan DEQ would not contribute to the best comprehensive use of the Elk River water resources, do not exhibit sufficient nexus to project environmental effects, or would not result in benefits to non-power resources that would be worth their costs. The following discusses the basis for staff's conclusion not to recommend such measures.

Water Quality Monitoring

Michigan DEQ recommends that Antrim County operate the project in such a manner as to adhere to state water quality standards (for temperature and DO) in the Elk River downstream of the powerhouse. However, Michigan DEQ states that deviations from these water temperature standards would be

acceptable when natural temperatures of Elk Lake, as measured in the Elk River upstream of the project, exceed these specified monthly average temperature values. Michigan DEQ also recommends that project operation not cause DO concentrations to be less than the state standard of 7.0 mg/L in the Elk River downstream of the powerhouse at any time. To verify project-related effects on water quality, Michigan DEQ recommends that Antrim County monitor temperature and DO concentrations in the Elk River downstream of the project on an hourly basis from July 1 through August 31 beginning the first year after license issuance, for a minimum of one year.

Continued operation of the project in the same mode of operation that it has been would likely result in the same water quality in the Elk River downstream of the dam. As discussed in section 3.3.1, *Aquatic Resources,* recent and previous water quality studies demonstrate that surface water temperatures of Elk Lake occasionally exceed state standards usually in late summer, while water surface DO concentrations typically exceed state minimum standards throughout the year. Because any deviations in water temperatures would be caused by natural phenomena and not project operation, monitoring water temperature downstream of the project would not provide any additional benefits.

Additionally, given that downstream of the project the less than 0.5-mile-long Elk River flows directly into Grand Traverse Bay, any temporary decreases in DO levels that may occur in the tailrace would be quickly mitigated by the high DO levels present in the bay. Therefore, continued operation of the project in the same mode of operation it has used in the past, would likely not effect water quality in the Elk River downstream of the powerhouse and that the state DO standard of 7 mg/L would continue to be met. For these reasons, we do not recommend adopting Michigan DEQ's water quality monitoring recommendations because the information obtained from conducting this water quality monitoring is not worth the estimated levelized annual costs of $158.

5.1.4 Conclusion

Based on our review of the resource agency and public comments filed on the project and our independent analysis pursuant to sections 4(e), 10(a)(1), and 10(a)(2) of the FPA, we conclude that licensing the Elk Rapids Project, as proposed by Antrim County, with staff-recommended additional measures, would be best adapted to a plan for improving or developing the Elk River waterway.

6.0 CONSISTENCY WITH COMPREHENSIVE PLANS

Section 10(a)(2)(A) of the FPA, 16 U.S.C. 803(a)(2)(A), requires the Commission to consider the extent to which a project is consistent with the federal or state comprehensive plans for improving, developing, or conserving a waterway or waterways affected by the project. We reviewed eight comprehensive plans that are applicable to the project.[26] No inconsistencies were found.

7.0 FINDING OF NO SIGNIFICANT IMPACT

On the basis of our independent analysis, the issuance of a subsequent license for the Elk Rapids Hydroelectric Project with our recommended environmental measures would not constitute a major federal action significantly affecting the quality of the human environment.

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9.0 LIST OF PREPARERS

Patrick Ely—Lead Project Coordinator, Aquatic Resources, Terrestrial Resources, and Threatened and Endangered Species (Fisheries Biologist; B.S., Wildlife and Fisheries Biology; M.S., Fisheries Biology)
Lee Emery—Assistant Project Coordinator, Aquatic Resources (Fisheries Biologist; B.S., Biology; M.S., Zoology)
Chelsea Hudock—Recreation Resources, Land Use, and Cultural Resources (Outdoor Recreation Planner; M.S., Recreation, Park and Tourism Sciences; B.S., Parks, Recreation and Tourism Management)
Paul Makowski—Need for Power and Developmental Analysis (Civil Engineer; B.S., Civil Engineering; M. Eng., Hydrosystems)

[FR Doc. 2015–12463 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3590–014]

El Dorado Hydro; El Dorado Hydro, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Montgomery Creek Project, FERC No. 3590, originally issued June 23,

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

1982,[3] has been transferred to El Dorado Hydro, LLC, an affiliate of Enel Green Power. The project is located on Montgomery Creek in Shasta County, California. The transfer of an exemption does not require Commission approval.

2. El Dorado Hydro, LLC is now the exemptee of the Montgomery Creek Project, FERC No. 3590. All correspondence should be forwarded to: El Dorado Hydro, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose

Secretary.

[FR Doc. 2015–12472 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[3] 19 FERC ¶ 62,509, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1982).

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 16 FERC ¶ 62,009, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1981).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3503–011]

El Dorado Hydro; Elk Creek Hydro, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Elk Creek Hydroelectric Project, FERC No. 3503, originally issued July 1, 1981,[3] has been transferred to Elk Creek Hydro, LLC, an affiliate of Enel Green Power. The project is located on the Elk and Little Creeks and the Little Salmon River in Idaho County, Idaho. The transfer of an exemption does not require Commission approval.

2. Elk Creek Hydro, LLC is now the exemptee of the Elk Creek Hydroelectric Project, FERC No. 3503. All correspondence should be forwarded to: Elk Creek Hydro, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12470 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 19 FERC ¶ 62,570, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3519–006]

Beaver Valley Power Company; Beaver Valley Power Company, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Patterson Hydro Project, FERC No. 3519, originally issued June 30, 1982,[3] has been transferred to Beaver Valley Power Company, LLC, an affiliate of Enel Green Power. The project is located on the Beaver River in Beaver County, Pennsylvania. The transfer of an exemption does not require Commission approval.

2. Beaver Valley Power Company, LLC is now the exemptee of the Patterson Hydro Project, FERC No. 3519. All correspondence should be forwarded to: Beaver Valley Power Company, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12471 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG15–85–000.
Applicants: Alpaca Energy LLC.
Description: Alpaca Energy LLC EWG Self-Certification.
Filed Date: 5/18/15.
Accession Number: 20150518–5226.
Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: EG15–86–000.
Applicants: Beaver Dam Energy LLC.
Description: Beaver Dam Energy LLC EWG Self-Certification.
Filed Date: 5/18/15.
Accession Number: 20150518–5227.
Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: EG15–87–000.
Applicants: Milan Energy LLC.
Description: Milan Energy LLC EWG Self-Certification.
Filed Date: 5/18/15.
Accession Number: 20150518–5228.
Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: EG15–88–000.
Applicants: Oxbow Creek Energy LLC.
Description: Oxbow Creek Energy LLC EWG Self-Certification.
Filed Date: 5/18/15.
Accession Number: 20150518–5229.
Comments Due: 5 p.m. ET 6/8/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2397–002; ER10–2402–003; ER10–2403–003; ER14–1933–003; ER11–2935–005; ER10–2425–003; ER14–1934–003; ER14–1935–003.
Applicants: Arlington Wind Power Project LLC, Blue Canyon Windpower V LLC, Cloud County Wind Farm, LLC, Headwaters Wind Farm LLC, Paulding Wind Farm II LLC, Pioneer Prairie Wind Farm I, LLC, Rising Tree Wind Farm LLC, Rising Tree Wind Farm II LLC.
Description: Notice of Non-Material Change in Status of Arlington Wind Power Project LLC, *et al.*
Filed Date: 5/18/15.
Accession Number: 20150518–5193.
Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER10–2570–017.
Applicants: Shady Hills Power Company, L.L.C.
Description: Supplement to December 16, 2014 Triennial Market Power Analysis of Shady Hills Power Company, L.L.C.
Filed Date: 5/18/15.
Accession Number: 20150518–5158.
Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER10–2881–020; ER10–2882–020; ER10–2883–020; ER10–2884–020; ER10–2885–020; ER10–2641–020; ER10–2663–020; ER10–2886–020; ER13–1101–015; ER13–1541–014; ER14–787–008; ER14–661–007; ER15–54–001; ER15–55–001; ER15–1475–002.
Applicants: Alabama Power Company, Southern Power Company,

Mississippi Power Company, Georgia Power Company, Gulf Power Company, Oleander Power Project, Limited Partnership, Southern Company—Florida LLC, Southern Turner Cimarron I, LLC, Spectrum Nevada Solar, LLC, Campo Verde Solar, LLC, Macho Springs Solar, LLC, SG2 Imperial Valley LLC, Lost Hills Solar, LLC, Blackwell Solar, LLC, North Star Solar, LLC.

Description: Notification of Non-Material of Change in Status of Alabama Power Company, et al.

Filed Date: 5/15/15.

Accession Number: 20150515–5228.

Comments Due: 5 p.m. ET 6/5/15.

Docket Numbers: ER10–3125–010, ER11–4050–004; ER10–3102–010; ER11–4027–006; ER11–4028–006; ER15–1447–002; ER10–3100–010; ER12–1275–001; ER10–3107–010; ER10–3109–010.

Applicants: AL Sandersville, LLC, Cogentrix of Alamosa, LLC, Effingham County Power, LLC, James River Genco, LLC, Portsmouth Genco, LLC, Mid-Georgia Cogen L.P., MPC Generating, LLC, Red Oak Power, LLC, Walton County Power, LLC, Washington County Power, LLC.

Description: Notice of Non-Material Change in Status of the Carlyle Group MBR Sellers.

Filed Date: 5/15/15.

Accession Number: 20150515–5252.

Comments Due: 5 p.m. ET 6/5/15.

Docket Numbers: ER13–366–006.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing per 35: Order 1000 Regional Compliance Filing to be effective 3/30/2014.

Filed Date: 5/18/15.

Accession Number: 20150518–5222.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER13–1928–003.

Applicants: Duke Energy Progress, Inc., Duke Energy Carolinas, LLC.

Description: Compliance filing per 35: Order No. 1000 Interregional—SERTP & SPP to be effective 1/1/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5184.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER13–1930–003.

Applicants: Louisville Gas and Electric Company.

Description: Compliance filing per 35: Order No 1000 SERTP–SPP 2nd Interregional Compliance to be effective 1/1/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5239.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER13–1941–003.

Applicants: Alabama Power Company.

Description: Compliance filing per 35: Order No. 1000 Second Interregional Compliance Filing—SERTP–SPP Seam to be effective 1/1/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5208.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER14–108–000.

Applicants: Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Texas, Inc., Entergy Louisiana, LLC.

Description: eTariff filing per 35.19a(b): Refund Report to be effective N/A.

Filed Date: 5/18/15.

Accession Number: 20150518–5200.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER14–2875–001.

Applicants: UNS Electric, Inc.

Description: Compliance filing per 35: Formula Rate Protocols Compliance Filing to be effective 11/14/2014.

Filed Date: 5/18/15.

Accession Number: 20150518–5182.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER14–2884–001.

Applicants: KCP&L Greater Missouri Operations Company.

Description: Compliance filing per 35: Formula Rate Protocols Compliance Filing to be effective 3/1/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5241.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1047–002.

Applicants: R.E. Ginna Nuclear Power Plant, LLC.

Description: Compliance filing per 35: Compliance to 134 to be effective 4/1/2015.

Filed Date: 5/14/15.

Accession Number: 20150514–5196.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15–1067–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing per 35: 2015–05–18_MMTG RTO Adder Compliance Filing to be effective 6/16/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5171.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1086–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing per 35: 2015–05–18_SA 765 Compliance ATC–WPL Bill of Sale to be effective N/A.

Filed Date: 5/18/15.

Accession Number: 20150518–5217.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1087–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing per 35: 2015–05–18_SA 2748 Compliance ATC–WPL CFA to be effective N/A.

Filed Date: 5/18/15.

Accession Number: 20150518–5209.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1571–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment per 35.17(b): 2015–05–18 Amendment RSG NCA BCA Filing to be effective 6/30/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5155.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1729–000.

Applicants: Southwest Power Pool, Inc.

Description: Section 205(d) rate filing per 35.13(a)(2)(iii): Ministerial Filing of Non-Substantive Tariff Revisions to be effective 1/1/2015.

Filed Date: 5/15/15.

Accession Number: 20150515–5212.

Comments Due: 5 p.m. ET 6/5/15.

Docket Numbers: ER15–1730–000.

Applicants: Duke Energy Carolinas, LLC.

Description: Section 205(d) rate filing per 35.13(a)(2)(iii): EUEMC NITSA Amendment SA No. 366 to be effective 5/1/2015.

Filed Date: 5/15/15.

Accession Number: 20150515–5222.

Comments Due: 5 p.m. ET 6/5/15.

Docket Numbers: ER15–1731–000.

Applicants: Celesta Energy, Inc.

Description: Initial rate filing per 35.12 Celesta Energy, Inc. Market Based Rate Tariff to be effective 6/30/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5145.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1732–000.

Applicants: PJM Interconnection, L.L.C.

Description: Section 205(d) rate filing per 35.13(a)(2)(iii): Original Interconnection Service Agreement No. 4135; Queue X1–078 to be effective 4/21/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5159.

Comments Due: 5 p.m. ET 6/8/15.

Docket Numbers: ER15–1733–000.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing per 35: Compliance Filing Revising Empire's Formula Rate Protocols to be effective 4/1/2015.

Filed Date: 5/18/15.

Accession Number: 20150518–5230.

Comments Due: 5 p.m. ET 6/8/15.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD15–4–000.

Applicants: North American Electric Reliability Corp.

Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed Reliability Standard CIP–014–2.

Filed Date: 5/15/15.

Accession Number: 20150515–5215.

Comments Due: 5 p.m. ET 6/15/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 18, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–12436 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14317–001]

Grand Coulee Project Hydroelectric Authority; Notice of Surrender of Preliminary Permit

Take notice that Grand Coulee Project Hydroelectric Authority, permittee for the proposed Scooteney Outlet Drop Hydroelectric Project, has requested that its preliminary permit be terminated. The permit was issued on March 26, 2013, and would have expired on February 29, 2016.[1] The project would have been located on the Potholes East Canal, near Othello in Franklin County, Washington.

The preliminary permit for Project No. 14317 will remain in effect until the close of business, June 14, 2015. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

Dated: May 15, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12464 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] 142 FERC ¶ 62,251 (2013).

[2] 18 CFR § 385.2007(a)(2) (2014).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2695–005]

Hydro Development Group, Inc., Hydro Development Group Acquisition, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Dexter Project, FERC No. 2695, originally issued June 4, 1982,[3] has been transferred to Hydro Development Group Acquisition, LLC, an affiliate of Enel Green Power. The project is located on the Black River in Jefferson County, New York. The transfer of an exemption does not require Commission approval.

2. Hydro Development Group Acquisition, LLC is now the exemptee of the Dexter Project, FERC No. 2695. All correspondence should be forwarded to: Hydro Development Group Acquisition, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12467 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 19 FERC ¶ 61,229, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2911–039]

Southeast Alaska Power Agency; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 Code of Federal Regulations Part 380, Commission staff has reviewed the Southeast Alaska Power Agency's application for amendment of license for the Swan Lake Hydroelectric Project (FERC Project No. 2911) and has prepared an environmental assessment (EA). The project is located on Falls Creek on Revillagigedo Island near Ketchikan, Alaska. The project occupies federal lands administered by the U.S. Forest Service within the Tongass National Forest.

The EA contains Commission staff's analysis of the potential environmental effects of adding spillway gates to the project dam, raising the maximum elevation of the project impoundment by 15 feet, inundating an additional 93 acres, and making structural modifications to the dam and intake structure. The EA concludes that authorizing the amendment, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room, or it may be viewed on the Commission's Web site at *http://www.ferc.gov* using the e-Library link. Enter the docket number (P–2911) in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or call toll-free at 1–866–208–3676 or (202) 502–8659 (for TTY).

You may also register online at *http://www.ferc.gov/docs-filing/esubsription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed within 30 days of the date of this notice and should reference project no. 2911. The Commission strongly encourages electronic filing. Please file comments using the Commission's efiling system at *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. In lieu of electronic filing, please send a paper copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

For further information, contact Steven Sachs by telephone at 202–502–8666 or by email at *Steven.Sachs@ferc.gov.*

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12468 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meeting related to the transmission planning activities of ISO New England Inc.

ISO New England Inc. Planning Advisory Committee Meeting.

May 21, 2015, 9:30 a.m.–2:00 p.m. (Eastern Standard Time).

The above-referenced meeting will be held at: Doubletree Hotel, 5400 Computer Drive, Westborough, MA 01581.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.iso-ne.com/committees/planning/planning-advisory.*

The discussions at the meeting described above may address matters at issue in the following proceedings:

Docket No. ER13–193, *ISO New England Inc.*

Docket No. ER13–196, *ISO New England Inc.*

Docket No. ER13–1957, *ISO New England Inc. et al.*

Docket No. ER13–1960, *ISO New England Inc. et al.*

For more information, contact Michael Cackoski, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–6169 or *Michael.Cackoski@ferc.gov.*

Dated: May 18, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–12437 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TX14–1–000]

Consolidated Edison Company of New York, Inc.; Notice of Filing

Take notice that on May 11, 2015, Consolidated Edison Company of New York, Inc. (Con Edison) filed a joint offer of settlement to amend its March 18, 2014 filed application for an order directing Cogen Technologies Linden Venture, L.P. to modify the physical connection that currently exists between its transmission facilities and those of Con Edison.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on June 1, 2015.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12477 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3181–004]

Hydro Development Group, Inc.; Hydro Development Group Acquisition, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Number 6 Mill Project, FERC No. 3181, originally issued September 17, 1981,[3] has been transferred to Hydro Development Group Acquisition, LLC, an affiliate of Enel Green Power. The project is located on the Oswegatchie River in Lawrence County, New York. The transfer of an exemption does not require Commission approval.

2. Hydro Development Group Acquisition, LLC is now the exemptee of the Number 6 Mill Project, FERC No. 3181. All correspondence should be forwarded to: Hydro Development Group Acquisition, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12469 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 16 FERC ¶ 62,453, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1981).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3754–006]

Copenhagen Associates, Copenhagen Hydro, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the High Falls Project, FERC No. 3754, originally issued January 14, 1982,[3] has been transferred to Copenhagen Hydro, LLC, an affiliate of Enel Green Power. The project is located on the Deer River in Lewis County, New York. The transfer of an exemption does not require Commission approval.

2. Copenhagen Hydro, LLC is now the exemptee of the High Falls Project, FERC No. 3754. All correspondence should be forwarded to: Copenhagen Hydro, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose

Secretary.

[FR Doc. 2015–12473 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 18 FERC ¶ 62,018, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4827–003]

Mill Shoals Hydro Company, Inc.; High Shoals, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the High Shoals Project, FERC No. 4827, originally issued November 10, 1981,[3] has been transferred to High Shoals, LLC, an affiliate of Enel Green Power. The project is located on the Catawba River in Gaston County, North Carolina. The transfer of an exemption does not require Commission approval.

2. High Shoals, LLC is now the exemptee of the High Shoals Project, FERC No. 4827. All correspondence should be forwarded to: High Shoals, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12475 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 17 FERC ¶ 62,224, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less and Denying Application for Preliminary Permit (1981).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5307–002]

Sweetwater Hydroelectric, Inc.; Sweetwater Hydroelectric, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Woodsville Reactivation Project, FERC No. 5307, originally issued February 5, 1982,[3] has been transferred to Sweetwater Hydroelectric, LLC, an affiliate of Enel Green Power. The project is located on the Ammonoosuc River in Grafton County, New Hampshire. The transfer of an exemption does not require Commission approval.

2. Sweetwater Hydroelectric, LLC is now the exemptee of the Woodsville Reactivation Project, FERC No. 5307. All correspondence should be forwarded to: Sweetwater Hydroelectric, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose

Secretary.

[FR Doc. 2015–12476 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 18 FERC ¶ 62,158, Order Granting Exemption from Licensing of a Small Hydroelectric Project of 5 Megawatts or Less and Denying Competing Application for Preliminary Permit (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 4337–007]

Consolidated Hydro New Hampshire, Inc.; West Hopkinton Hydro, LLC; Notice of Transfer of Exemption

1. By letter filed April 24, 2015,[1] William B. Conway, Jr., Counsel for Enel Green Power North America, Inc. (EGPNA),[2] informed the Commission that the exemption from licensing for the Hoague-Sprague Project, FERC No. 4337, originally issued March 11, 1982,[3] has been transferred to West Hopkinton Hydro, LLC, an affiliate of Enel Green Power. The project is located on the Contoocook River in Merrimack County, New Hampshire. The transfer of an exemption does not require Commission approval.

2. West Hopkinton Hydro, LLC is now the exemptee of the Hoague-Sprague Project, FERC No. 4337. All correspondence should be forwarded to: West Hopkinton Hydro, LLC, c/o Enel Green Power North America, Inc., Attn: General Counsel, 1 Tech Drive, Suite 220, Andover, MA 01810.

Dated: May 18, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12474 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

[1] Seventeen other exempted projects which are to be transferred were included in the April 24, 2015 letter. These exemptions will be handled under separate proceedings.

[2] Enel Green Power North America, Inc. is a wholly owned subsidiary of Enel Green Power. Enel Green Power is a well-capitalized publicly traded company.

[3] 18 FERC ¶ 62,419, Order Granting Exemption from Licensing for a Small Hydroelectric Project (5 MW or Less) (1982).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2677–028]

City of Kaukauna; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time.

b. *Project No:* 2677–028.

c. *Date Filed:* February 13, 2015.

d. *Applicant:* Kaukauna Utilities (licensee).

e. *Name of Project:* Badger-Rapide Croche Hydroelectric Project.

f. *Location:* Outagamie County, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

h. *Applicant Contact:* Mr. Jeffery Feldt, General Manager—Kaukauna Utilities, 777 Island Street, Kaukauna, WI 54130, 920–419–2421.

i. *FERC Contact:* Mr. Michael T. Calloway, (202) 502–8041, *michael.calloway@ferc.gov*.

j. Deadline for filing comments, motions to intervene, and protests is June 15, 2015.

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 at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. 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.

Please include the project number (P–2677–028) on any comments, motions, or recommendations filed.

k. *Description of Request:* The licensee is requesting a three year extension of time, pursuant to Article 408 of the project license issued May 18, 2011, and Condition 9 of the Wisconsin section 401 Clean Water Certification, to build a new boat launch area on the southern shoreline of the Rapide Croche impoundment to include an access road, boat ramp, parking area, pier, and an accessible ADA compliant fishing pier with signage and lighting. This request was made so the Wisconsin Department of Natural Resources can consider whether introducing invasive species via the boat ramp may lead them to amend the state water quality certification to remove the requirement to build a boat ramp.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling 202–502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call 202–502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS''; ''PROTESTS'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the extension of time. 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. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: May 15, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12465 Filed 5–21–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9021–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 05/11/2015 Through 05/15/2015

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20150131, Final, FHWA, TX, US 281, Review Period Ends: 06/22/2015, Contact: Carlos Swonke 512 416–2734.

EIS No. 20150132, Draft Supplement, FTA, MN, Southwest Light Rail Transit (Metro Green Line Extension) Comment Period Ends: 07/06/2015, Contact: Maya Sarna 202–366–5811.

EIS No. 20150133, Draft, NRC, WI, Construction Permit for the SHINE

Medical Radioisotope Production Facility, Comment Period Ends: 07/06/2015, Contact: Michelle Moser 301–415–6509.

EIS No. 20150134, Final, USACE, CA, Encinitas-Solana Beach Coastal Storm Damage Reduction Project, Review Period Ends: 06/22/2015, Contact: Lee Ware 202–761–0523.

EIS No. 20150135, Draft, USFS, CA, King Fire Restoration, Comment Period Ends: 06/22/2015, Contact: Katy Parr 530–621–5203.

The U.S. Department of Agriculture's Forest Service requested and was granted approval to shorten the public comment period for this Draft EIS from 45 to 30 days, reflecting the President's Council on Environmental Quality (CEQ) alternative arrangement granted in accordance with 40 CFR 1506.11.

EIS No. 20150136, Final, USN, GU, Mariana Islands Training and Testing, Review Period Ends: 06/22/2015, Contact: Nora Macariola-See 808–472–1402.

Dated: May 19, 2015.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015–12508 Filed 5–21–15; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

[Public Notice 2015–0009]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088934XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction. Comments received will be made available to the public.

DATES: Comments must be received on or before May 29, 2015 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter *EIB–2015–0009* under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and *EIB–2015–0009* on any attached document.

Reference: AP088934XX.

* This notice is a continuation of the posting of the notice FR Doc. 2015–10250 published on May 4, 2015 to extend the comment period to May 29, 2015.

Purpose and Use:

Brief description of the purpose of the transaction: To support the export of U.S.-manufactured commercial aircraft to the United Arab Emirates.

Brief non-proprietary description of the anticipated use of the items being exported: To be used for passenger air service between the United Arab Emirates and other countries.

To the extent that Ex-Im Bank is reasonably aware, the items being exported may be used to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Suppliers: The Boeing Company

Obligor: Emirates Airline

Guarantor(s): N/A

Description of Items Being Exported:

Boeing 777 aircraft

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Lloyd Ellis,

Program Specialist, Office of the General Counsel.

[FR Doc. 2015–12421 Filed 5–21–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2015–6001]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

Title: EIB 15–01, Generic Clearance for the Collection of Feedback on Electronic Interfaces with Customers

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a 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 information collections, as required by the Paperwork Reduction Act of 1995.

Ex-Im Bank is soliciting comments on the following proposed Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Electronic Interfaces with Customers'' for approval under the Paperwork Reduction Act. This collection was developed as an effort to streamline the process for seeking feedback from the public on the electronic interfaces (Web site and online application systems) used by Ex-Im Bank customers. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

DATES: Comments should be received on or before June 22, 2015, to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *http://www.regulations.gov*) or by mail to Michele Kuester, Export-Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION:

Title: EIB 15–01, Generic Clearance for the Collection of Feedback on Electronic Interfaces with Customers.

OMB Number: TBD.

Type of Review: New.

Need and Use: This is a request for a new three-year generic clearance for the Export-Import Bank of the United States (Ex-Im Bank) that will allow it to develop, test and improve its digital customer interfaces—including on-line applications for financing support, other on-line reporting, and the agency's Web site. The procedures used to this effect include, but are not limited to, tests of various interfaces through focus groups, cognitive testing, web-based experiments and usability testing.

Ex-Im Bank is requesting the generic clearance in order to test new or proposed methodologies for customer interfaces, data collection activities, and Web site design. We believe the generic clearance will be a helpful vehicle for evaluating the usability and effectiveness of these methodologies.

In the past, Ex-Im Bank has approached design and testing through convenience samples of nine or fewer persons to provide input and feedback or by relying on employee feedback. Neither of these approaches meets Ex-Im Bank's needs to collect meaningful information on the usability and effectiveness of its customer interfaces.

In the reference document we have provided a description of the scope of possible activities that might be covered under this clearance. The requested clearance is important to Ex-Im Bank's usability testing program, because of the length of time required to develop customer interfaces.

The specific methods proposed for coverage by this clearance are listed below. Also outlined are the procedures Ex-Im Bank plans to put in place for keeping OMB informed about the identity of the usability tests and the nature of the research activities being conducted.

The methods proposed for use in system development are as follows:

- Pilot testing,
- Behavior coding,
- Exploratory interviews,
- Split sample experiments,
- Cognitive and usability interviews, and
- Focus groups.

Before each testing activity is undertaken, Ex-Im Bank will provide OMB with a memo describing the study to be conducted and a copy of the instrumentation and instruction materials that will be used. Depending on the stage of instrumentation development, this may be a printed questionnaire, a set of prototype items showing each item type to be used and the range of topics to be covered by the questionnaire, or an interview script. When split sample experiments are conducted, either in small group sessions or as part of a field test, the different versions of the questionnaires to be used will be provided. For a test of alternative procedures, the description and rationale for the procedures will be submitted. A brief description of the planned field activity will also be provided.

Affected Public: Individuals representing companies engaged in business with the Export-Import Bank of the U.S.

Annual Number of Respondents: 72.

Estimated Time per Respondent: 12 hours.

Annual Burden Hours: 864 hours.

Frequency of Reporting or Use: On occasion.

Government Expenses: TBD.

Toya Woods,

Records Management Division, Office of the Chief Information Officer.

[FR Doc. 2015–12430 Filed 5–21–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–0008]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088734XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction. Comments received will be made available to the public.

DATES: Comments must be received on or before May 29, 2015 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter *EIB–2015–0008* under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and *EIB–2015–0008* on any attached document.

Reference: AP088734XX.

*This notice is a continuation of the posting of the notice FR Doc. 2015–10251 published on May 4, 2015 to extend the comment period to May 29, 2015.

Purpose and Use:

Brief description of the purpose of the transaction:

To support the export of U.S.-manufactured commercial aircraft to Luxembourg.

Brief non-proprietary description of the anticipated use of the items being exported:

To be used for air cargo services globally. To the extent that Ex-Im Bank is reasonably aware, the items being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Suppliers: The Boeing Company.

Obligor: Cargolux Airlines International S.A.

Guarantor(s): N/A.

Description of Items Being Exported:

Boeing 747 aircraft.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Lloyd Ellis,

Program Specialist, Office of the General Counsel.

[FR Doc. 2015–12420 Filed 5–21–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK OF THE UNITED STATES

[Public Notice: 2015–0010]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million: AP088976XX

AGENCY: Export-Import Bank of the United States.

ACTION: Notice.

SUMMARY: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action

on this Transaction. Comments received will be made available to the public.

DATES: Comments must be received on or before May 29, 2015 to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through Regulations.gov at *WWW.REGULATIONS.GOV.* To submit a comment, enter EIB–2015–0010 under the heading ''Enter Keyword or ID'' and select Search. Follow the instructions provided at the Submit a Comment screen. Please include your name, company name (if any) and EIB–2015–0010 on any attached document.

Reference: AP088976XX.

* This notice is a continuation of the posting of the notice FR Doc. 2015–10327 published on May 4, 2015 to extend the comment period to May 29, 2015.

Purpose and Use:

Brief description of the purpose of the transaction: To support the export of U.S.-manufactured commercial aircraft to China.

Brief non-proprietary description of the anticipated use of the items being exported: To be used for cargo air service between China and other countries.

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: The Boeing Company

Obligor: China Southern Airlines

Guarantor(s): N./A.

Description of Items Being Exported:

Boeing 777 aircraft

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://exim.gov/newsandevents/boardmeetings/board/.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

Lloyd Ellis,

Program Specialist, Office of the General Counsel.

[FR Doc. 2015–12422 Filed 5–21–15; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0854]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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 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 PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 21, 2015. 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 Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0854.

Title: Section 64.2401, Truth-in-Billing Format, CC Docket No. 98–170 and CG Docket No. 04–208.

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: 4,447 respondents; 36,699 responses.

Estimated Time per Response: 2 to 230 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is found at section 201(b) of the Communications Act of 1934, as amended, 47 U.S.C. 201(b), and section 258, 47 U.S.C. 258, Public Law 104–104, 110 Stat. 56. The Commission's implementing rules are codified at 47 CFR 64.2400–01.

Total Annual Burden: 2,129,905 hours.

Total Annual Cost: $15,918,200.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: In 1999, the Commission released the Truth-in-Billing and Billing Format, CC Docket No. 98–170, First Report and Order and Further Notice of Proposed Rulemaking, (*1999 TIB Order*); published at 64 FR 34488, June 25, 1999, which adopted principles and guidelines designed to reduce telecommunications fraud, such as slamming and cramming, by making bills easier for consumers to read and understand, and thereby, making such fraud easier to detect and report. In 2000, Truth-in-Billing and Billing Format, CC Docket No. 98–170, Order on Reconsideration, (*2000 Reconsideration Order*); published at 65 FR 43251, July 13, 2000, the Commission, granted in part petitions for reconsideration of the requirements that bills highlight new service providers and prominently display inquiry contact numbers. On March 18,

2005, the Commission released Truth-in-Billing and Billing Format; National Association of State Utility Consumer Advocates' Petition for Declaratory Ruling Regarding Truth-in-Billing, Second Report and Order, Declaratory Ruling, and Second Further Notice of Proposed Rulemaking, CC Docket No. 98–170, CG Docket No. 04–208, (*2005 Second Report and Order and Second Further Notice*); published at 70 FR 29979 and 70 FR 30044, May 25, 2005, which determined, inter alia, that Commercial Mobile Radio Service providers no longer should be exempted from 47 CFR 64.2401(b), which requires billing descriptions to be brief, clear, non-misleading and in plain language. The *2005 Second Further Notice* proposed and sought comment on measures to enhance the ability of consumers to make informed choices among competitive telecommunications service providers.

On April 27, 2012, the Commission released the Empowering Consumers to Prevent and Detect Billing for Unauthorized Charges (''Cramming''), Report and Order and Further Notice of Proposed Rulemaking, CG Docket No. 11–116, CG Docket No. 09–158, CC Docket No. 98–170, FCC 12–42 (*Cramming Report and Order and Further Notice of Proposed Rulemaking*); published at 77 FR 30972, May 24, 2012, which determined that additional rules are needed to help consumers prevent and detect the placement of unauthorized charges on their telephone bills, an unlawful and fraudulent practice commonly referred to as ''cramming.''

Federal Communications Commission.

Marlene H. Dortch,

Secretary. Office of the Secretary.

[FR Doc. 2015–12365 Filed 5–21–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0876]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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 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 PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before July 21, 2015. 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 Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0876.

Title: Sections 54.703, USAC Board of Directors Nomination Process and Sections 54.719 through 54.725, Review of the Administrator's Decision.

Form Number(s): N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities and not-for-profit institutions.

Number of Respondents and Responses: 557 respondents; 557 responses.

Estimated Time per Response: 20–32 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151 through 154, 201 through 205, 218 through 220, 254, 303(r), 403 and 405.

Total Annual Burden: 17,680 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting that respondents submit confidential information to the FCC. However, respondents may request confidential treatment of their information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The information in this collection is used by the Commission to select Universal Service Administrative Company (USAC) Board of Directors and to ensure that requests for review are filed properly the Commission.

Section 54.703 states that industry and non-industry groups may submit to the Commission for approval nominations for individuals to be appointed to the USAC Board of Directors.

Sections 54.719 through 54.725 describes the procedures for Commission review of USAC decisions including the general filing requirements pursuant to which parties may file requests for review.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–12427 Filed 5–21–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting Thursday, May 21, 2015

May 14, 2015.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, May 21, 2015. The meeting is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item No.	Bureau	Subject
1	CONSUMER & GOVERNMENTAL AFFAIRS.	TITLE: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010, Section 105, Relay Services for Deaf-Blind Individuals (CC Docket No. 10–210). SUMMARY: The Commission will consider an Order to extend the National Deaf-Blind Equipment Distribution Program and a Notice of Proposed Rulemaking to permanently extend the program. The program provides up to $10 million annually from the Interstate Telecommunications Relay Service Fund to support programs that distribute communications equipment to low-income individuals who are deaf-blind.
2	MEDIA	TITLE: Accessible Emergency Information, and Apparatus Requirements for Emergency Information and Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010 (MB Docket No. 12–107). SUMMARY: The Commission will consider a Second Report and Order and Second Further Notice of Proposed Rulemaking to extend accessibility rules for emergency alerts to ''second screens,'' including tablets, smartphones, laptops, and similar devices. The proposal would take additional steps to make emergency information in video programming accessible to individuals who are blind or visually impaired.

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from Meribeth McCarrick, Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–12364 Filed 5–21–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the notices must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 9, 2015.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. *Commonwealth Bank of Australia*, Sydney, Australia; to engage *de novo* through its wholly-owned subsidiary, First State Investments (US) LLC, New York, New York, in financial and investment advisory activities, pursuant to section 225.28(b)(6)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, May 19, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–12495 Filed 5–21–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 132–3272]

Nice-Pak Products, Inc.; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 19, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/nicepakconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Nice-Pak Products—Consent Agreement; File No. 132–3272'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/nicepakconsent* by following the instructions on the Web-based form. If

you prefer to file your comment on paper, write ''Nice-Pak Products—Consent Agreement; File No. 132–3272'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Sylvia J. Kundig, FTC Western Region, (415) 848–5188, 901 Market Street, Suite 570, San Francisco, CA 94103.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for May 18, 2015), on the World Wide Web at: *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 19, 2015. Write ''Nice-Pak Products—Consent Agreement; File No. 132–3272'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/nicepakconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Nice-Pak Products—Consent Agreement; File No. 132–3272 on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 19, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing consent order from Nice-Pak Products, Inc. (''Nice-Pak'').

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Nice-Pak is a manufacturer of ''flushable'' moist toilet tissue made from non-elemental chlorine bleached wood pulp, bicomponent fibers and EP907 repulpable binder. It advertised the flushable moist toilet tissue as being safe for sewer and septic systems, and breaking apart shortly after flushing. The Commission's complaint, however, alleges that Nice-Pak did not have adequate substantiation for the claims, because its substantiation did not accurately reflect the real-world conditions that the moist toilet tissue encounters after flushing. In addition, the complaint alleges that Nice-Pak provided retailers, such as Costco, CVS, Target, and BJ's, that sold the Nice-Pak flushable moist toilet tissue under their private labels with the inadequate substantiation and the retailers then repeated the unsubstantiated claims.

The proposed consent order contains provisions designed to prevent Nice-Pak from engaging in similar acts or practices in the future.

Part I of the order prohibits Nice-Pak from misrepresenting that any wipe is safe to flush unless Nice-Pak's substantiation demonstrates that the wipe will disperse in a sufficiently short amount of time after flushing to avoid clogging or other operational problems in household and municipal sewage lines, septic systems and other standard wastewater equipment, and that those tests substantially replicate the physical conditions of the environment the wipe will be disposed in.

Part II of the proposed order prohibits Nice-Pak from making any representation about moist toilet tissue unless the representation is non-misleading, and, at the time it is made, Nice-Pak possesses and relies upon competent and reliable evidence that substantiates the representation.

Part III of the proposed order prohibits Nice-Pak from providing the means and instrumentalities to others to make the representations that Nice-Pak would be prohibited from making by Parts I and II of the proposed order.

Part IV of the proposed order contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Parts V, VII and VIII of the proposed order require Nice-Pak to: Deliver a copy of the order to certain personnel having managerial responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part VI of the proposed order requires Nice-Pak to provide notice of the order to its private label customers.

Part IX of the proposed order provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–12462 Filed 5–21–15; 8:45 am]

BILLING CODE 6750–01–P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket Number: 105002015– 1111–04]

Notice and Request for Comment on Local Contracting Preference Interpretation

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Notice of interpretation and implementation with request for comment.

SUMMARY: The Gulf Coast Ecosystem Restoration Council (Council) is seeking comment on its planned implementation of the local contracting preference requirement of the Resources and Ecosystem Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act).

DATES: Comments on this notice of interpretation and implementation are due June 22, 2015.

ADDRESSES: The Council invites comments on its planned implementation of the local contracting preference requirement. Comments may be submitted through one of these methods:

Electronic Submission of Comments: Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Council to make them available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public.

Mail: Send to Gulf Coast Ecosystem Restoration Council, 500 Poydras Street, Suite 1117, New Orleans, LA 70130.

Email: Send to *frcomments@restorethegulf.gov*.

In general, the Council will make such comments available for public inspection and copying on its Web site, *http://www.restorethegulf.gov/* without change, including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. All comments received, including attachments and other supporting materials, will be part of the public record and subject to public disclosure. You should only submit information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Jeffrey Roberson at 202–482–1315.

SUPPLEMENTARY INFORMATION:

I. Background

The RESTORE Act, Public Law 112–141 (July 6, 2012), codified at 33 U.S.C. 1321(t) and note, makes funds available for the restoration and protection of the Gulf Coast Region through a new trust fund in the Treasury of the United States, known as the Gulf Coast Restoration Trust Fund (Trust Fund). The Trust Fund will contain 80 percent of the administrative and civil penalties paid by the responsible parties after July 6, 2012, under the Federal Water Pollution Control Act in connection with the *DEEPWATER HORIZON* oil spill. These funds will be invested and made available through five components of the RESTORE Act. On August 15, 2014, the Department of Treasury (Treasury) issued regulations (79 FR 48039) applicable to all five components, and which generally describe the responsibilities of the Federal and State entities that administer RESTORE Act programs and carry out restoration activities in the Gulf Coast Region.

Two of the five components, the Comprehensive Plan and Spill Impact Components, are administered by the Council, an independent federal entity created by the RESTORE Act. Under the Comprehensive Plan component (33 U.S.C. 1321(t)(2)), the subject of this notice, 30 percent of funds in the Trust Fund will be used to fund the operations of the Council and to carry out projects and programs adopted in the Council's Comprehensive Plan. An Initial Comprehensive Plan was adopted by the Council in August 2013 and is available at *http://www.restorethegulf.gov/sites/default/files/Initial%20Comprehensive%20Plan%20Aug%202013.pdf*. In the coming months, the Council will create a Funded Priorities List (FPL) to fund and/or prioritize for further review programs and projects that restore and protect the natural resources, ecosystems, fisheries, marine and wildlife habitats, beaches, and coastal wetlands of the Gulf Coast region.

Programs and projects selected for funding in the FPL will be funded either through grants to the State members of the Council (Alabama, Florida, Louisiana, Mississippi, and Texas) or interagency agreements to the Federal members of the Council (the Departments of Agriculture, Army, Commerce, and the Interior, the Department in which the Coast Guard is operating, and the Environmental Protection Agency). Those State and Federal members of the Council may in turn award grants or contracts to carry out the funded programs and projects.

II. Discussion of This Interpretation and Implementation

The RESTORE Act requires the Council to ''develop standard terms to include in contracts for projects and programs awarded pursuant to the Comprehensive Plan that provide a preference to individuals and companies that reside in, are headquartered in, or are principally engaged in business in a Gulf Coast State''. 33 U.S.C. 1321(t)(2)(C)(vii)(V). Application of a local contracting preference at the State and Federal level require separate analysis.

At the State level, the Council will not impose any special grant award

condition requiring a local contracting preference. Each of the five Gulf Coast States already has a state law or laws pertaining to local contracting preferences. Most of these laws do not provide for any sort of preference for firms local to any other State or, in some cases, prohibit preferences for firms local to other States. Were the Council to require the States to provide a preference for firms local to the other States, those States with prohibitions against such preferences would be unable to participate in the grant program. Having one or more of the Gulf Coast States ineligible to receive grants under the Comprehensive Plan component would be antithetical to the purpose of the RESTORE Act. As such, the Council policy for State contracting action using RESTORE Act funds is to have each State act in conformance with its State law on contracting preferences with no further requirements. This practice is consistent with 2 CFR part 200.319(b) which permits grant recipients to apply state or local geographic preferences in the evaluation of bids or proposals in cases only where a Federal statute, such as the RESTORE Act, expressly mandates or encourages geographical preference.

At the Federal level a local contracting preference is permitted only when a statute expressly authorizes or requires it. See 41 U.S.C. 3304(a)(5). It is the position of the Council that 33 U.S.C. 1321(t)(2)(C)(vii)(V) provides such an express authorization. However, given that the Council intends that Federal agencies contracting to implement a program or project under the FPL have discretion to make an award to the offeror whose proposal provides the best value to the Government, the Council has decided that a minimally restrictive form of a local contracting preference is appropriate. Accordingly, contracting Federal agencies may provide a preference to Gulf Coast firms if proposals are determined equivalent under all other evaluation factors or, alternatively, may include a weighted evaluation factor providing a preference to Gulf Coast firm offers.

In order to prevent a Gulf Coast firm from serving as merely a pass-through for a firm outside the Gulf Coast region, to be considered a ''local firm'' an offeror must certify that it resides, is headquartered or is principally engaged in business in a Gulf Coast State. Further, the offeror must certify that it will perform at least a minimum percentage of the work under the contract. The methodology for determining whether an offeror meets this test is based on the Small Business Administration's regulation found at 13 CFR 125.6.

The text below would be included in solicitations for Comprehensive Plan contracts that apply a local preference, and would be incorporated into the award. This term requires an offeror to disclose its status as a Gulf Coast firm and represent that it will perform a minimum percentage of the cost of the contract.

(a) The offeror represents as part of its offer that it ( ) is, ( ) is not a firm residing, headquartered or principally engaged in business in a Gulf Coast state.

(b) If the offeror represents that it is a firm residing, headquartered or principally engaged in business in a Gulf Coast state, the offeror shall furnish documentation to support the representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(c) The offeror represents that in the case of a contract for services (except construction), the firm will perform services representing at least 50 percent of the total labor costs under the contract with its own employees.

(d) The offeror represents that in the case of a contract for supplies or products (other than procurement from a non-manufacturer of such supplies or products), the firm will itself manufacture such supplies or products representing at least 50 percent of the total manufacturing costs under the contract (excluding costs of materials).

(e) The offeror represents that in the case of a contract for general construction services, the firm will perform services representing at least 15 percent of the total labor costs under the contract with its own employees.

The text below would be included in solicitations for Comprehensive Plan contracts. This term notifies prospective vendors that the contracting agency will prefer Gulf Coast firms in making the award.

Proposal Preparation Instructions—Each offeror shall identify whether it is a firm residing, headquartered or principally engaged in business in a Gulf Coast state.

Evaluation Factor 1—It is the policy of [Contracting Agency] to encourage the participation of Gulf Coast firms in the procurement process. As a result, this solicitation includes a preference for Gulf Coast firms. If [Contracting Agency] determines all other factors to be equivalent, [Contracting Agency] will give preference to a Gulf Coast firm. [Contracting Agency] will review your Gulf Coast firm status at the time the solicitation closes.

Evaluation Factor 2 [to be assigned relative weight by the Contracting Agency]—It is the policy of [Contracting Agency] to encourage the participation of Gulf Coast firms in the procurement process. As a result, this solicitation includes a preference for Gulf Coast firms. The Government will evaluate your proposal to determine if you are a Gulf Coast firm.

The Council invites comments on the proposed evaluation factors.

Will D. Spoon,

Program Analyst, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2015–12408 Filed 5–21–15; 8:45 am]

BILLING CODE 3510–EA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–0953]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) 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; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written

comments should be received within 30 days of this notice.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—Extension—Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH).

As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the CDC has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

To request additional information, please contact Kimberly S. Lane, Reports Clearance Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on April 30, 2014 (79 FR 24432).

This is an Extension information collection request. During the past three years the information has been used by programs within NIOSH to collect feedback from customers and stakeholders. Respondents will be screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government. Below we provide CDC's projected annualized estimate for the next three years. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 28,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Individuals and Households, Businesses, Organizations	Print Surveys	108,000	1	15/60
	Focus Groups	500	1	2
	Online Surveys	3,000	1	15/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–12479 Filed 5–21–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–372(S)]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 22, 2015.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS–R–284; OMB control number 0938–0345) report and FFP claimed on a state's Quarterly Expenditure Report (CMS–64; OMB control number 0938–1265), to determine whether to continue the state's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS–372(S) reports. *Form Number:* CMS–372(S) (OMB Control Number: 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 48; *Total Annual Responses:* 315; *Total Annual Hours:* 13,545. (For policy questions regarding this collection contact Ralph Lollar at 410–786–0777).

Dated: May 19, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–12497 Filed 5–21–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1638–N]

Medicare Program; Announcement of the Advisory Panel on Hospital Outpatient Payment (HOP Panel) Meeting on August 24–25, 2015

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the summer meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2015. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on the clinical integrity of the Ambulatory Payment Classification (APC) groups and their associated weights and hospital outpatient therapeutic services supervision issues.

DATES: *Meeting Dates:* The second semi-annual meeting in 2015 is scheduled for the following dates and times. The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times; consequently, the meetings may last longer than the times listed in this notice, but will not begin before the posted times:

- Monday, August 24, 2015, 9 a.m. to 5 p.m. EDT
- Tuesday, August 25, 2015, 9 a.m. to 5 p.m. EDT

Meeting Information Updates:

The actual meeting hours and days will be posted in the agenda. As information and updates regarding the onsite, webcast, and teleconference meeting, and agenda become available, they will be posted to the CMS Web site at: *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*

Deadlines:

Deadline for Presentations and Comments:

Presentations and Comments can be submitted by email only. Presentations or comments and form CMS–20017 must be in the Designated Federal Official's (DFO's) email inbox (*APCPanel@cms.hhs.gov*) by 5 p.m. EDT, Friday, July 24, 2015. Presentations and comments that are not received by the due date will be considered late and will not be included on the agenda. (See below for submission instructions for electronic submissions.)

Meeting Registration Timeframe: Monday, June 29, 2015, through Friday, July 31, 2015 at 5 p.m. EDT.

Participants planning to attend this meeting in person must register online, during the above specified timeframe at: *https://www.cms.gov/apps/events/default.asp.* On this Web page, double click the ''Upcoming Events'' hyperlink, and then double click the ''HOP Panel'' event title link and enter the required information. Include any requests for special accommodations.

Note: Participants who do not plan to attend the meeting in person should not register. No registration is required for participants who plan to view the meeting via webcast.

In commenting, please refer to file code CMS–1638–N. Because of staff and resource limitations, we cannot accept comments and presentations by facsimile (FAX) transmission or hard copy.

Meeting Location, Webcast, and Teleconference:

The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view this meeting via a webcast or listen by teleconference.

During the scheduled meeting, webcasting is accessible online at: *http://cms.gov/live*. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*

FOR FURTHER INFORMATION CONTACT:

Designated Federal Official (DFO):

Carol Schwartz, DFO, 7500 Security Boulevard, Mail Stop: C4–04–25,Woodlawn, MD 21244–1850.

Phone: (410) 786–3985.

Email: *APCPanel@cms.hhs.gov*

Send email copies to the following address:

Email: *APCPanel@cms.hhs.gov*

News Media:

Representatives must contact our Public Affairs Office at (202) 690–6145.

Advisory Committees' Information Lines:

The phone number for the CMS Federal Advisory Committee Hotline is (410) 786–3985.

Web sites:

For additional information on the Panel and updates to the Panel's activities, we refer readers to view our Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

Information about the Panel and its membership in the Federal Advisory Committee Act (FACA) database are also located at: *http://facadatabase.gov/*.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and is allowed by section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside panel, that is, the Advisory Panel on Hospital Outpatient Payment (the Panel) regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory panels.

The Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the Outpatient Prospective Payment System (OPPS).

II. Agenda

The agenda for the August 25, 2015 through August 26, 2015, meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Evaluating APC group weights.
- Reviewing the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.
- Removing procedures from the inpatient-only list for payment under the OPPS.
- Using single and multiple procedure claims data for CMS' determination of APC group weights.
- Addressing other technical issues concerning APC group structure.
- Recommending the appropriate supervision level (general, direct, or personal) for individual hospital outpatient therapeutic services.

The Agenda will be posted on the CMS Web site approximately 1 week before the meeting.

III. Presentations

The presentation subject matter must be within the scope of the Panel designated in the Charter. Any presentations outside of the scope of this Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to, the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services.

The Panel may use data collected or developed by entities and organizations other than DHHS and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either one or more agenda items.

All presentations will be shared with the public. Presentations may not contain any pictures, illustrations, or personally identifiable information.

In order to consider presentations and/or comments, we will need to receive the following information by email only. We cannot accept hardcopy submittals.

1. An *email copy* of the presentation sent to the DFO mailbox, *APCPanel@cms.hhs.gov*.

2. Form *CMS–20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation.

- Presenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's relationship with the organization that they represent must also be clearly listed.
- The form is now available through the CMS Forms Web site. The UniformResource Locator (URL) for linking to this form is as follows: *http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf*

IV. Oral Comments

In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of three minutes per organization.

V. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal property, must register by following the instructions in the ''*Meeting Registration Timeframe*'' section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

VI. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid

photo ID, persons may not be permitted entry to the building.

- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- Foreign nationals visiting any CMS facility require prior approval. If you are a foreign national and wish to attend the meeting onsite, in addition to registering for the meeting, you must also send a separate email to *APCPanel@cms.hhs.gov* prior to the close of registration to request authorization to attend as a foreign national.

VII. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

VIII. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 5, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–12527 Filed 5–21–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–668B]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by *July 21, 2015.*

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs Division of Regulations Development Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–668B Post Clinical Laboratory Survey Questionnaire and Supporting Regulations

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Post Clinical Laboratory Survey Questionnaire and Supporting Regulations; *Use:* Form CMS–668B is used by a Clinical Laboratory Improvement Amendments (CLIA) laboratory to express its satisfaction with the survey process and to make recommendations for improvement. Surveyors furnish this form to all laboratories that receive

either an onsite survey or the Alternate Quality Assessment Survey (*i.e.,* paper survey of quality indicators). We perform an overview evaluation of the completed forms. Each calendar year, a summary of the information collected is sent to the State and CMS Regional Offices. *Form Number:* CMS–668B (OMB Control Number 0938–0653); *Frequency:* Biennially; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions), State, Local, or Tribal Government; *Number of Respondents:* 19,051; *Total Annual Responses:* 9,526; *Total Annual Hours:* 2,382. (For policy questions regarding this collection contact Kathleen Todd at 410–786–3385.)

Dated: May 19, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–12498 Filed 5–21–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3307–FN]

Medicare and Medicaid Programs; Continued Approval of The Joint Commission's Hospice Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization for hospices that wish to participate in the Medicare or Medicaid programs. A hospice that participates in Medicaid must also meet the Medicare Conditions of Participation (CoPs).

DATES: This final notice is effective June 18, 2015 through June 18, 2021.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636, Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for hospices.

Generally, to enter into an agreement, a hospice must first be certified as complying with the conditions set forth in part 418 and recommended to the Center for Medicare & Medicaid (CMS) for participation by a state survey agency. Thereafter, the hospice is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, CMS may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide CMS with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Joint Commission's (TJC's) current term of approval for its hospice accreditation program expires June 18, 2015.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the December 19, 2014 **Federal Register** (79 FR 75817), we published a proposed notice announcing TJC's request for continued approval of its Medicare hospice accreditation program. In the December 19, 2014 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of TJC's Medicare hospice accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospice surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospices; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare hospice accreditation program standards to our current Medicare hospice CoPs.
- A documentation review of TJC's survey process to—

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospices.

++ Evaluate TJC's procedures for monitoring hospices it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.7(d)).

++ Assess TJC's ability to report deficiencies to the surveyed hospice and respond to the hospice's plan of correction in a timely manner.

++ Establish TJC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies with respect to surveys being unannounced.

++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the December 19, 2014 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for hospices. No comments were received in response to the proposed notice.

IV. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's hospice accreditation requirements and survey process with the Medicare CoPs of part 418, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's hospice application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, TJC is in the process of or has completed revising its standards and certification processes to meet the requirements at:

- § 418.52(a)(1), to ensure hospices' provide verbal notification of the patient's rights and responsibilities.
- § 418.52(b)(4)(i), to ensure all alleged violations of mistreatment are immediately reported to the hospice administrator.
- § 418.54(c)(6) and § 418.54(c)(6)(v), to ensure the patient's prescriptions, over the counter drugs, including herbal remedies and other alternative treatments, and drug therapy associated with laboratory monitoring are reviewed when completing the comprehensive assessment.
- § 418.58(d)(1), to ensure that the number and scope of distinct performance improvement projects conducted annually, based on the needs of the hospice's population and internal organizational needs, reflect the scope, complexity, and past performance of the hospice's operations.
- § 418.58(e)(1), to ensure the ongoing quality improvement and patient safety program is evaluated annually.
- § 418.64(d)(3)(iv), to ensure the family is advised of the availability of spiritual counseling services.
- § 418.76(c)(4), to ensure the direct supervision of the hospice aide training is completed by a registered nurse.
- § 418.76(g)(1), to ensure written patient care instructions for the hospice aide are prepared by a registered nurse who is responsible for the supervision of the hospice aide.
- § 418.76(h)(1)(i), to ensure the registered nurse's supervision of the hospice aide includes an assessment of the quality of care and services provided by the hospice aide and to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs.
- § 418.78(a), to ensure the hospice maintains, documents, and provides volunteer orientation and training that is consistent with hospice industry standards.
- § 418.104(a)(2), to address the requirement that hospices include a signed copy of the election statement in the patient's clinical record.
- § 418.106(a)(1), to ensure the interdisciplinary group ''confers'' with an individual with education and training in drug management to make sure drugs and biologicals meet the patient's needs.
- § 418.106(e)(2)(i)(B), to address the requirement for the hospice to educate the patient, or representative and the family on the safe use and disposal of controlled drugs ''in a language and manner that they understand.''
- § 418.106(e)(3)(i), to address the requirement that only personnel authorized to administer controlled drugs have access to the locked compartments.
- § 418.108(c)(5), to address when inpatient care is provided under arrangement, that the hospice retains a description of the training provided and documents the names of those giving the training.
- § 418.110(d), to ensure the Life Safety Code (LSC) requirements apply to all certified in-patient hospice facilities regardless of the number of certified beds.
- § 418.110(f)(3)(vi), to ensure patient rooms are equipped with an easily-activated, functioning and accessible device that is used for calling for assistance.
- § 418.110(m), to ensure all patients have the right to be free from physical or mental abuse and corporal punishment.
- § 418.110(m)(7)(ii), to address that each order for restraint used ensures the physical safety of the non-violent or non-self-destructive patients.
- § 418.114(d)(1), to address the requirement that all contracted entities obtain criminal background checks on contracted employees who have direct patient contact or access to patient records.
- § 488.4(a)(3)(ii), to ensure compliance with its own policies related to the minimum number of medical records reviewed while conducting an onsite hospice survey.
- § 488.4(a)(4)(i), to clarify the minimum size and composition of its survey team for its Medicare hospice accreditation program.
- § 488.4(a)(4)(ii) through (v), to ensure its surveyors are appropriately qualified, trained, and evaluated.
- § 488.4(a)(6), to ensure the minimum number of medical records are reviewed for complaint surveys.
- § 488.8(a)(2)(v), to ensure data reported to CMS is accurate and complete.
- § 488.26(b), to improve surveyors' abilities to—

++ Accurately and completely document instances of non-compliance at the appropriate level of citation (condition versus standard level citations).

++ Ensure that all instances of observed non-compliance are documented in the survey report.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for hospices that request participation in the Medicare program, effective June 18, 2015 through June 18, 2021.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: May 5, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–12524 Filed 5–21–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Community Services Block Grant (CSBG) Model State Plan.

OMB No.: 0970–0382.

Description: Section 676 of the Community Services Block Grant (CSBG) Act requires States, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (Model State Plan). The Model State Plan must meet statutory requirements prior to being funded with CSBG funds. Applicants have the option to submit a detailed plan annually or biannually. Entities that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur.

This request is to revise the Model State Plan format for States by automating the form, streamlining the information, and incorporating accountability measures. The revised and automated form may impose an added first-use burden; however, this burden will diminish substantially in subsequent years. Copies of the proposed collection of information/Model State Plan can be obtained by visiting *http://www.acf.hhs.gov/programs/ocs/programs/csbg.*

Respondents: State Governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Model State Plan	56	1	33	1,848

Estimated Total Annual Burden Hours: 1,848.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–12392 Filed 5–21–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1152]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 22, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0608. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road, COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii) (OMB Control Number 0910–0608)—Reinstatement

The Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

Part 111 (21 CFR part 111) establishes the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1) an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 (21 CFR 10.30)and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

In the **Federal Register** of March 9, 2015 (80 FR 12491), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, but was not responsive to the four collection of information topics solicited in the notice and, therefore, is not discussed in this document.

We estimate the annual burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; CGMP requirements for dietary supplements	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii)	1	1	1	8	8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the last 3 years, we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Based on our experience with petition processes, we estimate it will take a requestor about 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition. Although we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, we believe that OMB approval of these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients.

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12398 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pharmacy Compounding 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: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on June 17, 2015, from 8:30 a.m. to 5 p.m., and on June 18, 2015, from 8:30 a.m. to 11:30 a.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/*

AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PCAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Background: Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act adds a new section, 503B, to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee–1), but not section 501(a)(2)(B).

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the drug that is compounded does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (''withdrawn or removed list'') (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list (''section 503A bulk drug substances list'') developed by the Secretary through regulations issued by the Secretary (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list published by the Secretary of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in accordance with all applicable conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA will discuss with the committee drugs proposed for inclusion on the withdrawn or removed list pursuant to sections 503A and 503B and on the section 503A bulk drug substances list. FDA will also discuss with the committee the criteria FDA proposes to use to evaluate candidates to be identified as difficult to compound pursuant to sections 503A and 503B.

Agenda: On June 17, 2015, during the morning session, the committee will receive updates on certain issues to follow up on discussions from the last meeting including the options for obtaining access to investigational new drugs and the processes FDA plans to use to add or remove drugs from the section 503A bulk drug substances list. During this session, the committee will also discuss revisions FDA is considering to the list of drug products that may not be compounded under the exemptions provided by the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. The list of those drug products is currently codified at 21 CFR 216.24. FDA now is considering whether to amend the rule to add four more drugs to the list: Aprotinin, ondansetron hydrochloride, bromocriptine mesylate, and acetaminophen. As previously explained in the **Federal Register** of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list because an approved drug containing the same active ingredient(s) has not been withdrawn or removed from the market. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA plans to seek the committee's advice concerning the inclusion of these drug products.

On June 17, 2015, during the afternoon session, the committee will discuss four bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA intends to discuss the following nominated bulk drug substances: Brilliant Blue G, tranilast, N-acetyl-D-glucosamine, and oxitriptan. The nominators of these substances will be invited to make a short presentation supporting the nomination. Other nominated substances will be discussed at future committee meetings.

During the morning session on June 18, 2015, the committee will discuss the criteria FDA is proposing to use to evaluate drug products or categories of

drug products for identification as demonstrably difficult to compound.

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 meeting 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 June 9, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:15 a.m. and 3:45 p.m. to 4 p.m. on June 17, 2015, and between approximately 9:15 a.m. to 9:45 a.m. on June 18, 2015. 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 June 4, 2015. 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 June 8, 2015.

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 Jayne E. Peterson 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: May 19, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–12512 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0639]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 3, 2014, the Agency submitted a proposed collection of information entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0569.

The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12399 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0781]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 22, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health

Claim—21 CFR 101.82(c)(2)(ii)(B)

OMB Control Number 0910–0428—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of our regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (CHD). To bear the soy protein and CHD health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, we must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, we require manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

In the **Federal Register** of March 10, 2015 (80 FR 12640), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the annual burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon our experience with the use of health claims, we estimate that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, *e.g.,* the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which we estimate will take 1 hour annually.

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12402 Filed 5–21–15; 08:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0482]

Determination That VAGIFEM (Estradiol) Vaginal Tablets, 25 Micrograms, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that VAGIFEM (estradiol) Vaginal Tablets, 25 micrograms, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6214, Silver Spring, MD 20993–0002, 301–796–3602, *Elaine.Lippmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug product listed in the table in this document is no longer being marketed.

Application No.	Drug	Applicant
NDA 020908	VAGIFEM (estradiol) Vaginal Tablets, 25 micrograms	Novo Nordisk Inc., 800 Scudders Mill Rd., Plainsboro, NJ 08536.

FDA has reviewed its records and, under § 314.161, has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug product listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDA listed in this document are unaffected by the discontinued marketing of the product subject to this NDA. Additional ANDAs that refer to this product may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for estradiol vaginal tablets should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12396 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0510]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Substances Prohibited From Use in Animal Food or Feed'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 17, 2015, the Agency submitted a proposed collection of information entitled, ''Substances Prohibited From Use in Animal Food or Feed'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0627. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12404 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0535]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 13, 2015, the Agency submitted a proposed collection of information entitled, ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12400 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and

recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 9, 2015, from 8 a.m. to 12:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss biologics license application 125547, necitumumab injection, application submitted by Eli Lilly and Company. The proposed indication (use) for this product is in combination with gemcitabine and cisplatin for first-line treatment of patients with locally advanced or metastatic squamous non-small cell lung cancer.

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 meeting 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 June 24, 2015. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 16, 2015. 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 June 17, 2014.

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 Lauren D. Tesh 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: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12403 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Advisory Committee; Medical Imaging Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Medical Imaging Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Medical Imaging Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 18, 2015, expiration date.

DATES: Authority for the Medical Imaging Drugs Advisory Committee will expire on May 18, 2017, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, Division of Advisory Committee and Consultant Management, Office of Executive Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002; 301–796–9001, email: *MIDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Medical Imaging Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/MedicalImagingDrugsAdvisoryCommittee/default.htm* or by contacting the Designated Federal Officer (Please see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12401 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–0307]

Determination of Regulatory Review Period for Purposes of Patent Extension; STIVARGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for STIVARGA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product STIVARGA (regorafenib). STIVARGA is indicated for treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and if KRAS wild type, an anti-EGRF therapy. Subsequent to this approval, the USPTO received a patent term restoration application for STIVARGA (U.S. Patent No. 7,351,834) from Bayer HealthCare LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 23, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of STIVARGA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for STIVARGA is 2,234 days. Of this time, 2,080 days occurred during the testing phase of the regulatory review period, while 154 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* August 18, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 18, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* April 27, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for STIVARGA (NDA 203085) was submitted on April 27, 2012.

3. *The date the application was approved:* September 27, 2012. FDA has verified the applicant's claim that NDA 203085 was approved on September 27, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 898 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 21, 2015. Furthermore, any interested person may petition FDA for a determination

regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 18, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12577 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–0126]

Determination of Regulatory Review Period for Purposes of Patent Extension; FLUCELVAX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FLUCELVAX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product FLUCELVAX (A/Brisbane/10/2010 (wild type), A/California 7/2009-like virus (H1N1), A/Victoria/361/2011 virus IVR–165(H3N2, B/Wisconsin/1/2010 (wildtype) B Yamagata lineage)). FLUCELVAX is indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. Subsequent to this approval, the USPTO received a patent term restoration application for FLUCELVAX (U.S. Patent No. 6,656,720) from Novartis AG, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 2014, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of FLUCELVAX represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FLUCELVAX is 2,589 days. Of this time, 2,224 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* October 21, 2005. The applicant claims March 31, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 21, 2005, which was the date the IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 22, 2011. The applicant claims October 31, 2011, as the date the biologics license application (BLA) for FLUCELVAX (BLA 125408) was initially submitted. However, FDA records indicate that BLA 125408 was submitted on November 22, 2011.

3. *The date the application was approved:* November 20, 2012. FDA has verified the applicant's claim that BLA 125408 was approved on November 20, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,773 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 21, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for

extension acted with due diligence during the regulatory review period by November 18, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12397 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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/contract proposals 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/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Peptide Reagents for Proteomics.

Date: June 15, 2015.

Time: 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 5W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Mobile Health Monitoring Devices.

Date: June 16, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2E030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Wound Healing Materials.

Date: June 17, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 4E030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; R13 Conference Grant Review.

Date: June 23, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Bratin K. Saha, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20850, 240–276–6411, *sahab@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Opportunities for Collaborative Research at the NIH Clinical Center (U01).

Date: July 22, 2015.

Time: 9:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2E908, Rockville, MD 20850.

Contact Person: Caron A. Lyman, Ph.D., Chief, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Bethesda, MD 20892, 240–276–6348, *lymanc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 19, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12542 Filed 5–21–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: June 11–12, 2015.

Time: June 11, 2015, 8:30 a.m. to 6:00 p.m.

Agenda: NIH Director's Report, ACD Working Group reports.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Time: June 12, 2015, 8:00 a.m. to 2:00 p.m.

Agenda: NIH IC Director Reports and other business of the committee.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6C6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive,

Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should be submitted electronically to *woodgs@od.nih.gov* by close of business June 10, 2015, and include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 18, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12389 Filed 5–21–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2015–0073; OMB Control Number 1625–0045]

Collection of Information Under Review by Office of Management and Budget

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval of a revision of a currently approved collection: 1625–0045, Adequacy Certification for Reception Facilities and Advance Notice—33 CFR part 158. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before June 22, 2015.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2015–0073] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) and/or to OIRA. To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* (a) To Coast Guard docket at *http://www.regulations.gov.* (b) To OIRA by email via: *OIRA-submission@omb.eop.gov*.

(2) *Mail:* (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. (b) To OIRA, 725 17th Street NW., Washington, DC 20503, attention Desk Officer for the Coast Guard.

(3) *Hand Delivery:* To DMF address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in a timely manner, mark the fax, attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12–140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at *http://www.regulations.gov.*

Copies of the ICRs are available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, US Coast Guard, 2703 Martin Luther King Jr Ave. SE., STOP 7710, Washington DC 20593–7710.

For Further Information: Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532 or fax 202–372–8405, for questions on these documents. Contact Ms. Cheryl Collins, Program Manager, Docket Operations, 202–366–9826, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collections. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICRs referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG 2015–0073], and must be received by June 22, 2015. We will post all comments received, without change, to *http://www.regulations.gov.* They will include any personal information you provide. We have an agreement with DOT to use their DMF. Please see the ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number [USCG–2014–0713]; indicate the specific section of the document to which each comment applies, providing a reason for each comment. You may submit your comments and material online (via *http://www.regulations.gov*), by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *www.regulations.gov,* it will be

considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the DMF. We recommend you include your name, mailing address, an email address, or other contact information in the body of your document so that we can contact you if we have questions regarding your submission.

You may submit comments and material by electronic means, mail, fax, or delivery to the DMF at the address under **ADDRESSES**, but please submit them by only one means. To submit your comment online, go to *http://www.regulations.gov,* and type ''USCG–2015–0073'' in the ''Search'' box. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and will address them accordingly.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this Notice as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Search'' box insert ''USCG–2015–0073'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the DMF in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

OIRA posts its decisions on ICRs online at *http://www.reginfo.gov/public/do/PRAMain* after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Numbers: 1625–0045.

Privacy Act

Anyone can search the electronic form of comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act statement regarding Coast Guard public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (80 FR 12507, March 9, 2015) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments.

Information Collection Request

1. *Title:* Adequacy Certification for Reception Facilities and Advance Notice—33 CFR part 158.

OMB Control Number: 1625–0045.

Type of Request: Revision of a currently approved collection.

Respondents: Owners and operators of reception facilities and owners and operators of vessels.

Abstract: This information collection is needed to evaluate the adequacy of reception facilities prior to issuance of a Certificate of Adequacy. Information for the advance notice ensures effective management of reception facilities and reduces the burden to facilities and ships.

Forms: CG–5401, CG–5401A, CG–5401B, CG–5401C and CG–5401D.

BURDEN ESTIMATE: The estimated burden has increased from 1,497 hours to 4,979 hours a year due to an increase in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: May 12, 2015.

Thomas P. Michelli,

U.S. Coast Guard, Chief Information Officer, Acting.

[FR Doc. 2015–12525 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Revision of Agency Information Collection Activity Under OMB Review: TSA Pre✓® Application Program

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0059, abstracted below to the Office of Management and Budget (OMB) for review and approval of a revision of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on January 5, 2015, 80 FR 515. The collection involves the submission of biographic and biometric information by individuals seeking to enroll in the TSA Pre✓®Application Program, as well as an optional customer satisfaction survey.

DATES: Send your comments by June 22, 2015. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–2062; email *TSAPRA@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: TSA Pre✓® Application Program.

Type of Request: Revision of currently approved collection.

OMB Control Number: 1652–0059.

Form(s): NA.

Affected Public: Air Travelers.

Abstract: The Transportation Security Administration (TSA) implemented the TSA Pre✓® Application Program pursuant to its authority under sec. 109(a)(3) of the Aviation and Transportation Security Act (ATSA), Public Law 107–71 (115 Stat. 597, 613, Nov. 19, 2001, codified at 49 U.S.C. 114 note), as well as the DHS Appropriations Act, 2006, Public Law 109–90 (119 Stat. 2064, 2088–89, Oct. 18, 2005), which authorizes TSA to establish and collect a fee for any registered traveler program by publication of a notice in the **Federal Register**.

Under the TSA Pre✓® Application Program, individuals may submit biographic and biometric information directly to TSA, which in turn uses the information to conduct a security threat assessment (STA) of law enforcement, immigration, and intelligence databases, including a criminal history check. The results are used by TSA to decide if an individual poses a low risk to transportation or national security. Approved applicants are issued a Known Traveler Number (KTN) that may be used when making travel reservations. Airline passengers who submit their KTN when making airline reservations are eligible for expedited screening on flights originating from U.S. airports with TSA Pre✓® lanes.[1] TSA uses the traveler's KTN and other information during passenger pre-screening to verify that the individual traveling matches the information on TSA's list of known travellers and to confirm TSA Pre✓® expedited screening eligibility.

TSA plans to expand enrollment options for the TSA Pre✓® Application Program by using additional contractor options or capabilities to market, enroll and pre-screen applicants. Approved contractors will provide secure enrollment options to collect biographic and biometric (*e.g.,* fingerprints, iris scans, and/or photo) information, validate identity, collect citizenship/immigration information, and perform a criminal history records check to ensure that applicants do not have convictions for criminal offenses that would disqualify them from the TSA Pre✓® Application Program (please refer to the list of current disqualifiers available at *www.tsa.gov/tsa-precheck/eligibility-requirements*). These expansion options may include the use of commercial and other publicly available data to verify identity and citizenship/immigration status, and conduct a criminal check.

For enrolled and prescreened applicants, these additional contractors will transmit via a secure interface certain minimum required data elements (including, but not limited to, name, date of birth, gender, address, contact information, country of birth, images of identity documents, proof of citizenship/immigration status, and biometrics) to enable TSA to conduct a STA, make a final eligibility determination for the TSA Pre✓® Application Program, and for screening purposes, including to verify TSA Pre✓® enrolled and approved individuals when they are travelling.

Applicants who are found to be ineligible as a result of prescreening by a contractor shall be notified by the respective contractor of the reason. The notification will include, when relevant, information about the available correction of criminal or immigration records process and any alternatives available for identity verification, as well as other available channels for TSA Pre✓® expedited screening. Those who apply through TSA's existing program contractor will be notified of their eligibility for the program by TSA after completion of the STA.

The TSA-conducted STA for applicants forwarded by the contractors will include checks against government watchlists and databases associated with security and immigration. TSA will make the final determination on eligibility for the TSA Pre✓® Application Program and notify the applicant of the decision. Applicants generally should expect to receive notification from TSA within 2–3 weeks of the submission of their completed applications.

Eligibility for the TSA Pre✓® Application Program is within the sole discretion of TSA, which will notify applicants who are denied eligibility in writing of the reasons for the denial. If initially deemed ineligible by TSA, applicants will have an opportunity to correct cases of misidentification or inaccurate criminal or immigration records. If advised during the application eligibility review process that the criminal record discloses a disqualifying criminal offense, the applicant must submit in writing within a specified period of his or her intent to correct any information he or she believes to be inaccurate. The applicant must provide a certified revised record, or the appropriate court must forward a certified true copy of the information, prior to TSA approving eligibility of the applicant for the TSA Pre✓® Application Program. With respect to citizenship and/or immigration records, within 60 days after being advised that the citizenship or immigration records indicate that the applicant is ineligible for the TSA Pre✓® Application Program, the applicant must notify TSA in writing of his or her intent to correct any information believed to be inaccurate. TSA will review any information submitted and make a final decision. If neither notification nor a corrected record is received by TSA, the agency may make a final determination to deny eligibility. Individuals who TSA determines are ineligible for the TSA Pre✓® Application Program will be screened at airport security checkpoints pursuant to standard screening protocols.

TSA invites all TSA Pre✓® applicants to complete an optional survey to gather information on the applicants' overall customer satisfaction with the service received at the enrollment center. The optional survey is administered at the end of the in-person enrollment service. TSA will use the information to determine whether any trends exist regarding customer service at a particular enrollment center or particular application enrollment activity and to take steps to improve service. TSA will encourage the additional contractors to offer a similar customer satisfaction survey.

The TSA Pre✓® Application Program enhances aviation security by permitting TSA to better focus its limited security resources on passengers who are more likely to pose a threat to civil aviation, while also facilitating and improving the commercial aviation travel experience for the public. Travelers who choose not to enroll in this initiative are not subject to any limitations on their travel because of their choice; they will be processed through normal TSA screening before entering the sterile areas of airports. TSA also retains the authority to perform standard or other screening on a random basis on TSA Pre✓® Application Program participants and any other travelers authorized to receive expedited physical screening.

Average Annual Number of Respondents: An estimated 5,458,919 annualized respondents enrollments over a four year period.

Estimated Annual Burden Hours: An estimated 4,596,547 annualized hours

[1] Passengers who are eligible for expedited screening through a dedicated TSA Pre✓® lane typically will receive more limited physical screening, *e.g.,* will be able to leave on their shoes, light outerwear, and belt, to keep their laptop in its case, and to keep their 3–1–1 compliant liquids/gels bag in a carry-on. For airports with TSA Pre✓® lanes, see *http://www.tsa.gov/tsa-precheck/tsa-precheck-participating-airports.*

based on a four-year projection. This estimate includes the time for pre-enrollment, all aspects of enrollment (including a voluntary customer satisfaction survey), and correction of records if needed.

Estimated Cost Burden: $143,500,886 annualized cost burden based on a four-year projection. The TSA fee per respondent for those who apply for the program directly with TSA will remain $85, which covers TSA's program costs and the FBI fee for the criminal history records check. The fee charged by contractor under the expansion of the program may differ, as it may include, but not be limited to, fees for other services that the companies provide separately to their customers and the option to utilize FBI for the criminal checks at a charge of $12.75 per applicant. TSA estimates contractors would remit approximately $25 to TSA for each prescreened applicant.

Dated: May 18, 2015.

Christina A.Walsh,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2015–12485 Filed 5–21–15; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5831–C–24]

30-Day Notice of Proposed Information Collection: Production of Material or Provision of Testimony by HUD in Response to Demands in Legal Proceedings Among Private Litigants

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Correction, Notice.

SUMMARY: This notice corrects the notice HUD published on May 18, 2015 at 80 FR 28294. HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment. The OMB number will be changed from 2501–0022 to 2510–0014.

DATES: *Comments Due Date: June 25, 2015.*

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: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Anna Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email at *Anna Guido@hud.gov* or telephone 202–402–5535. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD has submitted to OMB a request for approval of the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 6, 2015 at 80 FR 12192.

A. Overview of Information Collection

Title of Information Collection: Production of Material or Provision of Testimony by HUD Response to Demands in Legal Proceedings Among Private Litigants.

OMB Approval Number: 2510–0014.

Type of Request: Revision.

Form Numbers: N/A.

Description of the need for the information and proposed use: Section 15.203 of HUD's regulations in 24 CFR specify the manner in which demands for documents and testimony from the Department should be made. Providing the information specified in 24 CFR 15.203 allows the Department to more promptly identify documents and testimony which a requestor may be seeking and determine whether the Department should produce such documents and testimony.

Members of affected public: All types of entities, private and non-profit organizations, individuals and households.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response:

Number of respondents	Frequency of response	Hours per response	Total burden hours
106	1	1.5	159

Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on 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.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 12, 2015.

Anna Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2015–12521 Filed 5–21–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5828–N–21]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Agriculture:* Ms. Debra Kerr, Department of Agriculture, Reporters Building, 300 7th Street SW., Room 300, Washington, DC 20024, (202) 720–8873; *Army:* Ms. Veronica Rines, Office of the Assistant Chief of Staff for Installation Management, Department of Army, Room 5A128, 600 Army Pentagon, Washington, DC 20310, (571) 256–8145; *COE:* Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street NW., Washington, DC 20314; (202) 761–5542; *GSA:* Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501–0084; *Navy:* Mr. Steve Matteo, Department of the Navy, Asset Management; Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374; (202) 685–9426;

(These are not toll-free numbers.)

Dated: May 14, 2015.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 05/22/2015

Suitable/Available Properties

Building

Missouri

Toilet, Type III, CWATER–4386
Bluff View Park Hwy AA
Piedmont MO 63957
Landholding Agency: COE
Property Number: 31201520003
Status: Underutilized
Comments: 34+ years old, 10X7; restroom/shower house; 8 mos. vacant; deterioration & decay; contact COE for more information.

Virginia

T–482
JB Myer Henerson Hall
Ft. Myer VA 22211
Landholding Agency: Army
Property Number: 21201520003
Status: Excess
Comments: off-site removal only; 8,267 sq. ft.; relocation may be difficult to size; office; 6+ months vacant; contact Army for more information

Idaho

PVT Lloyd G. McCarter USARC
1662 W. Wyoming Ave.
Hayden ID 83835
Landholding Agency: GSA
Property Number: 54201520010
Status: Excess
GSA Number: 9–D–ID–0583
Directions: Disposal Agency: GSA; Land Holding Agency: COE
Comments: 11,000 sq. ft., sits on 4.62 acres leased until 10/2046; 35+ yrs. old; land lease government use only; Army Reserve Center; vacant 20+ months; Contact GSA for more information.

Guam

6 Buildings
Navy Base Guam PSC 455, Box 152
FPO AP GU 96549

Landholding Agency: Navy
Property Number: 77201520008
Status: Underutilized
Directions: Building #275, #368–PV, #2, #210376, #100, #1801(S. Finegayan Housing Area (71 acres); Confined Disposal Facility (24 acres) (24 acres); Commissary Store (Building 275—Building size is 58,663 SF with open grass area behind facility, 25 acres); Harmon Booster Pump Station (Facility #210376, 4 acres); Waste Water Treatment Plant (Facility #1801, 16 acres); MWD PV Array (Facility #368–PV, 31 acres); Harmon Annex (Facility #2, Harmon Land Parcel 2, 4 acres); Tumon Tank Farm (Facility #100, 20 acres)
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

South Finegayan Housing Area
Navy Base Guam, PSC 455, Box 152
FPO AP GU 96540
Landholding Agency: Navy
Property Number: 77201520009
Status: Underutilized
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

Contained Disposal Facility
Route 1
Navy Base GU 96540
Landholding Agency: Navy
Property Number: 77201520010
Status: Unutilized
Comments: Public access denied and no alternative method to gain access without compromising National Security.
Reasons: Secured Area

Texas

Building 46 ID 620240B046
2881 F&B Road
College Station TX 77845
Landholding Agency: Agriculture
Property Number: 15201520027
Status: Unutilized
Comments: Tin roof in poor condition; ceiling falling down; exterior walls are rotten & pulling apart from the floor & roof; floor beams are rotten and unable to support the floor structure.
Reasons: Extensive deterioration

[FR Doc. 2015–12231 Filed 5–21–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW00000.L16100000.DQ0000. LXSS015F0000 241A; 12–08807; MO#4500073892; TAS: 14X5017]

Notice of Availability of the Winnemucca District Resource Management Plan and Record of Decision, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) for the Winnemucca District located in northern Nevada. The Nevada State Director signed the ROD on May 21, 2015, which constitutes the final decision of the BLM and makes the Approved RMP effective immediately.

ADDRESSES: Copies of the ROD/Approved RMP are available upon request from the Winnemucca District Manager, Bureau of Land Management, 5100 E. Winnemucca Blvd., Winnemucca, NV 89445 or via the Internet at *http://www.blm.gov/nv/st/en/fo/wfo/blm_information/rmp.html.* Copies of the ROD/Approved RMP are available for public inspection at the Winnemucca District at the above address.

FOR FURTHER INFORMATION CONTACT: Zwaantje Rorex, RMP Team Lead, telephone 775–623–1727; address 5100 E. Winnemucca Blvd., Winnemucca, Nevada 89445; email *zrorex@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Winnemucca District RMP will replace the existing 1982 Sonoma-Gerlach and Paradise-Denio Management Framework Plans (MFPs) and one land use plan amendment titled the Paradise-Denio and Sonoma-Gerlach Management Framework Plan-Lands Amendment (January 1999). The RMP and associated EIS were developed using a collaborative planning process. Collaboration included working with nine cooperating agencies, development of alternatives utilizing a sub-group of the Sierra Front-Northwestern Great Basin Resource Advisory Council and input through coordination and consultation with Native American/Tribal interests. The RMP planning area encompasses approximately 7.2 million acres of public land administered by the Winnemucca District, located in Humboldt, Pershing, and parts of Lyon, Churchill and Washoe counties, Nevada. The RMP decision area does not include private lands, State lands, Indian Reservations, Federal lands not administered by BLM or lands within the Black Rock Desert-High Rock Canyon, Emigrant Trails National Conservation Area (NCA), except for administratively combining portions of two herd management areas (HMAs) into one HMA. The NCA is covered under the ROD and RMP for the Black Rock Desert-High Rock Canyon Emigrant Trails NCA and associated wilderness, and other contiguous lands in Nevada (July 2004). The RMP describes the actions and landscape-level conservation and management to meet desired resource goals and objectives for natural resources including wildlife habitat, sensitive and threatened or endangered species habitat, watersheds, and wild horses and burros. While the RMP contains some conservation management measures for the Greater Sage-Grouse habitats, the Nevada and Northeastern California Greater Sage-Grouse Plan Amendment and EIS will fully analyze applicable Greater-Sage Grouse conservation measures, consistent with BLM Instruction Memorandum No. 2012–044. The BLM expects to make a comprehensive set of decisions for managing Greater-Sage Grouse on lands administered by the Winnemucca District in the Record of Decision for the Nevada and Northeastern California Greater Sage-Grouse Plan Amendment and EIS. The RMP addresses protection and preservation of cultural resources, scenic values and management of recreation. Multiple uses, including livestock grazing, minerals, and lands and realty actions, are also addressed.

The proposed RMP/Final EIS was made available to the public on September 6, 2013 in 78 FR 54909. Nine valid protest letters were received and 21 issues were identified. No comments were received as a result of the Governor's consistency review. The Director's Protest Resolution Report is available from the Winnemucca District's RMP Web site at: *http://www.blm.gov/nv/st/en/fo/wfo/blm_information/rmp.html.*

As a result of resolving protest issues, the following changes were made to the final RMP: added language to management action for vegetation-riparian/wetlands (action VRW 1.1.1) to clarify adaptive management; included the Snowstorms Mountains-fence for HMA boundary adjustments in action WHB 1.2; clarified management action for cooperative agreements with livestock permittees in action LG 5.4; and corrected response to public comment in Appendix M regarding areas to be closed to livestock grazing within certain allotments. Other minor editorial modifications to provide further clarification of some of the decisions were made. Reformatting of the final RMP resulted in renumbering

of some of the management actions, noted in the document itself. Clarifications on management actions and corrections regarding the analysis provided in the EIS are described in the ROD. These include actions pertaining to vegetation (range), fish and wildlife habitat, special status species habitat (specifically Greater Sage-Grouse), wild horse and burro, livestock grazing, and lands and realty.

During the development of the final RMP and ROD, the Pine Forest Range Wilderness was designated through the presidential approval of the National Defense Authorization Act (December 19, 2014) Public Law 113–291, section 3064. The ROD and RMP reflect changes to management actions based on this designation.

The EIS analyzed four alternatives: Alternative A (no action), Alternative B (use intensive), Alternative C (environmental protection), and Alternative D (the Preferred Alternative). The Preferred Alternative as described in the proposed RMP was selected in the ROD, with some minor clarifications based on protests. The ROD adopts the RMP's goals and objectives and management actions to reach those goals and objectives. The ROD does not directly implement any specific action. Future actions will be consistent with the management direction in the approved RMP and will be made through a future decision-making process, including appropriate environmental review. Examples of site-specific planning efforts for resource use activities are mine plans of operation or rangeland health assessments. The approved RMP provides for the development of future implementation plans for special recreation management areas, communication sites, acquired lands, and travel and transportation management.

The approved RMP also describes future step down plans for resource protection including rangeland health assessments, cultural and paleontological management plans, wild horse and burro herd management plans, and an invasive weed control plan.

Authority: 40 CFR 1506.6

Amy Lueders,

State Director, Nevada.

[FR Doc. 2015–12190 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMTC 00900.L16100000.DP0000 MO#4500079560]

Notice of Public Meeting, Dakotas Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Dakotas Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Dakotas Resource Advisory Council meeting will be held on June 9, 2015 in Deadwood, South Dakota. When determined, the meeting place will be announced in a news release. The meeting will start at 9:00 a.m. and adjourn at approximately 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mark Jacobsen, Public Affairs Specialist, BLM Eastern Montana/Dakotas District, 111 Garryowen Road, Miles City, Montana, 59301; (406) 233–2831; *mjacobse@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–677–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member council advises the Secretary of the Interior through the BLM on a variety of planning and management issues associated with public land management in North and South Dakota. At this meeting, topics will include: An Eastern Montana/Dakotas District report, North Dakota and South Dakota Field Office manager reports, Resource Management Plan updates, Ft. Meade Recreation Area trails projects report, individual RAC member reports and other issues the council may raise. All meetings are open to the public and the public may present written comments to the council. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations should contact the BLM as provided above.

Authority: 43 CFR 1784.4–2.

Diane M. Friez,

Eastern Montana/Dakotas District Manager.

[FR Doc. 2015–12452 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–18025; PPWOCRADN0–PCU00RP15.R50000]

Notice of Inventory Completion: The American Museum of Natural History, New York, NY; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The American Museum of Natural History has revised a Notice of Inventory Completion that was published in the **Federal Register** on February 4, 2015. This notice revises the listing of Indian tribes who are recognized as aboriginal to the area from which Native American human remains were removed.

ADDRESSES: Nell Murphy, Director of Cultural Resources, American Museum of Natural History, Central Park West at 79th Street, New York, NY 10024, telephone (212) 769–5837, email *nmurphy@amnh.org*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the revision of a Notice of Inventory Completion for human remains under the control of the American Museum of Natural History, New York, NY. The human remains were removed from the Grand Hotel vicinity, Mackinac Island, Mackinac County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice revises the listing of Indian tribes who are recognized as aboriginal to the area from which Native American human remains were removed. These remains were described in a Notice of Inventory Completion published in the **Federal Register** (80 FR 6120–6121, February 4, 2015).

In the **Federal Register** (80 FR 6121, February 4, 2015), paragraph 13, sentence 1 has been revised by substituting the following sentence:

According to final judgments of the Indian Claims Commission or the Court of Federal Claims, or indicated by Treaties, Acts of Congress, or Executive Orders, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.

In the **Federal Register** (80 FR 6120–6121, February 4, 2015), paragraph 14 is revised by deleting the entire paragraph.

The American Museum of Natural History is responsible for notifying The Tribes that this notice has been published.

Dated: April 22, 2015.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2015–12532 Filed 5–21–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–18132; PPWOCRADN0–PCU00RP15.R50000]

Notice of Inventory Completion: Indiana Department of Natural Resources, Division of Historic Preservation and Archeology, Indianapolis, IN; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Indiana Department of Natural Resources, Division of Historic Preservation and Archeology has corrected an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the **Federal Register** on August 30, 2013. This notice corrects the number of associated funerary objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request to the Indiana Department of Natural Resources, Division of Historic Preservation and Archeology. If no additional requestors come forward, transfer of control of the associated funerary objects to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these associated funerary objects should submit a written request with information in support of the request to the Indiana Department of Natural Resources, Division of Historic Preservation and Archeology at the address in this notice by June 22, 2015.

ADDRESSES: Dr. Christopher W. Schmidt, University of Indianapolis, 1400 E. Hanna Avenue, Indianapolis, IN 46227, telephone (317) 788–2103.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains and associated funerary objects under the control of the Indiana Department of Natural Resources, Division of Historic Preservation and Archeology, Indianapolis, IN. The human remains and associated funerary objects were removed from Meyer Site, Spencer County, IN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the number of associated funerary objects published in a Notice of Inventory Completion in the **Federal Register** (78 FR 53781, August 30, 2013). This correction comes after consultation with representatives from the Eastern Shawnee Tribe of Oklahoma; Miami Tribe of Oklahoma; and the Pokagon Band of the Potawatomi Indians, Michigan and Indiana. It was determined that all features from the Meyer site would be added to the inventory. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (78 FR 53781, August 30, 2013), paragraph 7, sentence 4 is corrected by substituting the following sentence:

The total number of associated funerary objects is 7,570.

In the **Federal Register** (78 FR 53781, August 30, 2013), paragraph 11, sentence 1 is corrected by substituting the following sentence:

Pursuant to 25 U.S.C. 3001(3)(A), the 7,570 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Christopher W. Schmidt, University of Indianapolis, 1400 E. Hanna Avenue, Indianapolis, IN 46227, telephone (317) 788–2103, by June 22, 2015. After that date, if no additional requestors have come forward, transfer of control of the associated funerary objects to Eastern Shawnee Tribe of Oklahoma; Miami Tribe of Oklahoma; and the Pokagon Band of the Potawatomi Indians, Michigan and Indiana may proceed.

The Indiana Department of Natural Resources, Division of Historic Preservation and Archeology is responsible for notifying the Eastern Shawnee Tribe of Oklahoma; Miami Tribe of Oklahoma; and the Pokagon Band of the Potawatomi Indians, Michigan and Indiana that this notice has been published.

Dated: April 14, 2014.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2015–12522 Filed 5–21–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–18165; PPWOCRADN0–PCU00RP15.R50000]

Notice of Intent to Repatriate Cultural Items: U.S. Department of Agriculture, Forest Service, Hiawatha National Forest, Gladstone, MI

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture (USDA), Forest Service, Hiawatha National Forest, in consultation with the appropriate Indian tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Hiawatha National Forest. If no additional claimants come forward,

transfer of control of the cultural items to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Hiawatha National Forest at the address in this notice by June 22, 2015.

ADDRESSES: Eric Drake, Heritage Program Manager, Hiawatha National Forest, 820 Rains Drive, Gladstone, MI 49837, telephone (906) 428–5817, email *ericdrake@fs.fed.us*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Hiawatha National Forest and in the possession of the Field Museum of Natural History, Chicago, IL, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item(s)

At an unknown date prior to 1943, 116 cultural items were removed from gravesites associated with the Ojibwa/Chippewa and Odawa/Ottawa Village and Cemetery/Ossuary site (20MK3), located on Round Island in Mackinac County, MI. Mr. Harvey E. Bouwknegt (1888–1967) of Grandville, MI, donated the Bouwknegt (Bowknegtt, or Brouwknect) Collection to the Chicago Natural History Museum (later renamed the Field Museum of Natural History), where the cultural items were accessioned in 1943.

Round Island is located within Royce Area 205, which was ceded to the U.S. Government by the Ottawa and Chippewa Tribes of Michigan in the 1836 Treaty of Washington. Under Article 3 of this treaty, Round Island is defined as ''a place of encampment for the Indians, to be under the charge of the Indian department.'' In 1873, the U.S. Government set aside 8.24 acres of land on Round Island for the construction of a lighthouse, and in 1875, deeded the remainder of the island, including the location of site 20MK3, to the State of Michigan for the creation of a state park. A state park was never created, however, and so the ownership of the island reverted to the Federal government in 1935, and Round Island was established as National Forest Land in 1938.

The 116 objects in the Bouwknegt Collection, therefore, were more than likely removed from site 20MK3 during the period when the island was owned by the State of Michigan (1875–1935). The Michigan State Historic Preservation office, however, has formally deferred its responsibilities as the lead agency to the Hiawatha National Forest for this repatriation case.

The 116 unassociated funerary objects consist of 10 buckles, 39 links, 2 silver gorgets, 7 silver armbands, 4 silver bracelets, 1 silver Maltese cross, 1 silver Latin cross, 1 silver Florentine cross, 21 silver brooches, 1 silver hair tube, 2 silver beaver effigies, 1 silver breast ornament, 5 silver breast ornament pieces, 1 silver ornament, 15 silver earrings, and 5 beads. The Field Museum catalog numbers for these items are 47832–47838, 47840–47843, 47845–47870, 47872, 47873, and 47875. Sixteen of the silver trade items have maker's marks stamped on them that roughly date between1760 and 1810. These objects and the other items in the Bouwknegt Collection are comparable to silver trade items recovered from contemporary Ojibwa and Odawa village sites and cemeteries located throughout Michigan and the Upper Great Lakes.

Twenty-one tribes (see list below) were consulted through a combination of formal letters, emails, and phone conversations to determine the disposition of these cultural items. Seven formally expressed their support for repatriating the Bouwknegt Collection to the Sault Ste. Marie Tribe of Chippewa Indians who submitted the formal claim to repatriate this collection. The remaining fourteen tribes did not formally respond to our invitation to comment. None, however, expressed concern or disapproval.

Determinations Made by the Hiawatha National Forest

Officials of the Hiawatha National Forest have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the 116 unassociated funerary objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Sault Ste. Marie Tribe of Chippewa Indians.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Eric Drake, Heritage Program Manager, Hiawatha National Forest, 820 Rains Drive, Gladstone, MI 49837, telephone (906) 428–5817, email *ericdrake@fs.fed.us,* by June 22, 2015. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects to the Sault Ste. Marie Tribe of Chippewa Indians may proceed.

The Hiawatha National Forest is responsible for notifying the Bad River Band of Lake Superior Chippewa Indians of the Bad River Reservation, Wisconsin; Bay Mills Indian Community, Michigan; Fond du Lac Band of the Minnesota Chippewa Tribe, Minnesota; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Mille Lacs Band of the Minnesota Chippewa Tribe, Minnesota; Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.); Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; St. Croix Chippewa Indians of Wisconsin; and the non-federally recognized Indian groups, Burt Lake Band of Ottawa and Chippewa Indians and Grand River Band of Ottawa Indians, that this notice has been published.

Dated: April 16, 2015.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2015–12533 Filed 5–21–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–18039; PPWOCRADN0–PCU00RP15.R50000]

Notice of Inventory Completion: Grand Valley State University, Allendale, MI; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: Grand Valley State University has corrected an inventory of human remains published in a Notice of Inventory Completion in the **Federal Register** on February 2, 2015. This notice corrects the minimum number of individuals listed in that notice. Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to Grand Valley State University. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Grand Valley State University at the address in this notice by June 22, 2015.

ADDRESSES: Janet G. Brashler, Professor and Curator of Anthropology, Grand Valley State University, 1 Campus Drive, Allendale, MI 49401, telephone (616) 331–3694, email *brashlej@gvsu.edu*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains under the control of Grand Valley State University, Allendale, MI. The human remains were removed from near Muir, Ionia County, MI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

This notice corrects the minimum number of individuals published in a Notice of Inventory Completion in the **Federal Register** (80 FR 6014, February 4, 2015). Re-inventory of a collection donated to Grand Valley State University by an avocational archeologist in 2001 revealed the presence of several cranial elements from a minimum number of one individual. No other human remains were identified in the collection. Transfer of control of the items in this correction notice has not occurred.

Correction

In the **Federal Register** (80 FR 6018, February 4, 2015), paragraph 3 is corrected by inserting the following paragraph:

> On an unknown date between 1950 and 1990, human remains representing, at minimum, one individual were removed from an archeological site in the vicinity of Muir Michigan in Ionia County by avocational archeologist Buerl Guernsey. Guernsey subsequently donated his collection in 2001 to the Grand Valley State University Department of Anthropology Laboratory. The remains are those of an adult of undetermined sex and were recovered during surface collection from one of a series of sites in the vicinity. The date and time period for the remains is unknown because sites from the Woodland to Late Prehistoric (600 B.C.–A.D. 1640) are present in the area. No known individuals were identified. No associated funerary objects are present.

In the **Federal Register** (80 FR 6018, February 4, 2015), paragraph 4 is corrected by substituting the following paragraph:

> Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 112 individuals of Native American ancestry.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Janet G. Brashler, Professor and Curator of Anthropology, Grand Valley State University, 1 Campus Drive, Allendale, MI 49401, telephone (616) 331–3694, email *brashlej@gvsu.edu,* by June 22, 2015. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Absentee-Shawnee Tribe of Indians of Oklahoma; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin; Bay Mills Indian Community, Michigan; Bois Forte Band (Nett Lake) of the Minnesota Chippewa Tribe, Minnesota; Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana; Citizen Potawatomi Nation, Oklahoma; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Eastern Shawnee Tribe of Oklahoma; Fond du Lac Band of the Minnesota Chippewa Tribe, Minnesota; Forest County Potawatomi Community, Wisconsin; Grand Portage Band of the Minnesota Chippewa Tribe, Minnesota; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Hannahville Indian Community, Michigan; Keweenaw Bay Indian Community, Michigan; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Leech Lake Band of the Minnesota Chippewa Tribe, Minnesota; Little River Band of Ottawa Indians, Michigan; Little Traverse Bay Bands of Odawa Indians, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Miami Tribe of Oklahoma; Mille Lacs Band of the Minnesota Chippewa Tribe, Minnesota; Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as the Huron Potawatomi, Inc.); Ottawa Tribe of Oklahoma; Peoria Tribe of Indians of Oklahoma; Prairie Band Potawatomi Nation (previously listed as the Prairie Band of Potawatomi Nation, Kansas); Pokagon Band of Potawatomi Indians, Michigan and Indiana; Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Tribe of Oklahoma; Shawnee Tribe; Sokaogon Chippewa Community, Wisconsin; St. Croix Chippewa Indians of Wisconsin; Tonawanda Band of Seneca (previously

listed as the Tonawanda Band of Seneca Indians of New York); Turtle Mountain Band of Chippewa Indians of North Dakota; White Earth Band of the Minnesota Chippewa Tribe, Minnesota; and the Wyandotte Nation may proceed. Hereafter, all tribes listed in this section are referred to as ''The Tribes.''

Grand Valley State University is responsible for notifying The Tribes that this notice has been published.

Dated: April 16, 2015.

Mariah Soriano,

Acting Manager, National NAGPRA Program.

[FR Doc. 2015–12529 Filed 5–21–15; 8:45 am]

BILLING CODE 4312–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2015–0005; OMB Control Number 1014–0024; 15XE1700DX EEEE500000 EX1SF0000.DAQ000]

Information Collection Activities: Plans and Information; Proposed Collection; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns a renewal to the paperwork requirements in the regulations under Subpart B, Plans and Information.

DATES: You must submit comments by July 21, 2015.

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

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2015–0005 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *cheryl.blundon@bsee.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Cheryl Blundon; 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1014–0024 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR part 250, subpart B, *Plans and Information.*

OMB Control Number: 1014–0024.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1334), authorizes the Secretary of the Interior to prescribe rules and regulations necessary for the administration of the leasing provisions of that act related to mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-use and easement, or unit. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and OMB Circular A–25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's implementing policy, the Bureau of Safety and Environmental Enforcement (BSEE) is required to charge fees for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those which accrue to the public at large. Deepwater Operations Plans are subject to cost recovery, and BSEE regulations specify a service fee for this request.

Regulations implementing these responsibilities are among those delegated to BSEE. The regulations under 30 CFR 250, Subpart B, pertain to plans and information that are either submitted to BSEE and/or reviewed by BSEE.

We use the information under § 250.282, we analyze the information to verify that an ongoing/completed OCS operation is/was conducted in compliance with established environmental standards placed on the activity. Under §§ 250.286–295 we analyze and evaluate the information to ensure that planned operations are safe; will not adversely affect the marine, coastal, or human environment; and will conserve the resources of the OCS. We use the information to make an informed decision on whether to approve the proposed deepwater operations plans (DWOPs), or whether modifications are necessary without the analysis and evaluation of the required information.

No questions of a sensitive nature are asked. We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR 2); 30 CFR 250.197, *Data and information to be made available to the public or for limited inspectio*n; and 30 CFR part 252, *OCS Oil and Gas Information Program.* Responses are mandatory or are required to obtain or retain a benefit.

Frequency: On occasion.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 18,256 hours. In this submission, we are requesting a total of 37,084 burden hours and $39,589 non-hour cost burdens. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 250 Subpart B and NTLs	Reporting and recordkeeping requirement *	Non-hour cost burdens *		
		Hour burden	Average number of annual responses annual	Burden hours
201; 204; 205	General requirements for plans and information; service fees; confirmations; etc.	Burden included with specific requirements below.		0
Post-Approval Requirements for the EP, DPP, and DOCD [for BSEE apps/permits which include drilling, workovers, production, pipelay, facility installation, and decommissioning, etc.]				
282 282(b)	Retain monitoring data/information; upon request, make available to BSEE. Submit monitoring plan for approval. Submit monitoring reports and data.	All information that is submitted from industry is received by BOEM. Industry's hour burdens for these regulatory requirements are covered under 30 CFR 550, subpart B, 1010–0151. BSEE's Environmental Compliance Program reviews all monitoring plans and reports to verify industry's compliance.		
Submit DWOPs and Conceptual Plans				
287; 291; 292	Submit DWOP and accompanying/supporting information	1,140	11 plans	12,540
		$3,599 × 11 = $39,589		
288; 289	Submit a Conceptual Plan for approval	375	8 plans	3,000
294	Submit a combined Conceptual Plan/DWOP for approval before deadline for submitting Conceptual Plan.	748	27 plans	20,196
295	Submit a revised Conceptual Plan or DWOP for approval within 60-day of material change.	180	7 plan revisions	1,260
Subtotal			53 responses	36,96
			$39,589 non-hour costs.	
200 thru 295	General departure and alternative compliance requests not specifically covered elsewhere in subpart B regulations.	8	11 requests	88
Subtotal			11 responses	88
Total Burden			399 responses	37,084
			$39,589 Non-hour cost burdens.	

* In the future, BSEE may require electronic filing of some submissions.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified one non-hour cost associated with this ICR; DWOP's ($3,599) under § 250.292, and estimate that the total annual non-hour cost burden is $39,589. We have not identified any other non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .''. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email 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.

Dated: May 14, 2015.

Douglas W. Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–12300 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2015–0006; OMB Control Number 1014–0023; 15XE1700DX EEEE500000 EX1SF0000.DAQ000]

Information Collection Activities: Pollution Prevention and Control; Proposed Collection; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns a renewal to the paperwork requirements in the regulations under Subpart C, *Pollution Prevention and Control.*

DATES: You must submit comments by July 21, 2015.

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

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2015–0006 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *cheryl.blundon@bsee.gov.*

Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Cheryl Blundon; 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1014–0023 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart C, *Pollution Prevention and Control.*

OMB Control Number: 1014–0023.

Abstract: The Outer Continental Shelf (OCS) Lands Act, 43 U.S.C. 1334, authorizes the Secretary of the Interior to prescribe rules and regulations necessary for the administration of the leasing provisions of that Act related to mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-way, or a right-of-use and easement.

Section 1332(6) states that ''operations in the [O]uter Continental Shelf should be conducted in a safe manner by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health.'' Section 1843(b) calls for ''regulations requiring all materials, equipment, tools, containers, and all other items used on the Outer Continental Shelf to be properly color coded, stamped, or labeled, wherever practicable, with the owner's identification prior to actual use.''

In addition to the general rulemaking authority of the OCSLA at 43 U.S.C. 1334, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 108 of FOGRMA, 30 U.S.C. 1718, grants the Secretary broad authority to inspect lease sites for the purpose of determining whether there is compliance with the mineral leasing laws. Section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. Because the Secretary has delegated some of the authority under FOGRMA to BSEE, 30 U.S.C. 1751 is included as additional authority for these requirements.

Regulations implementing these responsibilities are among those delegated to BSEE. The regulations under 30 CFR 250, Subpart C, pertain to pollution prevention and control on the OCS and any related Notices to Lessees (NTLs) and Operators. BSEE has issued several NTLs to clarify and provide additional guidance on some aspects of the current Subpart C regulations.

We use the information collected under subpart C to ensure that:

- The lessee or operator records the location of items lost overboard to aid in recovery during site clearance activities on the lease;
- operations are conducted according to all applicable regulations, requirements, and in a safe and workmanlike manner;
- discharge or disposal of drill cuttings, sand, and other well solids, including those containing naturally occurring radioactive materials (NORM), are properly handled for the protection of OCS workers and the environment; and
- facilities are inspected daily for the prevention of pollution, and problems observed are corrected.

No questions of a sensitive nature are asked. We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR 2); and 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection*. Responses are mandatory or are required to obtain or retain a benefit.

Frequency: On occasion, annually, and as a result of situations encountered depending upon the requirement.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 124,665 hours. In this submission, we are requesting a total of 137,955 burden hours. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

BURDEN TABLE

Citation 30 CFR 250 Subpart C and related NTL(s)	Reporting and recordkeeping requirement*	Hour burden	Average number of annual responses	Annual burden hours
Pollution Prevention				
300(b)(1), (2)	Obtain approval to add petroleum-based substance to drilling mud system or approval for method of disposal of drill cuttings, sand, & other well solids, including those containing NORM.	Burden covered under APDs or APMs 1014–0025 or 1014–0026.		0
300(c)	Mark items that could snag or damage fishing devices	1 hour	133 markings	133
300(d)	Report and record items lost overboard	1 hour ea × 2 = 2 hours	116 reports/records ...	232
Subtotal	.....	.....	249 responses	365
Marine Trash and Debris Awareness/Elimination NTL				
300(a), (b)(6), (c), (d); NTL.	Submit request for training video	1 hour	106 requests	106
.....	Submit annual report to BSEE on training process and certification.	1.5 hours	212 records	318
.....	Training recordkeeping; make available upon request	3 hours	212 records	636
	Post placards on vessels and structures (exempt from information collection burden because BSEE is providing exact language for the trash and debris warning, similar to the "Surgeon General's Warning" exemption).			0
Subtotal	.....	.....	530 responses	1,060
Inspection of Facilities				
301; NTL	Inspect drilling/production facilities for pollution; maintain inspection/repair records 2 years.	22 min ea inspection × 365 days p/yr/60 mins p/hr = 134 hours.	898 manned facilities	120,332
		5 mins every 3rd day (365 days p/yr/3 = 121.6 days × 5 mins p/day/60 mins p/hr) = 10.14 hours.	1,596 unmanned facilities.	16,183
Subtotal			2,494 responses	136,515
300–301	General departure and alternative compliance requests not specifically covered elsewhere in subpart C regulations.	2.5 hours	6 requests	15
Subtotal	.....	.....	6 responses	15
Total Burden.	.....	.....	3,279 response	137,955

*In the future, BSEE may require electronic filing of some submissions.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified no non-hour cost burdens for this collection.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ". . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. . .". Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make

any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email 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.

Dated: May 14, 2015.

Douglas W. Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–12302 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement (BSEE)

[Docket ID BSEE–2015–0008; OMB Control Number 1014–0005; 15XE1700DX EEEE500000 EX1SF0000.DAQ000]

Information Collection Activities: Relief or Reduction in Royalty Rates; Proposed Collection; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns a renewal to the paperwork requirements in the regulations under *Relief or Reduction in Royalty Rates.*

DATES: You must submit comments by July 21, 2015.

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

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2015–0008 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *cheryl.blundon@bsee.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Cheryl Blundon; 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1014–0005 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR part 203, *Relief or Reduction in Royalty Rates.*

OMB Control Number: 1014–0005.

Abstract: The Outer Continental Shelf (OCS) Lands Act, 43 U.S.C. 1337, as amended by the OCS Deep Water Royalty Relief Act (DWRRA), Public Law 104–58 and the Energy Policy Act of 2005, Public Law 109–058, gives the Secretary of the Interior (Secretary) the authority to reduce or eliminate royalty or any net profit share specified in OCS oil and gas leases to promote increased production. The DWRRA also authorized the Secretary to suspend royalties when necessary to promote development or recovery of marginal resources on producing or non-producing leases in the Gulf of Mexico (GOM) west of 87 degrees, 30 minutes West longitude.

Section 302 of the DWRRA provides that new production from a lease in existence on November 28, 1995, in a water depth of at least 200 meters, and in the GOM west of 87 degrees, 30 minutes West longitude qualifies for royalty suspension in certain situations. To grant a royalty suspension, the Secretary must determine that the new production or development would not be economic in the absence of royalty relief. The Secretary must then determine the volume of production on which no royalty would be due in order to make the new production from the lease economically viable. This determination is done on a case-by-case basis. Production from leases in the same water depth and area issued after November 28, 2000, also can qualify for royalty suspension in addition to any that may be included in their lease terms.

In addition, Federal policy and statute require us to recover the cost of services that confer special benefits to identifiable non-Federal recipients. The Independent Offices Appropriation Act (31 U.S.C. 9701), Office of Management and Budget (OMB) Circular A–25, and the Omnibus Appropriations Bill (Pub. L. 104–134, 110 Stat. 1321, April 26, 1996) authorize the Bureau of Safety and Environmental Enforcement (BSEE) to collect these fees to reimburse us for the cost to process applications or assessments.

Regulations at 30 CFR part 203 implement these statutes and policy and require respondents to pay a fee to request royalty relief. The OMB approved the information collection burden under this collection 1014–0005. Section 203.3(a) states that, ''We will specify the necessary fees for each of the types of royalty-relief applications and possible BSEE audits in a Notice to Lessees. We will periodically update the fees to reflect changes in costs, as well as provide other information necessary to administer royalty relief.''

This authority and responsibility are among those delegated BSEE. The regulations at 30 CFR part 203, are the subject of this collection. This request also covers the related Notices to Lessees and Operators (NTLs) that BSEE issues to clarify, supplement, or provide additional guidance on some aspects

We use the information to make decisions on the economic viability of leases requesting a suspension or elimination of royalty or net profit share. These decisions have enormous monetary impact on both the lessee and the Federal Government. Royalty relief can lead to increased production of natural gas and oil, creating profits for lessees, and royalty and tax revenues for the Federal Government that they might not otherwise receive. We could not make an informed decision without the collection of information required by 30 CFR part 203.

No questions of a sensitive nature are asked. BSEE will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR 2) and under regulations at 30 CFR 203.61, How do I assess my chances for getting relief? and 30 CFR 250.197, Data and information to be made available to the public or for limited inspection. Responses are mandatory or are required to obtain or retain a benefit.

Frequency: On occasion or as a result of situations encountered depending upon the requirements.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 23,329 hours and $117,441 non-hour cost burdens. In this submission, we are requesting a total of 724 burden hours and $27,950 non-hour cost burdens. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 203 and related NTL(s)	Reporting or recordkeeping requirement +	Application/audit fees (rounded)		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
2; 3; 4; 70	These sections contain general references to submitting reports, applications, requests, copies, demonstrating qualifications, for BSEE approval—burdens covered under specific requirements.			0
Royalty Relief for Ultra-Deep Gas Wells and Deep Gas Wells on Shallow Water Leases				
31(c)	Request a refund of or recoup royalties from qualified ultra-deep wells.	1	1 request	1
35(a); 44(a); 47	Notify BSEE of intent to begin drilling and depth of target.	1	2 notifications	2
35(c), (d); 44(b), (d), (e).	Notify BSEE that production has begun, request confirmation of the size of RSV—provide any/all supporting documentation.	2	2 notifications	4
35(d); 44(e)	Request to extend the deadline for beginning production with required supporting documentation.	4	1 request	4
41(d)	Request a refund of or recoup royalties from qualified wells >200 meters but <400 meters.	1	1 request	1
35(a); 44(a); 47(a)	Notify BSEE of intent to begin drilling	1	2 notifications	2
35(c), (d); 44(b), (d), (e).	Notify BSEE that production has begun, request confirmation of the size of RSV, provide any/all supporting documentation (*i.e.,* request to extend deadline, credible activity schedule, etc).	2	2 notifications	4
46	Provide data from well to confirm and attest well drilled was an unsuccessful certified well with supporting documentation and request supplement (RSS).	8	1 response	8
49(b)	Notify BSEE or decision to exercise option to replace one set of deep gas royalty suspension terms for another set of such terms.	BSEE SOL requires that this reg text stay for legacy purposes only. Last time any respondent could use was 2004; hence, no burden.		
Subtotal			8 responses	20
End of Life and Special Royalty Relief *				
51; 83; 84; NTL	Application—leases that generate earnings that cannot sustain continued production (end-of-life lease); required supporting documentation; include payment confirmation receipt.	100	1 application every 10 years.	10
		application 1/10 × $8,000 = $800 * audit 1/10 × $12,500 = $1,250.		
52	Demonstrate ability to qualify/requalify for royalty relief or to re-qualify.	1	1 response	1
55	Renounce relief arrangement (end-of-life) (seldom, if ever will be used; minimal burden to prepare letter).	1	1 letter every 10 years.	1
80; NTL	Application—apart from formal programs for royalty relief for marginal producing lease (Special Case Relief); required supporting documentation; include payment confirmation receipt.	250	1 application every 10 years.	25
		application 1/10 × $8,000 ** = $ 800. audit 1/10 × $12,500 = $1,250.		
80; NTL	Application—apart from formal programs for royalty relief for marginal expansion project or marginal non-producing lease (Special Case Relief); required supporting documentation; include payment confirmation receipt.	1,000	1 application every 10 years.	100
		application 1/10 × $19,500 ** = $ 1,950. audit 1/10 × $18,750 = $1,875.		
Subtotal			2 responses (rounded).	137
			$7,925 fees	

Citation 30 CFR 203 and related NTL(s)	Reporting or recordkeeping requirement +	Application/audit fees (rounded)		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
CPA Report				
81; 83–90; 63	Required reports; extension justification	Burden included with applications.		0
		1 CPA report × $45,000/10 each report = $4,500.		
Subtotal			1 response	$4,500
Deep Water Royalty Relief Act (DWRAA)				
61; 62; 64; 65; 71; 83; 85–89;. NTL	Application—preview assessment (seldom if ever will be used as applicants generally opt for binding determination by BSEE instead) and required supporting documentation; include payment confirmation receipt.	900	1 application every 10 years.	90
		application 1/10 × $28,500 = $2,850.		
62; 64; 65; 71; 83; 85–89; NTL.	Application—leases in designated areas of GOM deep water acquired in lease sale before 11/28/95 or after 11/28/00 and are producing (deep water expansion project); required supporting documentation; include payment confirmation receipt.	2,000	1 application every 10 years.	200
		application 1/10 x $19,500 = $1,950.		
62; 64; 65; 203.71; 81; 83; 85–89; NTL.	Application—leases in designated areas of deep water GOM, acquired in lease sale before 11/28/95 or after 11/28/00 that have not produced (pre-act or post-2000 deep water leases); required supporting documentation; include payment confirmation receipt.	2,000	1 application every 10 years.	200
		application 1/10 × $34,000 = $3,400 * audit 1/10 × $37,500 = $3,750.		
69; NTL	Application—short form to add or assign pre-Act lease and required supporting documentation; include payment confirmation receipt.	40	1 application every 10 years.	4
		application 1/10 × $1,000 = $100.		
70; 81; 90; 76(c), (e); NTL.	Submit post-production development report; extension justification. # Reserve right to audit (1 audit every 6 years) after production starts to confirm cost estimates of the application; include payment confirmation receipt.	50	1 report * every 10 years.	5
		#1 audit 1/10 x $18,750 = $1,875.		
74; 75; 76(d); NTL	Redetermination and required supporting documentation; include payment confirmation receipt.	500	1 redetermination every 10 years.	50
		application 1/10 × $16,000 = $1,600 *		
77	Renounce relief arrangement (deep water) (seldom, if ever will be used; minimal burden to prepare letter).	1	1 letter every 10 years.	1
79	Request reconsideration of BSEE field designation	This was a regulatory requirement for leases issued prior to 1995.		0
79(c); 76(b)	Request extension of deadline to start construction	2	1 request every 10 years.	1
81; 83–90	Required reports; extension justification	Burden included with applications.		0
Subtotal			3 responses	551
			$15,525 fees	

Citation 30 CFR 203 and related NTL(s)	Reporting or recordkeeping requirement +	Application/audit fees (rounded)		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
Recordkeeping				
81(d)	Retain supporting cost records for post-production development/fabrication reports (records retained as usual/customary business practice; minimal burden to make available at BSEE request).	8	2 recordkeepers	16
Subtotal			2 recordkeepers	16
Total Annual Burden.			16 Responses	724
			$27,950 Fees	

+ In the future, BSEE may require electronic filing of some submissions.
* CPA certification expense burden also imposed on applicant.
** These applications currently do not have a set fee since they are done on a case-by-case basis.
Note: Applications include numerous items such as: transmittal letters, letters of request, modifications to applications, reapplications, etc.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified several non-hour cost burdens for this collection. Under § 203.3, we charge lessees (respondents) applying for royalty relief an amount that covers the cost of processing their applications and auditing financial data when necessary to determine the proposed development's economic situation. As discussed in section A.1, these fees may be revised as necessary to recover our costs in processing royalty relief applications.

This submission includes these audits and their associated fees. Since there have been no applications approved in the last 14 years under our formal programs for deepwater royalty relief or end of life, so their estimated number of submittals is one every 10 years; but we include the audit and their respective fees due to the potential situation arising.

We estimate this cost burden to be approximately $23,450 annually. Refer to the chart in Section A.12 of this supporting statement for a breakdown.

Under § 203.81, a report prepared by an independent certified public accountant (CPA) must accompany the application and post-production report (expansion project, short form, and preview assessment applications are excluded). The OCS Lands Act applications will require this report only once; the DWRRA applications will require this report at two stages—with the application and post-production development report for successful applicants. We estimate an average cost for a report is $45,000 and that one CPA certification, during the information collection extension period, will be necessary if the applications are approved. This annual cost burden is $45,000/10 years = $4,500.

Therefore, the total of the two burdens under Section A.13 (a) and (b) is estimated at $27,950. We have not identified any other non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .''. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email 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.

Dated: May 14, 2015.

Douglas W. Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–12304 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2015–0007; OMB Control Number 1014–0013; 15XE1700DX EEEE500000 EX1SF0000.DAQ000]

Information Collection Activities: Global Positioning Systems (GPS) for Mobile Offshore Drilling Units (MODUs) NTL; Proposed Collection; Comment Request

ACTION: 60-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BSEE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns a renewal to the paperwork burden under the collection, *GPS for MODUs NTL.*

DATES: You must submit comments by July 21, 2015.

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

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2015–0007 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *cheryl.blundon@bsee.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Cheryl Blundon; 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1014–0013 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607 to request additional information about this ICR.

SUPPLEMENTARY INFORMATION:

Title: Global Positioning Systems (GPS) for Mobile Offshore Drilling Units (MODUs) NTL.

OMB Control Number: 1014–0013.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations necessary for the administration of the leasing provisions of that Act related to mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-way, or a right-of-use and easement. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; to preserve and maintain free enterprise competition; and to ensure that the extent of oil and natural gas resources of the OCS is assessed at the earliest practicable time. Section 43 U.S.C. 1332(6) states that ''operations in the outer Continental Shelf should be conducted in a safe manner by well-trained personnel using technology, precautions, and techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstruction to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health.''

To carry out these responsibilities, the Bureau of Safety and Environmental Enforcement (BSEE) issues regulations to ensure that operations in the OCS will meet statutory requirements; provide for safety and protect the environment; and result in diligent exploration, development, and production of OCS leases. In addition, we also issue Notice to Lessees (NTLs) that provide clarification, explanation, and interpretation of our regulations. These NTLs are used to convey purely informational material and to cover situations that might not be adequately addressed in our regulations.

The subject of this information collection (IC) request is an NTL, GPS (Global Positioning System) for MODUs (Mobile Offshore Drilling Units). This NTL requires MODUs to be equipped with multiple tracking/location devices so that during a storm event (hurricane) the respondent, as well as BSEE, will have the capability to monitor their locations. This NTL also provides BSEE GPS data access thereby granting BSEE real-time location information as needed for the Hurricane Response Team (HRT).

The primary regulation for this IC is 30 CFR 250, Subpart A, approved under the OMB Control Number 1014–0013. However, in connection with this subpart, the burden requirements in the NTL are in addition to the currently approved paperwork burdens under those requirements.

After Hurricane Ike, 2008, due to the loss of an ENSCO MODU, the National Oceanic and Atmospheric Administration and US Army Corps of Engineers conducted numerous side-sonar searches for dangerous submerged debris in several places in and around the Gulf of Mexico waters, including off the Louisiana coast, the Houston Ship Channel, and the Galveston areas. These searches continued for numerous days, with multiple government agencies, and covered well over 75 square statute miles. Nothing was found.

On March 6, 2009, the SKS Satilla, a 900-ft Norwegian flagged tank ship carrying approximately 130K MT of crude oil, reported listing 8 degrees and taking on water about 65-miles offshore of Galveston, TX. It was determined that the SKS Satilla had hit the sunken MODU that was submerged approximately 24 feet below the surface of the water, that had been missing since Hurricane Ike. The MODU was displaced off the coast of Louisiana during Hurricane Ike and ended up off the coast of Galveston, roughly 105 miles away.

The information to be collected is necessary for BSEE to assess the whereabouts of any MODU becoming unmoored due to extreme weather situations; as well as, to follow the path of that facility to determine if other facilities/pipelines, etc., were damaged in any way. The offshore oil and gas industry will use the information to determine the safest and quickest way to either remove the obstacles or to fix and reuse them.

No questions of a sensitive nature are asked. We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and DOI's implementing regulations (43 CFR 2); 30 CFR 250.197, *Data and information to be made available to the public or for limited inspectio*n; and 30 CFR part 252, *OCS Oil and Gas Information Program.* Responses are mandatory.

Frequency: On occasion.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 1 hour and $102,500 non-hour cost burden. In this submission, we are requesting the same hour and non-hour cost burdens. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

BURDEN TABLE

NTL—Gulf of Mexico OCS region—GPS for MODUs	Non-hour cost burdens		
	Hour burden	Average number of annual responses	Annual burden hours
1—Notify BSEE with tracking/locator data access and supporting information; notify BSEE Hurricane Response Team as soon as operator is aware a rig has moved off location.	15 mins ..... 15 mins	1 rig* ..... 1 notification*	1 hour (rounded).
2—Purchase and install tracking/locator devices—(these are replacement GPS devices or new rigs).	20 devices per year for replacement and/or new × $325.00 = $6,500		
3—Pay monthly tracking fee for GPS devices already placed on MODUs/rig	40 rigs at $50/month = $600/year = $24,000		
4—Rent GPS devices and pay monthly tracking fee per rig	40 rigs @$1,800 per year = $72,000		
Total burden	.....	102 responses	1 hour.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified three non-hour cost burdens for this collection, which are described and shown in the table. We have not identified any other non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''. . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . .''. Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have other than hour burden costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. For further information on this burden, refer to 5 CFR 1320.3(b)(1) and (2), or contact the Bureau representative listed previously in this notice.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email 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.

Dated: May 14, 2015.

Douglas W. Morris,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–12303 Filed 5–21–15; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–956]

Certain Recombinant Factor VIII Products; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on April 16, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Baxter International Inc. of Deerfield, Illinois; Baxter Healthcare Corporation of Deerfield, Illinois; and Baxter Healthcare SA, of Switzerland. Letters supplementing the complaint were filed on April 21, 2015; May 1, 2015; and May 4, 2015. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of certain claims of U.S. Patent No. 6,100,061 (''the '061 patent''); U.S. Patent No. 6,936,441 (''the '441 patent''); and U.S. Patent No. 8,084,252 (''the '252 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. 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. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on May 15, 2015, **ordered that—**

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of one or more of claims 19–21, 36, 37, and 39 of the '061 patent; claims 20 and 21 of the '441 patent; claims 1, 5, 8, 10, 14, and 18 of the '252 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1)

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Baxter International Inc., One Baxter Parkway, Deerfield, IL 60015–4625.

Baxter Healthcare Corporation, One Baxter Parkway, Deerfield, IL 60015–4625.

Baxter Healthcare SA, Thursgauerstrasse 130, Glattpark (Opfikon),Switzerland.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd, Denmark.

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: May 18, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–12390 Filed 5–21–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0061]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Certification of Compliance

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tracey Robertson, *Tracey.Robertson@atf.gov,* Chief, Federal Firearms Licensing Center, 244 Needy Road, Martinsburg, WV 25405.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection 1140–0061:

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Certification of Compliance.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5330.20.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: The law at 18 U.S.C. 922(g)(5)(B) makes it unlawful for any nonimmigrant alien to ship or transport in interstate commerce, or possess in or affecting commerce, any firearm, ammunition, which has been shipped or transported in interstate or foreign

commerce. ATF F 5330.20 is used for nonimmigrant aliens to certify their compliance according to the law at 18 U.S.C. 922(g)(5)(B). The data provided on this form is used by ATF to certify the applicant's citizenship and legal eligibility for importation and or possession of firearms and ammunition.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 41,824 respondents will take 3 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 2,091 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12441 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0071]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Notification to Fire Safety Authority of Storage of Explosive Materials

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Anita Scheddel, Explosives Industry Programs Branch at *eipb-informationcollection@atf.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection 1140–0071:

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Notification to Fire Safety Authority of Storage of Explosive Materials.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Farms, State, local, or Tribal Governments, and Individuals or household.

Abstract: The information is necessary for the safety of emergency response personnel responding to fires at sites where explosives are stored. The information is provided both orally and in writing to the authority having jurisdiction for fire safety in the locality in which explosives are stored.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,025 respondents will complete the notification within 30 minutes.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 513 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12442 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0080]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Notification of Change of Mailing or Premise Address

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice

ACTION: 60-Day notice.

SUMMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Christopher Reeves, *Christopher.R.Reeves@usdoj.gov,* Chief, Federal Explosives Licensing Center, 244 Needy Road, Martinsburg, WV 25405.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection 1140–0080:

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Notification of Change of Mailing or Premise Address.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Not-for-profit institutions.

Other: Business or other for-profit.

Abstract: Licensees and permittees whose mailing address will change must notify the Chief, Federal Explosives Licensing Center, at least 10 days before the change. The information is used by ATF to identify correct locations of storage of explosives licensees/permittees and location of storage of explosive materials for purposes of inspection, as well as to notify permittee/licensees of any change in regulations or laws that may affect their business activities.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,000 respondents will take 10 minutes to respond via letter to the Federal Explosives Licensing Center.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 170 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray.

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12444 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0079]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Transactions Among Licensees/Permittees and Transactions Among Licensees and Holders of User Permits

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Anita Scheddel, Explosives Industry Programs Branch at *eipb-informationcollection@atf.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection 1140–0079

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Transactions Among Licensees/Permittees and Transactions Among Licensee and Holders of User Permits.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: The Safe Explosives Act requires an explosives distributor must verify the identity of the purchaser; an explosives purchaser must provide a copy of the license/permit to distributor prior to the purchase of explosive materials; possessors of explosive materials must provide a list of explosives storage locations; purchasers of explosive materials must provide a list of representatives authorized to purchase on behalf of the distributee; and an explosive purchaser must provide a statement of intended use for the explosives.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50,000 respondents will take 30 minutes to comply with the information.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 25,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12443 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On May 19, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of Ohio Western Division in the lawsuit entitled *United States* v. *Marathon Petroleum Corporation and Marathon Petroleum Company LP*, Civil Action No. 3:15-cv-00994.

The Consent Decree resolves claims for civil penalties and injunctive relief arising from alleged violations of the CAA, Sections 211(a), (f) and (k), 42 U.S.C. 7545(a), (f) and (k), and the fuel regulations published at 40 CFR parts 79 and 80, for potential violations of the fuel emission standards, volatile organic compound emissions reduction standards, and sulfur emissions reduction standards for certain batches of gasoline produced or blended at Marathon's Texas City and Catlettsburg refineries and its Viney Branch, Louisville-Kramer Lane, Jacksonville, Lexington, Charlotte, and Tampa Terminals. The Consent Decree also addresses alleged sampling, testing, reporting, and recordkeeping violations at various Marathon facilities. In exchange for a resolution of the foregoing allegations, Marathon will pay a civil penalty of $2.9 million, retire 5.5 billion sulfur credits, and install geodesic domes, fixed roofs, or secondary seals and deck fittings on 14 fuel storage tanks at several of its fuel distribution terminals that are primarily located in environmental justice areas. Marathon estimates that these projects will reduce volatile organic compound emissions, including toxics, by 36.8 tons per year. The total value of the proposed settlement is estimated to be about $5.71 million.

The publication of this notice opens a period for public comment on the _____. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Marathon Petroleum Corporation and Marathon Petroleum Company LP*, D.J. Ref. No., 90–5–2–1–11030. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $11.50 (with exhibits) payable to the United States Treasury.

Bob Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–12549 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0101]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Firearms and Explosives Services Division Customer Service Survey

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Thomas DiDomenico, Firearms and Explosives Services Division at *FESDsurvey@atf.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection 1140–0101

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Firearms and Explosives Services Division Customer Service Survey.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: The Firearms & Explosives Services Division (FESD) provides dealer licensing and other services related to the importation and transfers of weapons within the firearms and explosives industry. This anonymous survey allows FESD to gauge customer satisfaction, correct potential deficiencies, and improve overall customer satisfaction.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 18,200

respondents will take 5 minutes to complete the survey.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 1,517 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12445 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0040]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for an Amended Federal Firearms License

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until July 21, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tracey Robertson, *Tracey.Robertson@atf.gov,* Chief, Federal Firearms Licensing Center, 244 Needy Road, Martinsburg, WV 25405.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection 1140–0040

1. *Type of Information Collection:* Extension of an existing collection.

2. *The Title of the Form/Collection:* Application for an Amended Federal Firearms License.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5300.38.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: ATF F 5300.38 is used by existing Federal Firearms Licensees (FFL) to change the business address of the license and certify compliance with the provisions of the law for the new address. Licensees are required to notify ATF of the intent to move any business premises no later than 30 days prior to the intended move. The form is also used for changes of trade or business name, changes of mailing address, changes of contact information, changes of hours of operation/availability, and allows for licensees to indicate any changes of business structure.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 18,000 respondents will take 30 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 9,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: May 19, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–12440 Filed 5–21–15; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employee Retirement Income Security Act Procedure 1976–1: Advisory Opinion Procedure

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''Employee Retirement Income Security Act Procedure 1976–1; Advisory Opinion Procedure,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before June 22, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201504-1210-004* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA,

Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

For Further Information: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Employee Retirement Income Security Act (ERISA) Procedure 1976–1: Advisory Opinion Procedure information collection. The ERISA provides that the EBSA has a responsibility to administer reporting, disclosure, fiduciary, and other standards for pension and welfare benefit plans. *See* 29 U.S.C. 1021–1026, 1028–1030, 1052–1056, 1059–1061, 1085, 1101, 1103, 1104, 1107, 1108, 1111, 1112, 1114, 1132–1136, 1138, 1143, 1144, 1146–1151, 1164, 1166–1182, 1185a, 1185b, 1191c–1204, 1232, 1241, 1301, 1302, 1343, 1365, 1421, and 1451. The procedure for ERISA advisory opinions establishes a public process for requesting guidance from the EBSA on how the ERISA applies to particular circumstances. The procedure sets forth a specific administrative process to request either an advisory opinion or an information letter and describes the types of questions that may be submitted. As part of the procedure, a requester is instructed to provide information to the EBSA concerning the circumstances governing the request. The EBSA relies on the information provided by the requester to analyze the issue presented and provide guidance. ERISA section 108 authorizes this information collection. *See* 29 U.S.C. 1028.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0066.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on June 30, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 15, 2014 (79 FR 61903).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0066. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Employee Retirement Income Security Act Procedure 1976–1: Advisory Opinion Procedure.

OMB Control Number: 1210–0066.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 29.

Total Estimated Number of Responses: 29.

Total Estimated Annual Time Burden: 299 hours.

Total Estimated Annual Other Costs Burden: $731,000.

Dated: May 18, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–12483 Filed 5–21–15; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that 1 meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference from the National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506 as follows (all meetings are Eastern time and ending times are approximate):

Leadership (review of applications): This meeting will be closed.

DATES: June 4, 2015; 10:00 a.m. to 12:00 p.m. (Note: this meeting previously was announced for June 5, 2015 from 2:00 to 4:00 p.m.)

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; *plowitzk@arts.gov,* or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: May 18, 2015.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2015–12374 Filed 5–21–15; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL FOUNDATION FOR THE ARTS AND HUMANITIES

Submission for OMB Review, Comment Request, Proposed Collection: General Clearance for Guidelines, Applications, and Reporting Forms

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and Humanities.

ACTION: Submission for OMB Review, comment request.

SUMMARY: The Institute of Museum and Library Services announces the following information collection has been submitted to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). 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.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Comments must be submitted to the office listed in the Contact section below on or before June 22, 2015.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

ADDRESSES: Kim A. Miller, Management Analyst, Institute of Museum and Library Services, 1800 M Street NW., 9th Floor, Washington, DC 20036. *Telephone:* 202–653–4762; *Fax:* 202–653–4600; or email: *kmiller@imls.gov;* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION: The Institute of Museum and Library Services is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. The Institute's mission is to inspire libraries and museums to advance innovation, learning and civic engagement. We provide leadership through research, policy development, and grant making. IMLS provides a variety of grant programs to assist the Nation's museums and libraries in improving their operations and enhancing their services to the public. (20 U.S.C. 9101 *et seq.*). To administer these programs, IMLS must develop application guidelines and reporting forms.

Current Actions: This notice proposes general clearance of the agency's application guidelines and reporting forms. The 60-day Notice for the ''Notice of Continuance for General Clearance for Guidelines, Applications, and Reporting Forms'' was published in the **Federal Register** on February 6, 2015 (FR vol. 80, No. 25, pgs. 6771–6772). The agency has taken into consideration the one comment that was received under this notice.

Agency: Institute of Museum and Library Services.

Title: IMLS Guidelines, Applications and Reporting Forms.

OMB Number: 3137–0029, 3137–0071.

Agency Number: 3137.

Frequency: Annually, Semi-annually.

Affected Public: State Library Administrative Agencies, museums, libraries, institutions of higher education, library and museum professional associations, and museum and library professionals, Indian tribes (including Alaska native villages, regional corporations, or village corporations), and organizations that primarily serve and represent Native Hawaiians.

Number of Respondents: 8,375.

Estimated Time per Respondent: .08–90 hours.

Total Burden Hours: 61,076.

Total Annualized cost to respondents: $1,689,965.

Total Annualized capital/startup costs: 0.

Total Annualized Cost to Federal Government: $485,241.

Contact: Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395–7316.

Dated: May 19, 2015.

Kim A. Miller,

Management Analyst, Office of Policy, Planning, Research, and Evaluation.

[FR Doc. 2015–12451 Filed 5–21–15; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Behavioral and Cognitive Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

Name: Proposal Review Panel for SBE/Behavioral and Cognitive Sciences—The Science of Learning Center (#10747) Visual Language and Visual Learning (VL2), Gallaudet University Site Visit (V151599).

Dates & Times:

June 10, 2015; 6:00 p.m.–10:00 p.m.
June 11, 2015; 7:30 a.m.–8:30 p.m.
June 12, 2015; 7:30 a.m.–4:00 p.m.

Place: Gallaudet University, Washington, DC 20002.

Type of Meeting: Part Open.

Contact Person: Dr. Soo-Siang Lim, Program Director, Science of Learning Centers Program, Division of Behavioral and Cognitive Science, Room 995, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, Telephone (703) 292–7878.

Purpose of Meeting: To provide advice and recommendations concerning further support of the SLC program VL2 at the Gallaudet University.

Agenda:

Wednesday, June 10, 2015
- 6:00 p.m.–10:00 p.m.—Closed—Briefing of panel

Thursday, June 11, 2015
- 7:15 a.m.–3:50 p.m.—Open—Review of the MRSEC
- 3:50 p.m.–5:30 p.m.—Open—Break
- 5:30 p.m.–6:00 p.m.—Closed—Executive Session
- 6:45 p.m.–8:30 p.m.—Open—Dinner

Friday, June 12, 2015
- 7:30 a.m.–10:00 a.m.—Closed—Executive Session
- 10:00 a.m.–4:00 p.m.—Closed—Executive Session, Draft and Review Report

Reason for Closing: The work being reviewed during the site visit will include information of a proprietary or confidential nature, including technical information; financial data, such as salaries and personal information concerning individuals associated with the VL2. These matters are exempt under 5 U.S.C. 552 b(c), (4) and (6) of the Government in the Sunshine Act.

Date: May 19, 2015.

Suzanne Plimpton,

Acting, Committee Management Officer.

[FR Doc. 2015–12484 Filed 5–21–15; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 040–09067; NRC–2015–0126]

Uranerz Energy Corporation; Consideration of Approval of Transfer of License

AGENCY: Nuclear Regulatory Commission.

ACTION: Application for indirect transfer of license; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of an application filed by Uranerz Energy Corporation (Uranerz) on March 20, 2015. The application seeks NRC approval of the indirect transfer (change of control) of NRC Materials License SUA–1597 for the Nichols Ranch *In Situ* Recovery (ISR) Project from Uranerz to Energy Fuels Inc. (Energy Fuels).

DATES: Comments must be filed by June 22, 2015. A request for a hearing must be filed by June 11, 2015.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0126. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Hearingdocket@nrc.gov*. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on accessing information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ron C. Linton, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7777; email: *Ron.Linton@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0126 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0126.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The application related to this notice is entitled, ''Nichols Ranch ISR Project SUA–1597 Notice of Change of Control and Ownership Information,'' and is available in ADAMS under Accession No. ML15084A286.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0126 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Introduction

The NRC is considering an application dated March 20, 2015, by Uranerz, requesting consent for an indirect change of control with respect to its NRC Materials License SUA–1597. Under this license, Uranerz operates the Nichols Ranch ISR Project uranium milling facility located in Johnson and Campbell Counties, Wyoming. On January 4, 2015, Uranerz announced that it had executed a definitive agreement with Energy Fuels, a corporation organized under the laws of the province of Ontario, Canada and EFR Nevada Corporation, a corporation organized under the laws of the state of Nevada and an indirect wholly owned subsidiary of Energy Fuels, pursuant to which all issued and outstanding shares of Uranerz common stock would be acquired by Energy Fuels (the ''transaction''). Consummation of the transaction would result in the indirect change of control of license SUA–1597 from Uranerz to Energy Fuels. Uranerz is requesting that the NRC consent to this change of control.

The application states, ''Upon completion of the transaction, there will be no change in the Uranerz mine site key operation and health and safety personnel, licensed activities, or location of operations.'' Additionally, the application states, ''there will be no changes to the personnel having operational responsibility for the Nichols Ranch project or identified in the license having responsibility for radiation safety or authorized to use licensed material.'' After closing of the transaction, and if the indirect change of control is approved by the NRC, Uranerz would continue to be the holder of license SUA–1597. The application asserts that Uranerz would remain technically and financially qualified as the licensee and would continue to fulfill all responsibilities as the licensee. A license amendment will not be necessary because there are no requested changes in the license.

No physical changes to the Nichols Ranch ISR project uranium milling facility or operational changes are being proposed in the application.

Pursuant to section 184 of the Atomic Energy Act of 1954 (AEA), as amended and section 40.46 of Title 10 of the *Code of Federal Regulations* (CFR), no part 40 license shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the AEA, and gives its consent in writing. An Environmental Assessment (EA) will not be performed for this proposed action because it is categorically excluded from the requirement to perform an EA under 10 CFR 51.22(c)(21).

The Commission will approve an application for the indirect transfer of a license, if the Commission determines that the proposed transaction will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission. Upon completion of a safety review, the NRC staff will determine whether to consent to the March 12, 2015, application by issuing the necessary order, along with a supporting safety evaluation report. Uranerz may be required to obtain regulatory approvals by other Federal and State agencies or departments, independent of NRC review and approval.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the **ADDRESSES** section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC's E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309, which is available at the NRC's PDR, located at O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC regulations are accessible electronically from the NRC Library on the NRC's public Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

As required by 10 CFR 2.309, a request for hearing or petition for leave to intervene must set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The hearing request or petition must specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The hearing request or petition must also include the specific contentions that the requestor/petitioner seeks to have litigated at the proceeding.

For each contention, the requestor/petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the requestor/petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings that the NRC must make to support the granting of a license amendment in response to the application. The hearing request or petition must also include a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely at the hearing, together with references to those specific sources and documents. The hearing request or petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute. If the requestor/petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the requestor/petitioner must identify each failure and the supporting reasons for the requestor's/petitioner's belief. Each contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who does not satisfy these requirements for at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Requests for hearing, petitions for leave to intervene, and motions for leave to file contentions after the deadline in 10 CFR 2.309(b) will not be entertained absent a determination by the presiding officer that the new or amended filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1).

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by June 11, 2015. The petition must be filed in accordance with the filing instructions in Section IV of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited

appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by July 21, 2015.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. 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.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

Dated at Rockville, Maryland, this 11th day of May 2015.

For the Nuclear Regulatory Commission.

Andrew Persinko,

Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015–12375 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Metallurgy and Reactor Fuels; Notice of Meeting

The ACRS Subcommittee on Metallurgy and Reactor Fuels will hold a meeting on June 8, 2015, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Monday, June 8, 2015—8:30 a.m. Until 12:00 p.m.

The Subcommittee will discuss Regulatory Information System (RIS) on High Burnup Spent Fuel for dry cask storage and Transportation. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: *Christopher.Brown@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 14, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–12509 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS)

Meeting of the ACRS Subcommittee on Thermal-Hydraulic Phenomena; Notice of Meeting

The ACRS Subcommittee on Thermal-Hydraulic Phenomena will hold a meeting on June 9, 2015, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance, with the exception of portions that may be closed to protect information that is propriety pursuant to 5 U.S.C. 552(c)(4). The agenda for the subject meeting shall be as follows:

Tuesday, June 9, 2015—8:30 a.m. Until 5:00 p.m.

The Subcommittee will review the Westinghouse Full Spectrum Best Estimate Loss-of-Coolant-Accident (LOCA) Methodology licensing topical report, WCAP–16996P. The Subcommittee will hear presentations by and hold discussions with the licensee, the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Zena Abdullahi (Telephone 301–415–8716 or Email: *Zena.Abdullahi@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron

Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 14, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–12505 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on June 9, 2015, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, June 9, 2015—12:00 p.m. Until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: May 14, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–12504 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on June 10–12, 2015, 11545 Rockville Pike, Rockville, Maryland.

Wednesday, June 10, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–8:35 a.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

8:35 a.m.–10:15 a.m.: PSEG Site Early Site Permit (ESP) (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff regarding the safety evaluation associated with PSEG Site ESP.

10:30 a.m.–12:00 p.m.: Documents that Support the Mitigation of Beyond-Design-Basis Rulemaking (Open)—The Committee will hear presentations by and hold discussions with representatives of the staff and Nuclear Energy Institute (NEI) regarding review of draft regulatory guides and associated NEI documents that support the Mitigation of Beyond-Design-Basis Rulemaking.

1:00 p.m.–2:00 p.m.: Update on the Reactor Oversight Process (Open)—The Committee will hear a briefing by Member Skillman regarding the Reactor Oversight Process.

2:00 p.m.–3:00 p.m.: Grand Gulf MELLLA+ License Amendment (Open/Closed)—The Committee will hear presentations by and hold discussions with representatives of the staff and Entergy regarding the safety evaluation associated with the Grand Gulf MELLLA+ License Amendment. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

3:15 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

Thursday, June 11, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–9:45 a.m.: Preparation for Meeting with the Commission (Open)—The Committee will discuss topics in preparation for the meeting with the Commission.

10:00 a.m.–12:00 p.m.: Meeting with the Commission (Open)—The Committee will meet with the Commission to discuss items of mutual interest.

1:00 p.m.–2:30 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. **Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

2:30 p.m.–2:45 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and

recommendations included in recent ACRS reports and letters.

3:00 p.m.–4:00 p.m.: Meeting with the Executive Director for Operations (Open)—The Committee with the Executive Director for Operations to discuss items of mutual interest.

4:00 p.m.–6:00 p.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports on matters discussed during this meeting. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

Friday, June 12, 2015, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

8:30 a.m.–11:30 a.m.: Preparation of ACRS Reports (Open/Closed)—The Committee will continue its discussion of proposed ACRS reports. **Note:** A portion of this meeting may be closed in order to discuss and protect information designated as proprietary, pursuant to 5 U.S.C. 552b(c)(4).

11:30 a.m.–12:00 p.m.: Miscellaneous (Open)—The Committee will continue its discussion related to the conduct of Committee activities and specific issues that were not completed during previous meetings.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Quynh Nguyen, Cognizant ACRS Staff (Telephone: 301–415–5844, Email: *Quynh.Nguyen@nrc.gov*), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS Staff if such rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of the June 10th through 12th meeting dates may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov,* or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/.*

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated at Rockville, Maryland, this 18th day of May, 2015.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2015–12501 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of The ACRS Subcommittee on Regulatory Policies and Practices; Notice of Meeting

The ACRS Subcommittee on Regulatory Policies and Practices will hold a meeting on June 9, 2015, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, June 9, 2015—8:30 a.m. Until 12:00 p.m.

The Subcommittee will discuss PSEG Power, LLC and PSEG Nuclear, LLC (referred to as PSEG) Early Site Permit regarding hydrology. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland. After registering with security, please contact Mr. Theron

Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 14, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–12502 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Reliability and PRA; Notice of Meeting

The ACRS Subcommittee on Reliability and PRA will hold a meeting on June 8, 2015, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Monday, June 8, 2015—1:00 p.m. Until 5:00 p.m.

The Subcommittee will discuss a White Paper for Implementing a Risk Management Regulatory Framework (RMRF). The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mike Snodderly (Telephone 301–415–2241 or Email: *Mike.Snodderly@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 13, 2014 (79 FR 59307–59308).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: May 14, 2015.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2015–12503 Filed 5–21–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2011–49; Order No. 2486]

Amendment to Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an amendment to Priority Mail Contract 33 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 26, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Filings
III. Ordering Paragraphs

I. Introduction

On May 15, 2015, the Postal Service filed notice that it has agreed to an Amendment to the existing Priority Mail Contract 33 negotiated service agreement approved in this docket.[1] In support of its Notice, the Postal Service includes a redacted copy of the Amendment and a certification of compliance with 39 U.S.C. 3633(a), as required by 39 CFR 3015.5.

The Postal Service also filed the unredacted Amendment and supporting financial information under seal. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.*

The Amendment modifies the prices paid by the contract partner. *Id.,* Attachment A at 1.

The Postal Service intends for the Amendment to become effective one business day after the date that the Commission completes its review of the Notice. Notice at 1. The Postal Service asserts that the Amendment will not impair the ability of the contract to comply with 39 U.S.C. 3633. Notice, Attachment B at 1.

II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than May 26, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Cassie D'Souza to represent the interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2011–49 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Cassie D'Souza to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than May 26, 2015.

[1] Notice of United States Postal Service of Change in Prices Pursuant to Amendment to Priority Mail Contract 33, May 15, 2015 (Notice).

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–12382 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–50 and CP2015–72; Order No. 2492]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Parcel Return Service Contract 7 negotiated service agreement to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 26, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Parcel Return Service Contract 7 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–50 and CP2015–72 to consider the Request pertaining to the proposed Parcel Return Service Contract 7 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than May 26, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints James F. Callow to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–50 and CP2015–72 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than May 26, 2015.

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–12581 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Parcel Return Service Contract 7 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 15, 2015 (Request).

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–70; Order No. 2489]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Plus 1C negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 26, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On May 15, 2015, the Postal Service filed notice that it has entered into an additional Global Plus 1C negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–70 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than May 26, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–70 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 1C Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 15, 2015 (Notice).

interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than May 26, 2015.

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–12384 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–51 and CP2015–73; Order No. 2490]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Parcel Return Service Contract 8 negotiated service agreement to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 26, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Parcel Return Service Contract 8 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–51 and CP2015–73 to consider the Request pertaining to the proposed Parcel Return Service Contract 8 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than May 26, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–51 and CP2015–73 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Lyudmila Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than May 26, 2015.

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–12385 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–71; Order No. 2487]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Plus 2C negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 26, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On May 15, 2015, the Postal Service filed notice that it has entered into an additional Global Plus 2C negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–71 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than May 26, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–71 for consideration of the

[1] Request of the United States Postal Service to Add Parcel Return Service Contract 8 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, May 15, 2015 (Request).

[1] Notice of the United States Postal Service of Filing a Functionally Equivalent Global Plus 2C Contract Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, May 15, 2015 (Notice).

matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than May 26, 2015.

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–12383 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Parcel Return Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 15, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Return Service Contract 7 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–50, CP2015–72.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2015–12407 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Parcel Return Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Effective date:* May 22, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 15, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Parcel Return Service Contract 8 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2015–51, CP2015–73.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2015–12406 Filed 5–21–15; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Composite Solutions, Inc., Ruby Creek Resources, Inc., and Voyager Entertainment International Inc.; Order of Suspension of Trading

May 20, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Composite Solutions, Inc. (CIK No. 1061822), a dissolved Florida corporation with its principal place of business listed as La Jolla, California, with stock quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link'') under the ticker symbol CPUT, because it has not filed any periodic reports since the period ended June 30, 2005. On March 27, 2007, Composite Solutions, Inc. received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Ruby Creek Resources, Inc. (CIK No. 1379810), a Nevada corporation with its principal place of business listed as Los Angeles, California, with stock quoted on OTC Link under the ticker symbol RBYC, because it has not filed any periodic reports since the period ended May 31, 2012. On November 26, 2013, Ruby Creek Resources received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Voyager Entertainment International Inc. (CIK No. 1028394), a Nevada corporation with its principal place of business listed as Las Vegas, Nevada, with stock quoted on OTC Link under the ticker symbol VEII, because it has not filed any periodic reports since the period ended September 30, 2011. On October 15, 2013, Voyager Entertainment International received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EDT on May 20, 2015, through 11:59 p.m. EDT on June 3, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–12587 Filed 5–20–15; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74989; File No. SR–MIAX–2015–36]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rule 515A

May 18, 2015.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 13, 2015, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 515A.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 515A, MIAX Price Improvement Mechanism (''PRIME'') and PRIME Solicitation Mechanism, to provide that in instances where an Initiating Member [3] electronically submits an order that it represents as agent (an ''Agency Order'') into a PRIME Auction (''Auction''), which the Initiating Member is willing to automatically match (''auto-match'') as principal, the price and size of responses in the Auction to a Request for Response (''RFR response'') [4] up to an optional designated limit price and, at the price point where the balance of the Agency Order can be fully executed (the ''final auto-match price point'') [5] there is only one competing Member's response opposite the Agency Order, the Initiating Member may be allocated up to fifty percent (50%) of the remainder of the Agency Order. The Exchange also proposes to add language in Rule 515A to more fully describe the manner in which any remaining contracts will be allocated at the conclusion of an Auction, and to make other non-substantive changes to Rule 515A to update terminology in the Rule. This is a competitive filing that is substantially and materially based on the price improvement auction rules of BOX Options Exchange, LLC (''BOX),[6] and the Chicago Board Options Exchange, Inc. (''CBOE'').[7]

Pursuant to Exchange Rules 515A(a)(2)(iii)(H) and (I), upon conclusion of an Auction, an Initiating Member will retain certain priority and trade allocation privileges for an Agency Order that the Initiating Member seeks to cross at a single price (a ''single-price submission'') and for an Agency Order that the Initiating Member is willing to auto-match. Under current Rule 515A(a)(2)(iii)(H), if the best price equals the Initiating Member's single-price submission, the Initiating Member's single-price submission shall be allocated the greater of one contract or a certain percentage of the order, which percentage will be determined by the Exchange and may not be larger than 40%. However, if only one Member's response matches the Initiating Member's single price submission then the Initiating Member may be allocated up to 50% of the order.

Similarly, current Exchange Rule 515A(a)(2)(iii)(I) provides that if the Initiating Member selected the auto-match option of the Auction, the Initiating Member shall be allocated its full size of RFR responses [8] at each price point until the final auto-match price point is reached. At the final auto-match price point, the Initiating Member shall be allocated the greater of one contract or a certain percentage of the remainder of the Agency Order,[9] which percentage will be determined by the Exchange and may not be larger than 40%. Notably, unlike the single-price submission rules in Rule 515A(a)(2)(iii)(H), current Rule 515A(a)(2)(iii)(I) provides that an Initiating Member would only be entitled to receive an allocation of up to 40% for orders that are matched at the final auto-match price point regardless of the number of Member responses that match the Initiating Member's auto-match submission at the final auto-match price point, even when matched by only one competing Member's response. The Exchange believes this result to be inconsistent within the Rules and believes that Initiating Members that price orders more aggressively using the auto-match option should receive allocations at least equal to those that select a single-price submission option for an Auction.

The Exchange proposes to amend Rule 515A(a)(2)(iii)(I) to provide that if only one competing Member's response is present at the final auto-match price point then the Initiating Member may be allocated up to 50% of the remainder of the Agency Order at the final auto-match price point. As discussed above, current Rule 515A(a)(2)(iii)(I) provides that an Initiating Member will receive an allocation of up to 40% for orders that are matched at the final auto-match price point even when matched by only one competing Member's response. The Exchange believes this result to be inconsistent within the Exchange's Rules and believes that Initiating Members that price orders more aggressively using the auto-match option should receive allocations at least equal to those that select a single-price submission option. The Exchange also believes the proposed rule change will more closely align the language in Rule 515A(a)(2)(iii)(I) with the language in Rule 515A(a)(2)(iii)(H), and will thus provide additional internal consistency within the Exchange's Rules by harmonizing order allocations of single-price submissions and auto-match submissions in instances where there is only one competing Member's response at the final Auction price level. Furthermore, the proposed rule change will bring the Exchange's PRIME rules in line with the Rules of other competitor exchanges with which the Exchange competes for order flow.

The Exchange notes that the proposed rule change would not affect the priority

[3] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Act. *See* Exchange Rule 100.

[4] *See* Exchange Rule 515A(a)(2)(i). When the Exchange receives a properly designated Agency Order for auction processing, a Request for Responses (''RFR'') detailing the option, side, size, and initiating price will be sent to all subscribers of the Exchange's data feeds. The RFR will last for 500 milliseconds. Members may submit responses to the RFR (specifying prices and sizes). RFR responses shall be an Auction or Cancel (''AOC'') order or an AOC eQuote. Such responses cannot cross the disseminated MIAX Best Bid or Offer (''MBBO'') on the opposite side of the market from the response.

[5] For clarity and ease of reference, the Exchange is proposing to define such price point as the ''final auto-match price point'' in the rule text.

[6] *See* BOX Rule 7150(h).

[7] *See* Securities Exchange Act Release No. 74864 (May 4, 2015), 80 FR 26601 (May 8, 2015) (SR–CBOE–2015–043).

[8] When the Exchange receives a properly designated Agency Order for auction processing, a Request for Responses (''RFR'') detailing the option, side, size, and initiating price will be sent to all subscribers of the Exchange's data feeds. The RFR will last for 500 milliseconds. Members may submit responses to the RFR (specifying prices and sizes). *See* Exchange Rule 515A(a)(2)(i).

[9] For further clarity and ease of reference, the Exchange is proposing to amend the rule to refer to the ''Agency Order'' in the rule text.

of Priority Customers [10] under Rule 515A(2)(iii)(B). Priority Customers on the book would continue to have priority even in cases where a Priority Customer order is resting on the book at the final Auction price. For example, suppose that the National Best Bid (''NBB'') for a particular option is $1.00 and the national best offer for the option is $1.20, and that NBB is a Priority Customer order to buy 10 contracts on MIAX. The minimum trading increment in the option is $0.01. An Initiating Member submits an auto-match Agency Order to sell 100 contracts in the series. The Auction begins, and one responding Member submits a response to buy 50 contracts at $1.00. The Auction then concludes. In this case, the Priority Customer on the book would have priority and would be allocated 10 contracts, with the remaining 90 contracts being allocated 40% to the Initiating Member and 60% to the responding Member.[11] Thus, in this example, the Initiating Member is entitled to receive 40%, or 36 of the remaining 90 contracts, and the responding Member is entitled to receive up to 60%, or 54 of the remaining 90 contracts, but is limited to its full size of 50 contracts. Then the Initiating Member would be allocated the remaining 4 contracts (for a total of 40 to the Initiating Member), because the Initiating Member has guaranteed the entire size of the Agency Order and there are no other matching participants respecting the remaining 4 contracts.

Similarly, a Priority Customer order resting on the book at a final Auction price level that is worse than the best Member response will also retain priority in the book. For example, assume again that the NBB for a particular option is $1.00 and the NBO for the option is $1.20 and that the NBB is a Priority Customer order to buy 10 contracts at MIAX. The minimum increment in the option series is $0.01. An Initiating Member submits an auto-match Agency Order to sell 100 contracts in the series. The Auction begins and during the Auction, one responding Market Maker (''MM1'') submits an Auction response to buy 20 contracts at $1.02, a second Market-Maker (''MM2'') submits an Action response to buy 20 contracts at $1.01, and a third Market-Maker (''MM3'') submits an Auction response to buy 20 contracts at $1.00. The Auction then concludes. In this example, MM1 and the Initiating Member would each be allocated 20 contracts at $1.02 and MM2 and the Initiating Member would each be allocated 20 contracts at $1.01 since the Initiating Member is willing to match the price and size at each improved price level. The remaining 20 contracts would be allocated 10 to the Priority Customer order resting on the book at $1.00 because the Priority Customer would retain priority at that price level; the remaining 10 contracts would be allocated 50/50 to MM3 and the Initiating Member, 5 contracts each.[12]

The Exchange believes that increasing the Initiating Member's allocation priority for auto-match submissions that only have one competing Member's response at the final auto-match price point fairly distributes the Agency Order when there are only two counterparties to the Auction involved, and that doing so is reasonable because of the value that Initiating members provide to the market. Initiating Members selecting the auto-match option for Agency Orders guarantee an execution at the NBBO or at a better price, and are subject to a greater market risk than single-price submissions while the order is exposed to other PRIME participants. As such, the Exchange believes that the value added from Initiating Members guaranteeing execution of Agency Orders at a price equal to or better than the NBBO in combination with the additional market risk of initiating auto-match submissions warrants an allocation priority of at least the same percentage as Initiating Members who submit single-price orders into PRIME. The Exchange also believes that the proposed rule change, like other price improvement allocation programs currently offered by competitor exchanges, will benefit investors by attracting more order flow as well as increasing the frequency with which Members initiate Auctions, which may result in greater opportunities for customer order price improvement. Moreover, as discussed above, the proposed rule change is consistent with the rules and proposals of other exchanges.[13]

The Exchange also proposes to add text to Rules 515A(a)(2)(iii)(H) and (I) to describe the manner in which remaining contracts would be allocated at the conclusion of an Auction under the scenarios therein. Specifically, the Exchange proposes to amend sub-paragraphs (H) and (I) to provide that (subject to Priority Customer priority), after the Initiating Member has received an allocation of up to 40% or 50% of the Agency Order (or of the remainder of the Agency Order in the case of an auto-match submission) depending upon the number of Member's responses matching the Initiating Member's submission, contracts shall be allocated among remaining quotes, orders, and auction responses (*i.e.* interests other than the Initiating Member) at the final auction price in accordance with the matching algorithm in effect for the affected class. If all Member responses are filled (*i.e.* no other interests remain), any remaining contracts will be allocated to the Initiating Member at the single-price submission price for single-price submissions or, for auto-match submissions, at the designated limit price described in Rule 515A(a)(2)(i)(A). The Exchange believes that this additional language would add clarity in the Rules with respect to how remaining odd-lots will be allocated at the conclusion of an Auction.

For example, suppose that the NBBO for a particular option is $1.00–$1.20. The minimum increment for the series is $0.01 and the matching algorithm in effect for the option class is pro rata. An Initiating Member submits a matched Agency Order to sell 5 contracts at $1.10. The Auction begins and, during the Auction, one competing Market-Maker (''MM1'') submits a response to buy 5 contracts at $1.10, followed by another Market-Maker (''MM2'') submitting a response to buy 5 contracts at $1.10. The Auction concludes. In this case, under proposed Rule 515A(a)(2)(iii)(H), the Initiating Member

[10] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). *See* Exchange Rule 100.

[11] Although the Priority Customer order has been filled in its entirety, the System currently allocates the remaining 90 contracts as though there are still two participants (the already-filled Priority Customer, together with the responding Member) matching the Initiating Member at the final Auction price.

[12] The Exchange notes that if an unrelated market or marketable limit order on the opposite side of the market as the Agency Order was received during the Auction and ended the Auction, such unrelated order shall trade against the Agency Order at the midpoint of the best RFR response (or in the absence of a RFR response, the initiating price) and the NBBO on the other side of the market from the RFR responses (rounded towards the disseminated quote when necessary). *See* Exchange Rule 515A(2)(iii)(F). For example, assume that the NBBO is $1.00–$1.20. An Initiating Trading Permit Holder submits a matched Agency Order to sell 100 options contracts at in the series at $1.10. The Auction begins and during the Auction, one competing Market-Maker submits an Auction response to buy 100 contracts at $1.15. Assume that after the first response is received, an unrelated public customer order to buy 100 contracts at $1.20 is received. This would conclude the auction early after which the public customer order would trade 100 contracts with the Agency Order at $1.18 (*i.e.* the $1.175 midpoint between the best RFR response ($1.15) and the NBBO on the other side of the market from the RFR responses ($1.20), rounded up to the next minimum increment).

[13] *See supra* notes 6 and 7.

would receive an allocation up to 40%, or, in this case, 2 contracts at $1.10. MM1 and MM2 would then receive 1 contract each at $1.10 according to the pro rata allocation algorithm in place for the class with MM1, as the first responder, receiving the final 1 contract at the final auction price of $1.10.[14]

Similarly, suppose that the NBBO for a particular option is $1.00–$1.20. The minimum increment for the series is $0.01 and the matching algorithm in effect for the option class is pro rata. An Initiating Member submits a matched Agency Order to sell 5 contracts at $1.10. The Auction begins and, during the Auction, one competing Market-Maker (''MM1'') submits a response to buy 1 contract at $1.10, followed by another Market-Maker (''MM2'') submitting a response to buy 1 contract at $1.10. The Auction concludes. In this case, under proposed Rule 515A(a)(2)(iii)(H), the Initiating Member would receive an allocation up to 40% or, in this case, 2 contracts at $1.10. MM1 and MM2 would then receive 1 contract each at $1.10 according to the pro rata allocation algorithm in place for the class. With no other competing interest for the Auction, however, proposed Rule 515A(a)(2)(iii)(H) will simply make clear that if all Member responses are filled (*i.e.* no other interest remains), any remaining contracts will be allocated to the Initiating Member at the single-price submission price. In this case, the final 1 contract would be allocated to the Initiating Member at $1.10.

Remaining odd-lots for auto-match submissions would be similarly allocated under proposed Rule 515A(a)(2)(iii)(I), except that if all Member responses are filled (*i.e.* no other interest remains), any remaining contracts will be allocated to the Initiating Member at the designated limit price described in sub-paragraph (a)(2)(i)(A). For example, suppose that the NBBO for a particular option is $1.00–$1.20 and the offer is represented by a limit order on the book. The minimum increment for the series is $0.01 and the matching algorithm in effect for the option class is pro rata. An Initiating Member submits an auto-matched Agency Order to buy 5 contracts at $1.19, which is one price increment better than the booked order's limit price of $1.20.[15] Assume that the Auction begins and, during the Auction, one competing Market-Maker (''MM1'') submits a response to sell 1 contract at $1.18, followed by another Market-Maker (''MM2'') submitting a response to sell 1 contract at $1.17. The Auction concludes. In this case, MM2 and the Initiating Member would each receive 1 contract at $1.17 and MM1 and the Initiating Member would each receive 1 contract at $1.18. Because all Member responses would then be filled (*i.e.* no other interests remain), any remaining contracts will be allocated to the Initiating Member at the designated limit price described in sub-paragraph (a)(2)(i)(A), in this case, 1 contract at $1.19.

The Exchange notes that these proposed amendments are based on, and consistent with, the rules and proposals of other competitor exchanges.[16] The Exchange believes that the value added when Initiating Members guarantee the execution of Agency Orders at a price equal to or better than the NBBO warrants (to the extent that the Initiating Member is on the final Auction price), an Auction allocation priority of at least the same percentage of the order as any competing Auction responses. The Exchange also believes that the proposed rule change, like other price improvement allocation programs currently offered by competitor exchanges, will benefit investors by attracting more order flow and by increasing the frequency with which Members initiate Auctions, which may result in greater opportunities for price improvement.

Technical Amendments

The Exchange is also proposing two clarifying technical amendments. Specifically, The Exchange proposes to replace the word ''order'' with the more precise term ''Agency Order'' in the phrases that are currently in Rules 515A(a)(2)(iii)(H) and (I) for the avoidance of doubt.[17] Additionally, as stated above,[18] the Exchange is proposing to define, in proposed Rule 515A(a)(2)(iii)(I), the price point where the balance of the Agency Order can be fully executed as the ''final auto-match price point'' in the rule text. This proposed amendment is intended for clarity and ease of reference.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act[19] in general, and furthers the objectives of Section 6(b)(5) of the Act[20] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange further believes the proposed rule change is consistent with the Section 6(b)(5)[21] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change protects investors and is in the public interest because it fairly distributes the allocation of the PRIME Agency Order between the Initiating Member and the Member who responded when they are the only two counterparties to the Auction and/or the number of contracts remaining at the final Auction price cannot be evenly distributed at the end of an Auction. The proposed rule change is intended to enable the Exchange to compete with other exchanges that currently offer price improvement programs with the same trade allocation percentages, and should benefit investors by attracting more order flow and by increasing the number of orders submitted into the PRIME auction mechanism, which the Exchange believes will result in greater opportunity for price improvement. Moreover, the proposed rule change is consistent with the rules and proposals of other exchanges.

Additionally, the Exchange believes that the proposed technical clarifying and definitional amendments to Rule 515A will benefit market participants by enhancing transparency and clarity to the Rules.

With regard to the impact of this proposal on system capacity, the Exchange notes that it has analyzed its capacity and represents that it and the Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle any potential additional traffic associated with the proposed rule change. The Exchange believes that its members will not have a capacity issue as a result of this proposal.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not

[14] *See* Exchange Rule 514(c)(2)

[15] See Exchange Rule 515A(a)(2)(i)(A).

[16] *See supra* notes 6 and 7.

[17] *See supra* note 9.

[18] *See supra* note 5.

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] *Id.*

necessary or appropriate in furtherance of the purposes of the Act.

The proposed changes are meant to more fairly allocate an Agency Order submitted for price improvement using auto-match when there are only two competing participants on the contra-side of the Agency Order. The Exchange does not believe that this change will discourage any market participants from entering into the auto-match option of MIAX PRIME. Because auto-match is a more aggressive strategy than a single-price submission, increasing the Initiating Member's auto-match allocation to up to 50% of the remainder of the Agency Order when there is only one competing response at the final auto-match price point results in a fair and reasonable allocation methodology. This should encourage more Initiating Members to select the auto-match option when submitting Agency Orders for price improvement via MIAX PRIME, thus enhancing competition for participation in Agency Order allocations.

Furthermore, the Exchange notes that the proposed rule change is a competitive response to similar provisions in the price improvement auction rules of BOX [22] and CBOE [23] and thus should promote competition among the options exchanges and establish uniform price improvement auction rules on the various exchanges.

For all the reasons stated, the Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and believes the proposed change will in fact enhance competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [24] and Rule 19b–4(f)(6) [25] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [26] normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii) [27] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay. The Exchange states that waiver of the operative delay will allow the Exchange to compete with trade allocation entitlements in price improvement auctions that are currently in place on other exchanges.[28] For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission designates the proposed rule change to be operative upon filing.[29]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MIAX–2015–36 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2015–36. This file number should be included on the subject line if email 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2015–36 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Robert W. Errett,

Deputy Secretary.

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[22] *See supra* note 6.

[23] *See supra* note 7.

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6)(iii).

[28] *See supra* notes 6 and 7.

[29] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74990; File No. SR–CBOE–2015–047]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change Relating to Floor Broker Due Diligence

May 18, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange rules related to Floor Broker due diligence. The text of the proposed rule change is provided below (additions are *italicized;* deletions are [bracketed]).

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 6.53. Certain Types of Orders Defined

One or more of the following order types may be made available on a class-by-class basis. Certain order types may not be made available for all Exchange systems. The classes and/or systems for which the order types shall be available will be as provided in the Rules, as the context may indicate, or as otherwise specified via Regulatory Circular.

* * * * *

(g) *Not Held Order.* A not held order is an order marked ''not held'', ''take time'' or which bears any qualifying notation giving discretion as to the price or time at which such order is to be executed. *An order entrusted to a Floor Broker will be considered a Not Held Order, unless otherwise specified by a Floor Broker's client or the order was received by the Exchange electronically and subsequently routed to a Floor Broker or PAR Official pursuant to the order entry firm's routing instructions.*

* * * * *

Rule 6.73. Responsibilities of Floor Brokers

(a)–(c) No Change.

. . . *Interpretations and Policies:*

.01–.05 No Change.

.06 Pursuant to Rule 6.73(a), an order entrusted to a Floor Broker will be considered a Not Held Order as defined in Rule 6.53(g), unless otherwise specified by a Floor Broker's client or the order was received by the Exchange electronically and subsequently routed to a Floor Broker or PAR Official pursuant to the order entry firm's routing instructions.

* * * * *

Rule 6.75. Discretionary Transactions

No Floor Broker shall execute or cause to be executed any order or orders on this Exchange with respect to which such Floor Broker is vested with discretion as to: (1) The choice of the class of options to be bought or sold, (2) the number of contracts to be bought or sold, or (3) whether any such transaction shall be one of purchase or sale; however, the provisions of this paragraph shall not apply to any discretionary transaction executed by a Market-Maker for an account in which he has an interest. [Under normal market conditions, and in the absence of a ''not held'' instruction, a Floor Broker may not exercise time discretion on market or marketable limit orders and shall immediately execute such orders at the best price or prices available.] *Unless an order was received by the Exchange electronically and subsequently routed to a Floor Broker or PAR Official pursuant to the order entry firm's routing instructions or it is otherwise specified by a Floor Broker's client, an order entrusted to a Floor Broker will be considered a Not Held Order as defined in Rule 6.53(g).*

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rules 6.53, 6.73, and 6.75 in order to clarify a Floor Broker's due diligence obligations as it relates to executing orders on the Exchange's floor.

Currently, ''[a] Floor Broker handling an order is to use due diligence to execute the order at the best price or prices available to him, in accordance with the Rules.'' [3] Rule 6.73 also provides a non-exclusive list of the duties a Floor Broker must perform in order to satisfy the due diligence requirement.[4] For instance, interpretation and policy .01 states that ''[p]ursuant to Rule 6.73(a), a Floor Broker's use of due diligence in executing an order shall include ascertaining whether a better price than is being displayed by the Order Book Official is being quoted by another Floor Broker or a Market-Maker.'' [5] However, current Rule 6.73 is generally silent on the exact meaning of due diligence, including, for example, whether a Floor Broker must execute a portion of an order against an order in an applicable order book when the displayed size in the order book is less than the size of the Floor Broker's order. Additionally, Rule 6.75 provides that ''[u]nder normal market conditions, and in the absence of a ''not held'' instruction, a Floor Broker may not exercise time discretion on market or marketable limit orders and shall immediately execute such orders at the best price or prices available.'' The Exchange believes that this requirement from Rule 6.75 is applicable and generally intended for situations when an entire order represented by a Floor Broker can be executed.[6] Furthermore, even when that

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 6.73(a).

[4] *See, e.g.,* Rule 6.73 Interpretation and Policies .01–.05.

[5] *See* Rule 6.73.01.

[6] The Exchange notes that the rule filing that added the rule text in Rule 6.75, which this current proposal seeks to amend, did not specify whether brokers had to execute a portion of an order against a smaller sized order to satisfy the requirements of Rule 6.75. *See* Securities Exchange Act Release No.

Continued

is possible, Rule 6.73 requires a broker to ascertain if a better price is available in the trading crowd.[7] Thus, we strongly believe that these provisions are intended to protect against a broker failing to properly represent and ultimately execute orders. This makes even more sense when considering that virtually all options orders (large or small and retail or professional) were handled by Floor Brokers at the time these rules were adopted. Given the discrete profile of orders handled by Floor Brokers today (generally large size orders and often multi-leg) it is reasonable for Floor Brokers to ''work'' orders that are entrusted to them because that is the reason a customer would utilize a Floor Broker in today's environment. In order to address the above scenarios, as well as to provide clarity and latitude to Floor Brokers using their experience and expertise in the execution of orders, the Exchange is proposing to add new interpretation and policy .06 to Rule 6.73, which is proposed to state that ''[p]ursuant to Rule 6.73(a), an order entrusted to a Floor Broker will be considered a Not Held Order as defined in Rule 6.53(g), unless otherwise specified by a Floor Broker's client or the order was received by the Exchange electronically and subsequently routed to a Floor Broker or PAR Official pursuant to the order entry firm's routing instructions.'' [8] The Exchange is also proposing to make conforming changes to Rules 6.53 and 6.75 in order for an order received by a Floor Broker to be considered a Not Held Order, unless the order was routed to the Exchange electronically or otherwise specified by the Floor Broker's client.

The purpose of this filing is to codify the amount of discretion a Floor Broker has when they receive an order. As Rules 6.73 and 6.75 were adopted prior to electronic trading, the rules did not contemplate the interaction between an electronic environment and a trading floor, and they have not been amended to specifically address that interaction. While it is clear that Floor Brokers have more discretion with regards to the manner in which they represent and execute orders on a trading floor than does a computer routing an order to the Exchange for execution, the bounds of the discretion have not been entirely clear. Rules 6.73 and 6.75, among others, set certain boundaries to a Floor Broker's discretion, but the Exchange believes the current marketplace, with electronic and floor trading, favors an amendment to those boundaries.

Electronic and floor trading gives clients the choice between a Trading Permit Holder (''TPH'') that routes orders to the Exchange electronically or a TPH that executes orders via a Floor Broker. Clients are keenly aware that the differences between electronic and floor trading include at least the following factors: A computer cannot deviate from its programed instructions and a Floor Broker can take into account the nuisances [sic] of the marketplace, such as the makeup of a particular trading floor, the individuals on that trading floor, and how the electronic books interact with that environment. The Exchange argues that the reason clients use Floor Brokers is precisely because Floor Brokers can take into account the nuisances [sic] of the marketplace (*i.e.,* exercise a certain level of discretion) to potentially provide higher execution quality. The argument is furthered by the fact that if a client did not want a Floor Broker to use their expertise in the execution of an order, the client would simply send orders to the Exchange electronically.

It is evident that Floor Brokers have more discretion with regards to the manner in which they represent and execute orders than do computers executing electronic orders. With this rule change the Exchange seeks to amend certain boundaries related to that discretion. In particular, in recognition of the discretion implicit with the use of a Floor Broker, the Exchange seeks to provide notice to the marketplace that, unless otherwise specified by a Floor Broker's client or if the order is received by the Exchange electronically and routed to a Floor Broker, an order is deemed to be ''not held.'' The Exchange believes clients that choose to use Floor Brokers do so in order to utilize a Floor Broker's expertise in the execution of orders. This rule change updates Exchange rules by setting forth the presumptive discretion available to Floor Brokers in a manner consistent with modern market structure and the Floor Broker's role in the current trading environment. This filing also serves as notice to the investing community that orders sent to Floor Brokers will be deemed ''not held'' unless otherwise specified by the client or if the order is received by the Exchange electronically and routed to a floor broker. In addition, the Exchange will announce the implementation of this rule change in a Regulatory Circular to be published within 90 days of the effective date of this filing. The implementation date will be within 180 days of the effective date of this filing.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[9] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed change adds clarity and removes ambiguity related to the due diligence requirements of Floor Brokers, which helps serve the public interest and perfect the mechanism of a free and open market. In addition, the Exchange believes designating certain orders as ''not held'' is in the interest of facilitating transactions in securities and reflective of today's marketplace, which generally helps to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe the proposed rule change will impose any burden on competition because the rule change adds clarity to the due diligence requirements governing Floor Brokers, reflects the modern market structure, is consistent with the reasons customers utilize Floor Brokers, and will be applied equally to all TPHs. To the extent that the proposed rule change

24666, 50 FR 25679 (July 8, 1987) (SR–CBOE–85–31).

[7] *See* Rule 6.73.01.

[8] A ''Not Held Order'' is defined as an order marked ''not held'', ''take time'' or which bears any qualifying notation giving discretion as to the price or time at which such order is to be executed. *See* Rule 6.53(g).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

will cause clients or brokers to choose CBOE over other trading venues, market participants on other exchanges are welcome to become TPHs and trade at CBOE if they determine that this proposed rule change has made CBOE more attractive or favorable.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2015–047 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2015–047. This file number should be included on the subject line if email 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 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2015–047 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12417 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74987; File No. SR–BATS–2015–37]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of a Proposed Rule Change, and Amendment No. 1 Thereto, To Amend Rule 11.2 To State That the BATS Exchange, Inc. Will Not Designate for Trading Any Security Admitted to Unlisted Trading Privileges on the Exchange Unless That Security Satisfies Certain Liquidity Requirements

May 18, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On May 15, 2015, the Exchange filed Amendment No. 1 to the proposal. Amendment No. 1 amended and replaced the original proposal in its entirety. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.2 to state that the Exchange will not designate for trading any security admitted to unlisted trading privileges on the Exchange unless that security satisfies certain liquidity requirements, as further described below.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

With limited exception, the current equity market structure under Regulation NMS applies the same rules with respect to, among other things, tick sizes, order protection, locked and crossed markets, and access fees to all exchange-listed securities. The Exchange believes that Regulation NMS, along with technological advancements, has produced great efficiencies to the equity market, resulting in intense competition between exchanges and broker-dealers. The Exchange believes the net result for most exchange-listed securities has been decreases in transaction costs, including decreases in explicit commissions and the narrowing of effective spreads investors pay to enter and exit positions. However, the Exchange recognizes that not all

exchange-listed securities have benefited to the same extent under the current one-size fits all approach to the equity market. In particular, investors continue to experience difficulty trading illiquid securities, including paying higher effective spreads and difficulty sourcing liquidity across multiple exchanges and non-exchange trading venues while minimizing market impact.

The Exchange believes the market quality of securities that are today illiquid could benefit from a concentration of quoted liquidity on the listing exchange. By concentrating quoted liquidity on the listing exchange, for the reasons discussed below, the Exchange believes liquidity providers will quote more competitively, resulting in more efficient price formation and a narrower national best bid or offer (''NBBO''), as well as the display of more quoted size at price levels outside the NBBO (''depth of book''). In turn, the Exchange believes that these enhancements to market quality could ultimately increase investor and member interest in such securities resulting in greater average daily trading volume. As such, as described below, the Exchange is proposing to adopt rules to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain an average daily volume threshold indicative of increased liquidity.

In particular, the Exchange proposes to amend Rule 11.2 to state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange if that security falls below certain consolidated average daily volume requirements, as further described below. Rule 11.2 currently states that any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules [3] shall be eligible to become designated for trading on the Exchange. The Rule further states that all securities designated for trading are eligible for odd-lot, round-lot and mixed-lot executions, unless otherwise indicated by the Exchange or limited pursuant to Exchange rules. The Exchange proposes to include these existing provisions of Rule 11.2 within subparagraph (a) of the proposed rule in order to separately propose additional provisions under subparagraphs (b), (c), and (d).

The Exchange proposes to add new subparagraph (b) to Rule 11.2, which would state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules when that security's consolidated average daily trading volume is equal to or less than 2,500 shares during the preceding 90 calendar days.[4] The Exchange further proposes to add new subparagraph (c) to Rule 11.2, which would state that any security not designated for trading by the Exchange pursuant to subparagraph (b) of this Rule may be designated for trading by the Exchange if its consolidated average daily trading volume exceeds 5,000 shares over any 90 calendar day period since the security was not designated for trading pursuant to subparagraph (b). The Exchange also proposes to make clear that new subparagraph (c) is not intended to limit the Exchange's ability to designate any security for trading pursuant to the Exchange's general authority under subparagraph (a) of Rule 11.2. The Exchange also proposes to add new subparagraph (d) to Rule 11.2, which would require the Exchange to provide notice at least one trading day in advance of any securities it is making unavailable for trading pursuant to subparagraph (b) of Rule 11.2, and any securities it is making available for trading under subparagraph (c) of Rule 11.2.

While the Exchange is proposing to retain discretion over whether it will in fact determine not to quote and trade securities that meet the criteria described in proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange notes that nothing in its rules or applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes that adopting such a provision in its rules could enhance market quality for securities falling below the consolidated average daily volume threshold by facilitating the concentration of quoted liquidity on the listing exchange.[5] In determining whether to exercise its discretion under proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange would consider such factors as member and investor feedback as well as whether the other non-listing exchanges have decided to cease quoting and trading in the effected securities. The Exchange further believes that adoption of a rule requiring it to provide advance notice to its members of any securities the Exchange is choosing not to trade under proposed new subparagraph (b) of Rule 11.2 and any securities it is making available for trading pursuant to proposed new subparagraph (c) of Rule 11.2 will help avoid confusion by providing transparency and certainty to members and investors regarding the securities the Exchange is or is not designating for quoting and trading on the Exchange.

The Exchange believes that limiting the impact of paragraph (b) of the proposed rule change to securities with a consolidated average daily trading volume that is equal to or less than 2,500 shares during the preceding 90 calendar days is reasonable because such securities tend to be illiquid, as reflected by larger quoted and effective spreads, with smaller quoted size at both the NBBO and throughout the depth of book than more actively-traded securities. Similarly, the Exchange believes that considering to designate for trading those securities that have not been trading on the Exchange pursuant to paragraph (b) once such securities have a consolidated average daily trading volume that exceeds 5,000 shares over a 90 calendar day period since the security was not designated for trading pursuant to proposed subparagraph (b) of Rule 11.2 is reasonable because such activity may demonstrate that such securities are now trading more effectively. The Exchange believes that its proposed rule changes may facilitate an improvement in market quality for the effected securities.[6] In particular, the Exchange

[3] Chapter XIV of the Exchange's rules discusses the securities eligible to be designated for trading on the Exchange. Exchange Rule 14.11(j), in particular, states that the Exchange may extend unlisted trading privileges to NMS Stock (as defined in Rule 600 of Regulation NMS under the Act) that is listed on another national securities exchange.

[4] Based on internal statistics, the Exchange anticipates that limiting the rule's applicability to those securities with a consolidated average daily trading volume of 2,500 shares or less during the preceding 90 calendar days will affect approximately 700 securities.

[5] The Exchange understands that the EDGX Exchange, Inc., EDGA Exchange, Inc., and BATS Y-Exchange, Inc. will separately file substantially similar proposed rule changes with the Commission.

[6] Based on an internal study, the Exchange believes a majority of the securities that would be covered by the Rule's criteria are small-cap companies (*i.e.,* companies with a market capitalization of $250 million or less). Suggesting that the current U.S. equity market often fails to provide sufficient liquidity for the securities of small-cap companies, the Commission's Advisory Committee on Small and Emerging Companies (''Advisory Committee'') recommended to the Commission concentrating the market for such securities through the creation of a separate U.S. equity market. *See Recommendations Regarding*

believes that by concentrating the quoted liquidity in such securities on the listing exchange, liquidity providers will be incented to quote on such exchange more competitively, resulting in narrower bid-ask spreads and greater quoted depth of book. The Exchange believes liquidity providers would be so incented because concentrating the quoted liquidity in such securities on the listing exchange would: (i) Reduce liquidity providers' risk of adverse selection inherent in quoting in a fragmented market, (ii) provide greater certainty of execution on the one exchange at which liquidity providers are quoting, and (iii) enhance competition for order book priority at the NBBO and throughout the depth of book. Although the Exchange would be voluntarily foregoing potential market share by not quoting and trading securities subject to the Rule, the Exchange believes the aforementioned enhancements in market quality may increase investor interest in trading such securities, which in turn would generate increased volume and ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'')[7] and further the objectives of Section 6(b)(5) of the Act[8] because they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and, in general, to protect investors and the public interest.

The Exchange notes that nothing in its rules or any applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. However, the Exchange believes adopting a rule to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain a consolidated average daily volume threshold indicative of increased liquidity would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system by facilitating the concentration of displayed liquidity on the listing exchange for effected securities, which the Exchange believes could enhance the market quality of such securities.[9] The Exchange believes that concentrating displayed liquidity on the listing exchange in certain illiquid securities may enhance market quality of such securities by enabling liquidity providers to more efficiently form competitive prices at the NBBO, and to provide greater quoted depth of book. In addition, the Exchange believes that if displayed liquidity is concentrated on the listing exchange in such securities, the listing exchange may have flexibility to innovate with alternative market structures, such as variable tick sizes or periodic batch auctions that are not currently possible under Regulation NMS when multiple exchanges are quoting and trading the securities, and which may further enhance the market quality of the effected illiquid securities.[10]

The proposed rule change promotes just and equitable principles of trade because it will provide certainty and transparency to members and investors with respect to which securities the Exchange will or will not designate for quoting and trading on the Exchange, thereby avoiding confusion.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that nothing in its rules or any applicable securities regulation require it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes enacting such a provision in its rules would not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. While the Exchange will be voluntarily foregoing potential market share by not quoting and trading securities subject to the rule, the Exchange believes the proposal will enhance market quality in such securities by increasing quoting competition among liquidity providers on the listing exchange, which will result in better prices at the NBBO and greater depth of book. The Exchange further believes these enhancements in market quality may increase investor interest in trading such securities, which in turn would improve competition by generating increased volume which would also ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule changes.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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

Separate U.S. Equity Market for Securities of Small and Emerging Companies, by the Advisory Committee on Small and Emerging Companies, dated February 1, 2013. The Advisory Committee also stated that other actions with respect to trading venues may also be warranted to facilitate liquidity in small and emerging companies. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See supra* note 6.

[10] The Exchange is not proposing or advocating any form of trade-at prohibition, which, depending on its various iterations, would generally act to prevent trading off-exchange without first executing against all equal or better priced protected quotations. Rather, the Exchange is proposing and advocating a reduction in the number of displayed venues on which certain illiquid securities will be quoted and traded, which the Exchange believes will concentrate the quoting activity serving to enhance quote competition and thereby increase market quality by narrowing the NBBO and increasing the quoted depth of book for effected securities, without regard to off-exchange trading.

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–BATS–2015–37 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2015–37. This file number should be included on the subject line if email 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 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2015–37 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12414 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74986; File No. SR–EDGA–2015–19]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing of a Proposed Rule Change, and Amendment No. 1 Thereto, To Amend Rule 11.2 To State That EDGA Exchange, Inc. Will Not Designate for Trading Any Security Admitted to Unlisted Trading Privileges on the Exchange Unless That Security Satisfies Certain Liquidity Requirements

May 18, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On May 15, 2015, BATS filed Amendment No. 1 to the proposal. Amendment No. 1 amended and replaced the original proposal in its entirety. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.2 to state that the Exchange will not designate for trading any security admitted to unlisted trading privileges on the Exchange unless that security satisfies certain liquidity requirements, as further described below.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

With limited exception, the current equity market structure under Regulation NMS applies the same rules with respect to, among other things, tick sizes, order protection, locked and crossed markets, and access fees to all exchange-listed securities. The Exchange believes that Regulation NMS, along with technological advancements, has produced great efficiencies to the equity market, resulting in intense competition between exchanges and broker-dealers. The Exchange believes the net result for most exchange-listed securities has been decreases in transaction costs, including decreases in explicit commissions and the narrowing of effective spreads investors pay to enter and exit positions. However, the Exchange recognizes that not all exchange-listed securities have benefited to the same extent under the current one-size fits all approach to the equity market. In particular, investors continue to experience difficulty trading illiquid securities, including paying higher effective spreads and difficulty sourcing liquidity across multiple exchanges and non-exchange trading venues while minimizing market impact.

The Exchange believes the market quality of securities that are today illiquid could benefit from a concentration of quoted liquidity on the listing exchange. By concentrating quoted liquidity on the listing exchange, for the reasons discussed below, the Exchange believes liquidity providers will quote more competitively, resulting in more efficient price formation and a narrower national best bid or offer (''NBBO''), as well as the display of more quoted size at price levels outside the NBBO (''depth of book''). In turn, the Exchange believes that these enhancements to market quality could ultimately increase investor and member interest in such securities resulting in greater average daily trading volume. As such, as described below, the Exchange is proposing to adopt rules to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

certain specific illiquid securities until such securities meet and sustain an average daily volume threshold indicative of increased liquidity.

In particular, the Exchange proposes to amend Rule 11.2 to state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange if that security falls below certain consolidated average daily volume requirements, as further described below. Rule 11.2 currently states that any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules [3] shall be eligible to become designated for trading on the Exchange. The Rule further states that all securities designated for trading are eligible for odd-lot, round-lot and mixed-lot executions, unless otherwise indicated by the Exchange or limited pursuant to Exchange rules. The Exchange proposes to include these existing provisions of Rule 11.2 within subparagraph (a) of the proposed rule in order to separately propose additional provisions under subparagraphs (b), (c), and (d).

The Exchange proposes to add new subparagraph (b) to Rule 11.2, which would state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules when that security's consolidated average daily trading volume is equal to or less than 2,500 shares during the preceding 90 calendar days.[4] The Exchange further proposes to add new subparagraph (c) to Rule 11.2, which would state that any security not designated for trading by the Exchange pursuant to subparagraph (b) of this Rule may be designated for trading by the Exchange if its consolidated average daily trading volume exceeds 5,000 shares over any 90 calendar day period since the security was not designated for trading pursuant to subparagraph (b). The Exchange also proposes to make clear that new subparagraph (c) is not intended to limit the Exchange's ability to designate any security for trading pursuant to the Exchange's general authority under subparagraph (a) of Rule 11.2. The Exchange also proposes to add new subparagraph (d) to Rule 11.2, which would require the Exchange to provide notice at least one trading day in advance of any securities it is making unavailable for trading pursuant to subparagraph (b) of Rule 11.2, and any securities it is making available for trading under subparagraph (c) of Rule 11.2.

While the Exchange is proposing to retain discretion over whether it will in fact determine not to quote and trade securities that meet the criteria described in proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange notes that nothing in its rules or applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes that adopting such a provision in its rules could enhance market quality for securities falling below the consolidated average daily volume threshold by facilitating the concentration of quoted liquidity on the listing exchange.[5] In determining whether to exercise its discretion under proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange would consider such factors as member and investor feedback as well as whether the other non-listing exchanges have decided to cease quoting and trading in the effected securities. The Exchange further believes that adoption of a rule requiring it to provide advance notice to its members of any securities the Exchange is choosing not to trade under proposed new subparagraph (b) of Rule 11.2 and any securities it is making available for trading pursuant to proposed new subparagraph (c) of Rule 11.2 will help avoid confusion by providing transparency and certainty to members and investors regarding the securities the Exchange is or is not designating for quoting and trading on the Exchange.

The Exchange believes that limiting the impact of paragraph (b) of the proposed rule change to securities with a consolidated average daily trading volume that is equal to or less than 2,500 shares during the preceding 90 calendar days is reasonable because such securities tend to be illiquid, as reflected by larger quoted and effective spreads, with smaller quoted size at both the NBBO and throughout the depth of book than more actively-traded securities. Similarly, the Exchange believes that considering to designate for trading those securities that have not been trading on the Exchange pursuant to paragraph (b) once such securities have a consolidated average daily trading volume that exceeds 5,000 shares over a 90 calendar day period since the security was not designated for trading pursuant to proposed subparagraph (b) of Rule 11.2 is reasonable because such activity may demonstrate that such securities are now trading more effectively. The Exchange believes that its proposed rule changes may facilitate an improvement in market quality for the effected securities.[6] In particular, the Exchange believes that by concentrating the quoted liquidity in such securities on the listing exchange, liquidity providers will be incented to quote on such exchange more competitively, resulting in narrower bid-ask spreads and greater quoted depth of book. The Exchange believes liquidity providers would be so incented because concentrating the quoted liquidity in such securities on the listing exchange would: (i) Reduce liquidity providers' risk of adverse selection inherent in quoting in a fragmented market, (ii) provide greater certainty of execution on the one exchange at which liquidity providers are quoting, and (iii) enhance competition for order book priority at the NBBO and throughout the depth of book. Although the Exchange would be voluntarily foregoing potential market share by not quoting and trading securities subject to the Rule, the Exchange believes the aforementioned enhancements in market quality may increase investor interest in trading such securities, which in turn would generate increased volume and ultimately benefit the Exchange once such securities become eligible for

[3] Chapter XIV of the Exchange's rules discusses the securities eligible to be designated for trading on the Exchange. Exchange Rule 14.1, in particular, states that the Exchange may extend unlisted trading privileges to any Equity Security (as defined in the Rule) that is listed on another national securities exchange or with respect to which unlisted trading privileges may otherwise be extended in accordance with Section 12(f) of the Exchange Act.

[4] Based on internal statistics, the Exchange anticipates that limiting the rule's applicability to those securities with a consolidated average daily trading volume of 2,500 shares or less during the preceding 90 calendar days will affect approximately 700 securities.

[5] The Exchange understands that the EDGX Exchange, Inc., BATS Exchange, Inc., and BATS Y-Exchange, Inc. will separately file substantially similar proposed rule changes with the Commission.

[6] Based on an internal study, the Exchange believes a majority of the securities that would be covered by the Rule's criteria are small-cap companies (*i.e.,* companies with a market capitalization of $250 million or less). Suggesting that the current U.S. equity market often fails to provide sufficient liquidity for the securities of small-cap companies, the Commission's Advisory Committee on Small and Emerging Companies (''Advisory Committee'') recommended to the Commission concentrating the market for such securities through the creation of a separate U.S. equity market. *See Recommendations Regarding Separate U.S. Equity Market for Securities of Small and Emerging Companies,* by the Advisory Committee on Small and Emerging Companies, dated February 1, 2013. The Advisory Committee also stated that other actions with respect to trading venues may also be warranted to facilitate liquidity in small and emerging companies. *Id.*

trading on the Exchange under the rule in the future.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'')[7] and further the objectives of Section 6(b)(5) of the Act[8] because they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and, in general, to protect investors and the public interest.

The Exchange notes that nothing in its rules or any applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. However, the Exchange believes adopting a rule to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain a consolidated average daily volume threshold indicative of increased liquidity would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system by facilitating the concentration of displayed liquidity on the listing exchange for effected securities, which the Exchange believes could enhance the market quality of such securities.[9] The Exchange believes that concentrating displayed liquidity on the listing exchange in certain illiquid securities may enhance market quality of such securities by enabling liquidity providers to more efficiently form competitive prices at the NBBO, and to provide greater quoted depth of book. In addition, the Exchange believes that if displayed liquidity is concentrated on the listing exchange in such securities, the listing exchange may have flexibility to innovate with alternative market structures, such as variable tick sizes or periodic batch auctions that are not currently possible under Regulation NMS when multiple exchanges are quoting and trading the securities, and which may further enhance the market quality of the effected illiquid securities.[10]

The proposed rule change promotes just and equitable principles of trade because it will provide certainty and transparency to members and investors with respect to which securities the Exchange will or will not designate for quoting and trading on the Exchange, thereby avoiding confusion.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that nothing in its rules or any applicable securities regulation require it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes enacting such a provision in its rules would not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. While the Exchange will be voluntarily foregoing potential market share by not quoting and trading securities subject to the rule, the Exchange believes the proposal will enhance market quality in such securities by increasing quoting competition among liquidity providers on the listing exchange, which will result in better prices at the NBBO and greater depth of book. The Exchange further believes these enhancements in market quality may increase investor interest in trading such securities, which in turn would improve competition by generating increased volume which would also ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule changes.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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 email to *rule-comments@sec.gov*. Please include File Number SR–EDGA–2015–19 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGA–2015–19. This file number should be included on the subject line if email 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

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See supra* note 6.

[10] The Exchange is not proposing or advocating any form of trade-at prohibition, which, depending on its various iterations, would generally act to prevent trading off-exchange without first executing against all equal or better priced protected quotations. Rather, the Exchange is proposing and advocating a reduction in the number of displayed venues on which certain illiquid securities will be quoted and traded, which the Exchange believes will concentrate the quoting activity serving to enhance quote competition and thereby increase market quality by narrowing the NBBO and increasing the quoted depth of book for effected securities, without regard to off-exchange trading.

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 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2015–19 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12413 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31603; 812–14370]

BMO Funds, Inc. and BMO Asset Management Corp.; Notice of Application

May 15, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements.

SUMMARY OF APPLICATION: Applicants request an order that would permit them to enter into and materially amend sub-advisory agreements with Wholly-Owned Sub-Advisers (as defined below) and non-affiliated sub-advisers without shareholder approval and would grant relief from certain disclosure requirements.

APPLICANTS: BMO Funds, Inc. (the ''Company'') and BMO Asset Management Corp. (the ''Adviser'').

FILING DATES: The application was filed October 10, 2014, and amended on January 30, 2015, and May 8, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on June 9, 2015 and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 of the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants, 111 East Kilbourn Avenue, Suite 200, Milwaukee, WI 53202.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 551–6811, or Danielle Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Company is organized as a Wisconsin corporation and is registered under the Act as an open-end management investment company. The Company currently has, or intends to introduce, at least one series of shares (each, a ''Series''), with its own distinct investment objective, policies and restrictions, that would operate under a multi-manager structure. The Adviser is a Delaware corporation and is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act'').[1] The Adviser is an indirect wholly-owned subsidiary of the Bank of Montreal, a Canadian bank holding company.

2. Each Series has, or will have, as its investment adviser, the Adviser, or an entity controlling, controlled by or under common control with the Adviser or its successors (included in the term, the ''Adviser'').[2] An Adviser serves, or will serve, as the investment adviser to each Series pursuant to an investment advisory agreement with the Company (the ''Investment Management Agreement''). Each Investment Management Agreement has been or will be approved by the board of directors (the ''Board''),[3] including a majority of the members of the Board who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Series, or the Adviser (''Independent Board Members''), and by the shareholders of the relevant Series as required by sections 15(a) and 15(c) of the Act and rule 18f–2 thereunder. The terms of these Investment Management Agreements comply or will comply with section 15(a) of the Act.

3. Under the terms of each Investment Management Agreement, the Adviser, subject to the supervision of the Board, will provide continuous investment management of the assets of each Series. The Adviser will periodically review a Series' investment policies and strategies, and based on the need of a particular Series may recommend changes to the investment policies and strategies of the Series for consideration by the Board. For its services to each Series under the applicable Investment Management Agreement, the Adviser will receive an investment management fee from that Series. Each Investment Management Agreement provides that the Adviser may, subject to the approval of the Board, including a majority of the Independent Board Members, and the shareholders of the applicable Sub-Advised Series (if required), delegate portfolio management responsibilities of all or a portion of the assets of a Sub-Advised Series to one or more Sub-Advisers.[4]

[1] Applicants request that the relief apply to applicants, as well as to any future Series and any other existing or future registered open-end investment management company or series thereof that: (a) Is advised by the Adviser; (b) uses the multi-manager structure described in the application (''Multi-Manager Structure''); and (c) complies with the terms and conditions of the application (''Sub-Advised Series''). All registered open-end investment companies that currently intend to rely on the requested order are named as applicants. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application. If the name of any Sub-Advised Series contains the name of a sub-adviser (as defined below), the name of the Adviser that serves as the primary adviser to the Sub-Advised Series, or a trademark or trade name that is owned by or publicly used to identify that Adviser, will precede the name of the sub-adviser.

[2] Each Adviser is, or will be, registered with the Commission as an investment adviser under the Advisers Act. For the purposes of the requested order, ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[3] The term ''Board'' also includes the board of trustees or directors of a future Sub-Advised Series.

[4] A ''Sub-Adviser'' is (a) an indirect or direct ''wholly-owned subsidiary'' (as such term is

Continued

4. Applicants request an order to permit the Adviser, subject to the approval of the Board, including a majority of the Independent Board Members, to, without obtaining shareholder approval: (i) Select Sub-Advisers to manage all or a portion of the assets of a Series and enter into Sub-Advisory Agreements (as defined below) with the Sub-Advisers, and (ii) materially amend Sub-Advisory Agreements with the Sub-Advisers.[5] The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, that is an affiliated person, as defined in section 2(a)(3) of the Act, of the Sub-Advised Series, or the Adviser, other than by reason of serving as a sub-adviser to one or more of the Sub-Advised Series (''Affiliated Sub-Adviser'').

5. Pursuant to each Investment Management Agreement, the Adviser has overall responsibility for the management and investment of the assets of each Sub-Advised Series. These responsibilities include recommending the removal or replacement of Sub-Advisers, determining the portion of that Sub-Advised Series' assets to be managed by any given Sub-Adviser and reallocating those assets as necessary from time to time.

6. The Adviser may enter into sub-advisory agreements with various Sub-Advisers (''Sub-Advisory Agreements'') to provide investment management services to the Sub-Advised Series. The terms of each Sub-Advisory Agreement comply or will comply fully with the requirements of section 15(a) of the Act and have been or will be approved by the Board, including a majority of the Independent Board Members and the initial shareholder of the applicable Sub-Advised Series, in accordance with sections 15(a) and 15(c) of the Act and rule 18f–2 thereunder. The Sub-Advisers, subject to the supervision of the Adviser and oversight of the Board, will determine the securities and other investments to be purchased or sold by a Sub-Advised Series and place orders with brokers or dealers that they select. The Adviser will compensate the Sub-Advisers out of the fee paid to the Adviser under the Investment Management Agreement.[6]

7. Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) Within 90 days after a new Sub-Adviser is hired for any Sub-Advised Series, that Sub-Advised Series will send its shareholders either a Multi-manager Notice or a Multi-manager Notice and Multi-manager Information Statement;[7] and (b) the Sub-Advised Series will make the Multi-manager Information Statement available on the Web site identified in the Multi-manager Notice no later than when the Multi-manager Notice (or Multi-manager Notice and Multi-manager Information Statement) is first sent to shareholders, and will maintain it on that Web site for at least 90 days. In the circumstances described in the application, a proxy solicitation to approve the appointment of new Sub-Advisers provides no more meaningful information to shareholders than the proposed Multi-manager Information Statement. Applicants state that the Board would comply with the requirements of sections 15(a) and 15(c) of the Act before entering into or amending Sub-Advisory Agreements.

8. Applicants also request an order exempting the Sub-Advised Series from certain disclosure obligations that may require each Sub-Advised Series to disclose fees paid by the Adviser to each Sub-Adviser. Applicants seek relief to permit each Sub-Advised Series to disclose (as a dollar amount and a percentage of the Sub-Advised Series' net assets): (a) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Advisers; (b) the aggregate fees paid to Non-Affiliated Sub-Advisers; and (c) the fee paid to each Affiliated Sub-Adviser (collectively, the ''Aggregate Fee Disclosure'').

Applicants' Legal Analysis

1. Section 15(a) of the Act states, in part, that is unlawful for any person to act as an investment adviser to a registered investment company ''except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company.'' Rule 18f–2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the ''advisory fee payable'' by the investment company, including the total dollar amounts that the investment company ''paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years.''

3. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the Exchange Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fee,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X under the Securities Act of 1933 sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder

defined in the Act) of the Adviser for that Series; (b) a sister company of the Adviser for that Series that is an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in the Act) of the same company that, indirectly or directly, wholly owns the Adviser (each of (a) and (b), a ''Wholly-Owned Sub-Adviser'' and collectively, the Wholly-Owned Sub-Advisers''), or (c) an investment sub-adviser for that Series that is not an ''affiliated person'' (as such term is defined in section 2(a)(3) of the Act) of the Series, or the Adviser, except to the extent that an affiliation arises solely because the sub-adviser serves as a sub-adviser to one or more Series (each, a ''Non-Affiliated Sub-Adviser'').

[5] Shareholder approval will continue to be required for any other sub-adviser changes (not otherwise permitted by application, law or rule) and material amendments to an existing sub-advisory agreement with any sub-adviser other than a Non-Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser (all such changes and amendments referred to as ''Ineligible Sub-Adviser Changes'').

[6] A Sub-Advised Series also may pay advisory fees directly to a Sub-Adviser.

[7] A ''Multi-manager Notice'' will be modeled on a Notice of Internet Availability as defined in rule 14a–16 under the Securities Exchange Act of 1934 (''1934 Act''), and specifically will, among other things: (a) Summarize the relevant information regarding the new Sub-Adviser (except as modified to permit Aggregate Fee Disclosure (as defined below)); (b) inform shareholders that the Multi-manager Information Statement is available on a Web site; (c) provide the Web site address; (d) state the time period during which the Multi-manager Information Statement will remain available on that Web site; (e) provide instructions for accessing and printing the Multi-manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-manager Information Statement may be obtained, without charge, by contacting the Sub-Advised Series. A ''Multi-manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the 1934 Act for an information statement, except as modified by the requested order to permit Aggregate Fee Disclosure. Multi-manager Information Statements will be filed with the Commission via the EDGAR system.

reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission by order upon application may conditionally or unconditionally exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that their requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to the review and approval of the Board, to select the Sub-Advisers who are in the best position to achieve the Sub-Advised Series' investment objectives. Applicants assert that, from the perspective of the shareholder, the role of the Sub-Advisers is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of the Sub-Advised Series are paying the Adviser the selection, supervision and evaluation of the Sub-Advisers without incurring unnecessary delays or expenses is appropriate in the interests of the Sub-Advised Series' shareholders and will allow such Sub-Advised Series to operate more efficiently. Applicants state that each Investment Management Agreement will continue to be fully subject to section 15(a) of the Act and rule 18f–2 under the Act, and approved by the Board, including a majority of the Independent Board Members, in the manner required by sections 15(a) and 15(c) of the Act. Applicants are not seeking an exemption with respect to the Investment Management Agreements.

7. Applicants assert that disclosure of the individual fees that the Adviser would pay to the Sub-Advisers of Sub-Advised Series that operate under the multi-manager structure described in the application would not serve any meaningful purpose. Applicants contend that the primary reasons for requiring disclosure of individual fees paid to Sub-Advisers are to inform shareholders of expenses to be charged by a particular Sub-Advised Series and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the advisory fee paid to the Adviser will be fully disclosed and, therefore, shareholders will know what the Sub-Advised Series' fees and expenses are and will be able to compare the advisory fees a Sub-Advised Series is charged to those of other investment companies. Applicants assert that the requested disclosure relief would benefit shareholders of the Sub-Advised Series because it would improve the Adviser's ability to negotiate the fees paid to Sub-Advisers. Applicants state that the Adviser may be able to negotiate rates that are below a Sub-Adviser's ''posted'' amounts if the Adviser is not required to disclose the Sub-Advisers' fees to the public. Applicants submit that the relief requested to use Aggregate Fee Disclosure will encourage Sub-Advisers to negotiate lower subadvisory fees with the Adviser if the lower fees are not required to be made public.

8. For the reasons discussed above, applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act. Applicants state that the operation of the Sub-Advised Series in the manner described in the application must be approved by shareholders of a Sub-Advised Series before that Sub-Advised Series may rely on the requested relief. In addition, applicants state that the proposed conditions to the requested relief are designed to address any potential conflicts of interest, including any posed by the use of Wholly-Owned Sub-Advisers, and provide that shareholders are informed when new Sub-Advisers are hired. Applicants assert that conditions 6, 10 and 11 are designed to provide the Board with sufficient independence and the resources and information it needs to monitor and address any conflicts of interest with affiliated persons of the Adviser, including Wholly-Owned Sub-Advisers. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions: [8]

1. Before a Sub-Advised Series may rely on the order requested in the application, the operation of the Sub-Advised Series in the manner described in the application, including the hiring of Wholly-Owned Sub-Advisers, will be, or has been, approved by a majority of the Sub-Advised Series' outstanding voting securities, as defined in the Act, or, in the case of a new Sub-Advised Series whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the sole initial shareholder before offering the Sub-Advised Series' shares to the public.

2. The prospectus for each Sub-Advised Series will disclose the existence, substance, and effect of any order granted pursuant to the application. Each Sub-Advised Series will hold itself out to the public as employing the multi-manager structure described in the application. Each prospectus will prominently disclose that the Adviser has ultimate responsibility, subject to oversight by the Board, to oversee the Sub-Advisers and recommend their hiring, termination, and replacement.

3. The Adviser will provide general management services to each Sub-Advised Series, including overall supervisory responsibility for the general management and investment of the Sub-Advised Series' assets. Subject to review and approval of the Board, the Adviser will: (i) Set the Sub-Advised Series' overall investment strategies; (ii) evaluate, select and recommend Sub-Advisers to manage all or a portion of the Sub-Advised Series' assets; and (iii) implement procedures reasonably designed to ensure that Sub-Advisers comply with a Sub-Advised Series' investment objectives, policies and restrictions. Subject to review by the Board, the Adviser will (i) when appropriate, allocate and reallocate the Sub-Advised Series' assets among multiple Sub-Advisers; and (ii) monitor and evaluate the performance of Sub-Advisers.

4. A Sub-Advised Series will not make any Ineligible Sub-Adviser Changes without the approval of the shareholders of the applicable Sub-Advised Series.

5. A Sub-Advised Series will inform shareholders of the hiring of a new Sub-Adviser within 90 days after the hiring of the new Sub-Adviser pursuant to the Modified Notice and Access Procedures.

6. At all times, at least a majority of the Board will be Independent Board Members, and the selection and nomination of new or additional Independent Board Members will be

[8] Applicants will only comply with conditions 7, 8, 9 and 12 if they rely on the relief that would allow them to provide Aggregate Fee Disclosure.

placed within the discretion of the then-existing Independent Board Members.

7. Independent legal counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Board Members. The selection of such counsel will be within the discretion of the then existing Independent Board Members.

8. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Sub-Advised Series basis. The information will reflect the impact on profitability of the hiring or termination of any sub-adviser during the applicable quarter.

9. Whenever a sub-adviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

10. Whenever a sub-adviser change is proposed for a Sub-Advised Series with an Affiliated Sub-Adviser or a Wholly-Owned Sub-Adviser, the Board, including a majority of the Independent Board Members, will make a separate finding, reflected in the Board minutes, that such change is in the best interests of the Sub-Advised Series and its shareholders and does not involve a conflict of interest from which the Adviser or the Affiliated Sub-Adviser or Wholly-Owned Sub-Adviser derives an inappropriate advantage.

11. No director or officer of a Sub-Advised Series, or director or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person) any interest in a Sub-Adviser, except for (i) ownership of interests in the Adviser or any entity, other than a Wholly-Owned Sub-Adviser that controls, is controlled by, or is under common control with the Adviser; or (ii) ownership of less than 1% of the outstanding securities of any class of equity or debt of a publicly traded company that is either a Sub-Adviser or an entity that controls, is controlled by, or is under common control with a Sub-Adviser.

12. Each Sub-Advised Series will disclose the Aggregate Fee Disclosure in its registration statement.

13. In the event the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

14. Any new Sub-Advisory Agreement or any amendment to a Sub-Advised Series' existing Investment Management Agreement or Sub-Advisory Agreement that directly or indirectly results in an increase in the aggregate advisory fee rate payable by the Sub-Advised Series will be submitted to the Sub-Advised Series' shareholders for approval.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12381 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74985; File No. SR–EDGX–2015–21]

Self-Regulatory Organizations; EDGX Exchange, Inc.; Notice of Filing of a Proposed Rule Change, and Amendment No. 1 Thereto, To Amend Rule 11.2 To State That EDGX Exchange, Inc. Will Not Designate for Trading Any Security Admitted to Unlisted Trading Privileges on the Exchange Unless That Security Satisfies Certain Liquidity Requirements

May 18, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On May 15, 2015, BATS filed Amendment No. 1 to the proposal. Amendment No. 1 amended and replaced the original proposal in its entirety. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.2 to state that the Exchange will not designate for trading any security admitted to unlisted trading privileges on the Exchange unless that security satisfies certain liquidity requirements, as further described below.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

With limited exception, the current equity market structure under Regulation NMS applies the same rules with respect to, among other things, tick sizes, order protection, locked and crossed markets, and access fees to all exchange-listed securities. The Exchange believes that Regulation NMS, along with technological advancements, has produced great efficiencies to the equity market, resulting in intense competition between exchanges and broker-dealers. The Exchange believes the net result for most exchange-listed securities has been decreases in transaction costs, including decreases in explicit commissions and the narrowing of effective spreads investors pay to enter and exit positions. However, the Exchange recognizes that not all exchange-listed securities have benefited to the same extent under the current one-size fits all approach to the equity market. In particular, investors continue to experience difficulty trading illiquid securities, including paying higher effective spreads and difficulty sourcing liquidity across multiple exchanges and non-exchange trading venues while minimizing market impact.

The Exchange believes the market quality of securities that are today illiquid could benefit from a concentration of quoted liquidity on the listing exchange. By concentrating quoted liquidity on the listing exchange, for the reasons discussed below, the Exchange believes liquidity providers will quote more competitively, resulting in more efficient price formation and a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

narrower national best bid or offer (''NBBO''), as well as the display of more quoted size at price levels outside the NBBO (''depth of book''). In turn, the Exchange believes that these enhancements to market quality could ultimately increase investor and member interest in such securities resulting in greater average daily trading volume. As such, as described below, the Exchange is proposing to adopt rules to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain an average daily volume threshold indicative of increased liquidity.

In particular, the Exchange proposes to amend Rule 11.2 to state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange if that security falls below certain consolidated average daily volume requirements, as further described below. Rule 11.2 currently states that any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules [3] shall be eligible to become designated for trading on the Exchange. The Rule further states that all securities designated for trading are eligible for odd-lot, round-lot and mixed-lot executions, unless otherwise indicated by the Exchange or limited pursuant to Exchange rules. The Exchange proposes to include these existing provisions of Rule 11.2 within subparagraph (a) of the proposed rule in order to separately propose additional provisions under subparagraphs (b), (c), and (d).

The Exchange proposes to add new subparagraph (b) to Rule 11.2, which would state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules when that security's consolidated average daily trading volume is equal to or less than 2,500 shares during the preceding 90 calendar days.[4] The Exchange further proposes to add new subparagraph (c) to Rule 11.2, which would state that any security not designated for trading by the Exchange pursuant to subparagraph (b) of this Rule may be designated for trading by the Exchange if its consolidated average daily trading volume exceeds 5,000 shares over any 90 calendar day period since the security was not designated for trading pursuant to subparagraph (b). The Exchange also proposes to make clear that new subparagraph (c) is not intended to limit the Exchange's ability to designate any security for trading pursuant to the Exchange's general authority under subparagraph (a) of Rule 11.2. The Exchange also proposes to add new subparagraph (d) to Rule 11.2, which would require the Exchange to provide notice at least one trading day in advance of any securities it is making unavailable for trading pursuant to subparagraph (b) of Rule 11.2, and any securities it is making available for trading under subparagraph (c) of Rule 11.2.

While the Exchange is proposing to retain discretion over whether it will in fact determine not to quote and trade securities that meet the criteria described in proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange notes that nothing in its rules or applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes that adopting such a provision in its rules could enhance market quality for securities falling below the consolidated average daily volume threshold by facilitating the concentration of quoted liquidity on the listing exchange.[5] In determining whether to exercise its discretion under proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange would consider such factors as member and investor feedback as well as whether the other non-listing exchanges have decided to cease quoting and trading in the effected securities. The Exchange further believes that adoption of a rule requiring it to provide advance notice to its members of any securities the Exchange is choosing not to trade under proposed new subparagraph (b) of Rule 11.2 and any securities it is making available for trading pursuant to proposed new subparagraph (c) of Rule 11.2 will help avoid confusion by providing transparency and certainty to members and investors regarding the securities the Exchange is or is not designating for quoting and trading on the Exchange.

The Exchange believes that limiting the impact of paragraph (b) of the proposed rule change to securities with a consolidated average daily trading volume that is equal to or less than 2,500 shares during the preceding 90 calendar days is reasonable because such securities tend to be illiquid, as reflected by larger quoted and effective spreads, with smaller quoted size at both the NBBO and throughout the depth of book than more actively-traded securities. Similarly, the Exchange believes that considering to designate for trading those securities that have not been trading on the Exchange pursuant to paragraph (b) once such securities have a consolidated average daily trading volume that exceeds 5,000 shares over a 90 calendar day period since the security was not designated for trading pursuant to proposed subparagraph (b) of Rule 11.2 is reasonable because such activity may demonstrate that such securities are now trading more effectively. The Exchange believes that its proposed rule changes may facilitate an improvement in market quality for the effected securities.[6] In particular, the Exchange believes that by concentrating the quoted liquidity in such securities on the listing exchange, liquidity providers will be incented to quote on such exchange more competitively, resulting in narrower bid-ask spreads and greater quoted depth of book. The Exchange believes liquidity providers would be so incented because concentrating the quoted liquidity in such securities on the listing exchange would: (i) Reduce liquidity providers' risk of adverse selection inherent in quoting in a fragmented market, (ii) provide greater certainty of execution on the one

[3] Chapter XIV of the Exchange's rules discusses the securities eligible to be designated for trading on the Exchange. Exchange Rule 14.1, in particular, states that the Exchange may extend unlisted trading privileges to any Equity Security (as defined in the Rule) that is listed on another national securities exchange or with respect to which unlisted trading privileges may otherwise be extended in accordance with Section 12(f) of the Exchange Act.

[4] Based on internal statistics, the Exchange anticipates that limiting the rule's applicability to those securities with a consolidated average daily trading volume of 2,500 shares or less during the preceding 90 calendar days will affect approximately 700 securities.

[5] The Exchange understands that the EDGA Exchange, Inc., BATS Exchange, Inc., and BATS Y-Exchange, Inc. will separately file substantially similar proposed rule changes with the Commission.

[6] Based on an internal study, the Exchange believes a majority of the securities that would be covered by the Rule's criteria are small-cap companies (*i.e.,* companies with a market capitalization of $250 million or less). Suggesting that the current U.S. equity market often fails to provide sufficient liquidity for the securities of small-cap companies, the Commission's Advisory Committee on Small and Emerging Companies (''Advisory Committee'') recommended to the Commission concentrating the market for such securities through the creation of a separate U.S. equity market. *See Recommendations Regarding Separate U.S. Equity Market for Securities of Small and Emerging Companies,* by the Advisory Committee on Small and Emerging Companies, dated February 1, 2013. The Advisory Committee also stated that other actions with respect to trading venues may also be warranted to facilitate liquidity in small and emerging companies. *Id.*

exchange at which liquidity providers are quoting, and (iii) enhance competition for order book priority at the NBBO and throughout the depth of book. Although the Exchange would be voluntarily foregoing potential market share by not quoting and trading securities subject to the Rule, the Exchange believes the aforementioned enhancements in market quality may increase investor interest in trading such securities, which in turn would generate increased volume and ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'')[7] and further the objectives of Section 6(b)(5) of the Act[8] because they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and, in general, to protect investors and the public interest.

The Exchange notes that nothing in its rules or any applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. However, the Exchange believes adopting a rule to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain a consolidated average daily volume threshold indicative of increased liquidity would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system by facilitating the concentration of displayed liquidity on the listing exchange for effected securities, which the Exchange believes could enhance the market quality of such securities.[9] The Exchange believes that concentrating displayed liquidity on the listing exchange in certain illiquid securities may enhance market quality of such securities by enabling liquidity providers to more efficiently form competitive prices at the NBBO, and to provide greater quoted depth of book. In addition, the Exchange believes that if displayed liquidity is concentrated on the listing exchange in such securities, the listing exchange may have flexibility to innovate with alternative market structures, such as variable tick sizes or periodic batch auctions that are not currently possible under Regulation NMS when multiple exchanges are quoting and trading the securities, and which may further enhance the market quality of the effected illiquid securities.[10]

The proposed rule change promotes just and equitable principles of trade because it will provide certainty and transparency to members and investors with respect to which securities the Exchange will or will not designate for quoting and trading on the Exchange, thereby avoiding confusion.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that nothing in its rules or any applicable securities regulation require it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes enacting such a provision in its rules would not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. While the Exchange will be voluntarily foregoing potential market share by not quoting and trading securities subject to the rule, the Exchange believes the proposal will enhance market quality in such securities by increasing quoting competition among liquidity providers on the listing exchange, which will result in better prices at the NBBO and greater depth of book. The Exchange further believes these enhancements in market quality may increase investor interest in trading such securities, which in turn would improve competition by generating increased volume which would also ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule changes.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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 email to *rule-comments@sec.gov.* Please include File Number SR–EDGX–2015–21 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–EDGX–2015–21. This file number should be included on the subject line if email 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

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See supra* note 6.

[10] The Exchange is not proposing or advocating any form of trade-at prohibition, which, depending on its various iterations, would generally act to prevent trading off-exchange without first executing against all equal or better priced protected quotations. Rather, the Exchange is proposing and advocating a reduction in the number of displayed venues on which certain illiquid securities will be quoted and traded, which the Exchange believes will concentrate the quoting activity serving to enhance quote competition and thereby increase market quality by narrowing the NBBO and increasing the quoted depth of book for effected securities, without regard to off-exchange trading.

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 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGX–2015–21 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12412 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74988; File No. SR–BYX–2015–25]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing of a Proposed Rule Change, and Amendment No. 1 Thereto, To Amend Rule 11.2 To State That the BATS Y-Exchange, Inc. Will Not Designate for Trading Any Security Admitted to Unlisted Trading Privileges on the Exchange Unless That Security Satisfies Certain Liquidity Requirements

May 18, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 5, 2015, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On May 15, 2015, the Exchange filed Amendment No. 1 to the proposal. Amendment No. 1 amended and replaced the original proposal in its entirety. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.2 to state that the Exchange will not designate for trading any security admitted to unlisted trading privileges on the Exchange unless that security satisfies certain liquidity requirements, as further described below.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

With limited exception, the current equity market structure under Regulation NMS applies the same rules with respect to, among other things, tick sizes, order protection, locked and crossed markets, and access fees to all exchange-listed securities. The Exchange believes that Regulation NMS, along with technological advancements, has produced great efficiencies to the equity market, resulting in intense competition between exchanges and broker-dealers. The Exchange believes the net result for most exchange-listed securities has been decreases in transaction costs, including decreases in explicit commissions and the narrowing of effective spreads investors pay to enter and exit positions. However, the Exchange recognizes that not all exchange-listed securities have benefited to the same extent under the current one-size fits all approach to the equity market. In particular, investors continue to experience difficulty trading illiquid securities, including paying higher effective spreads and difficulty sourcing liquidity across multiple exchanges and non-exchange trading venues while minimizing market impact.

The Exchange believes the market quality of securities that are today illiquid could benefit from a concentration of quoted liquidity on the listing exchange. By concentrating quoted liquidity on the listing exchange, for the reasons discussed below, the Exchange believes liquidity providers will quote more competitively, resulting in more efficient price formation and a narrower national best bid or offer (''NBBO''), as well as the display of more quoted size at price levels outside the NBBO (''depth of book''). In turn, the Exchange believes that these enhancements to market quality could ultimately increase investor and member interest in such securities resulting in greater average daily trading volume. As such, as described below, the Exchange is proposing to adopt rules to clarify the circumstances under which the Exchange would voluntarily provide advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain an average daily volume threshold indicative of increased liquidity.

In particular, the Exchange proposes to amend Rule 11.2 to state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange if that security falls below certain consolidated average daily volume requirements, as further described below. Rule 11.2 currently states that any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules[3] shall be eligible to become designated for trading on the Exchange. The Rule further states that all securities designated for trading are eligible for odd-lot, round-lot and mixed-lot executions, unless otherwise indicated

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[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Chapter XIV of the Exchange's rules discusses the securities eligible to be designated for trading on the Exchange. Exchange Rule 14.1, in particular, states that the Exchange may extend unlisted trading privileges to any Equity Security (as defined in the Rule) that is listed on another national securities exchange or with respect to which unlisted trading privileges may otherwise be extended in accordance with Section 12(f) of the Exchange Act.

by the Exchange or limited pursuant to Exchange rules. The Exchange proposes to include these existing provisions of Rule 11.2 within subparagraph (a) of the proposed rule in order to separately propose additional provisions under subparagraphs (b), (c), and (d).

The Exchange proposes to add new subparagraph (b) to Rule 11.2, which would state that the Exchange may determine not to designate for trading any security admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules when that security's consolidated average daily trading volume is equal to or less than 2,500 shares during the preceding 90 calendar days.[4] The Exchange further proposes to add new subparagraph (c) to Rule 11.2, which would state that any security not designated for trading by the Exchange pursuant to subparagraph (b) of this Rule may be designated for trading by the Exchange if its consolidated average daily trading volume exceeds 5,000 shares over any 90 calendar day period since the security was not designated for trading pursuant to subparagraph (b). The Exchange also proposes to make clear that new subparagraph (c) is not intended to limit the Exchange's ability to designate any security for trading pursuant to the Exchange's general authority under subparagraph (a) of Rule 11.2. The Exchange also proposes to add new subparagraph (d) to Rule 11.2, which would require the Exchange to provide notice at least one trading day in advance of any securities it is making unavailable for trading pursuant to subparagraph (b) of Rule 11.2, and any securities it is making available for trading under subparagraph (c) of Rule 11.2.

While the Exchange is proposing to retain discretion over whether it will in fact determine not to quote and trade securities that meet the criteria described in proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange notes that nothing in its rules or applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes that adopting such a provision in its rules could enhance market quality for securities falling below the consolidated average daily volume threshold by facilitating the concentration of quoted liquidity on the listing exchange.[5] In determining whether to exercise its discretion under proposed new subparagraphs (b) and (c) of Rule 11.2, the Exchange would consider such factors as member and investor feedback as well as whether the other non-listing exchanges have decided to cease quoting and trading in the effected securities. The Exchange further believes that adoption of a rule requiring it to provide advance notice to its members of any securities the Exchange is choosing not to trade under proposed new subparagraph (b) of Rule 11.2 and any securities it is making available for trading pursuant to proposed new subparagraph (c) of Rule 11.2 will help avoid confusion by providing transparency and certainty to members and investors regarding the securities the Exchange is or is not designating for quoting and trading on the Exchange.

The Exchange believes that limiting the impact of paragraph (b) of the proposed rule change to securities with a consolidated average daily trading volume that is equal to or less than 2,500 shares during the preceding 90 calendar days is reasonable because such securities tend to be illiquid, as reflected by larger quoted and effective spreads, with smaller quoted size at both the NBBO and throughout the depth of book than more actively-traded securities. Similarly, the Exchange believes that considering to designate for trading those securities that have not been trading on the Exchange pursuant to paragraph (b) once such securities have a consolidated average daily trading volume that exceeds 5,000 shares over a 90 calendar day period since the security was not designated for trading pursuant to proposed subparagraph (b) of Rule 11.2 is reasonable because such activity may demonstrate that such securities are now trading more effectively. The Exchange believes that its proposed rule changes may facilitate an improvement in market quality for the effected securities.[6] In particular, the Exchange believes that by concentrating the quoted liquidity in such securities on the listing exchange, liquidity providers will be incented to quote on such exchange more competitively, resulting in narrower bid-ask spreads and greater quoted depth of book. The Exchange believes liquidity providers would be so incented because concentrating the quoted liquidity in such securities on the listing exchange would: (i) Reduce liquidity providers' risk of adverse selection inherent in quoting in a fragmented market, (ii) provide greater certainty of execution on the one exchange at which liquidity providers are quoting, and (iii) enhance competition for order book priority at the NBBO and throughout the depth of book. Although the Exchange would be voluntarily foregoing potential market share by not quoting and trading securities subject to the Rule, the Exchange believes the aforementioned enhancements in market quality may increase investor interest in trading such securities, which in turn would generate increased volume and ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

2. Statutory Basis

The Exchange believes that the proposed rule changes are consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act'')[7] and further the objectives of Section 6(b)(5) of the Act[8] because they are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and, in general, to protect investors and the public interest.

The Exchange notes that nothing in its rules or any applicable securities regulation requires it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. However, the Exchange believes adopting a rule to clarify the circumstances under which the Exchange would voluntarily provide

[4] Based on internal statistics, the Exchange anticipates that limiting the rule's applicability to those securities with a consolidated average daily trading volume of 2,500 shares or less during the preceding 90 calendar days will affect approximately 700 securities.

[5] The Exchange understands that the EDGA Exchange, Inc., EDGX Exchange, Inc., and BATS Exchange, Inc. will separately file substantially similar proposed rule changes with the Commission.

[6] Based on an internal study, the Exchange believes a majority of the securities that would be covered by the Rule's criteria are small-cap companies (*i.e.,* companies with a market capitalization of $250 million or less). Suggesting that the current U.S. equity market often fails to provide sufficient liquidity for the securities of small-cap companies, the Commission's Advisory Committee on Small and Emerging Companies (''Advisory Committee'') recommended to the Commission concentrating the market for such securities through the creation of a separate U.S. equity market. *See Recommendations Regarding Separate U.S. Equity Market for Securities of Small and Emerging Companies,* by the Advisory Committee on Small and Emerging Companies, dated February 1, 2013. The Advisory Committee also stated that other actions with respect to trading venues may also be warranted to facilitate liquidity in small and emerging companies. *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

advance notice to the industry that it is ceasing to quote and trade certain specific illiquid securities until such securities meet and sustain a consolidated average daily volume threshold indicative of increased liquidity would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system by facilitating the concentration of displayed liquidity on the listing exchange for effected securities, which the Exchange believes could enhance the market quality of such securities.[9] The Exchange believes that concentrating displayed liquidity on the listing exchange in certain illiquid securities may enhance market quality of such securities by enabling liquidity providers to more efficiently form competitive prices at the NBBO, and to provide greater quoted depth of book. In addition, the Exchange believes that if displayed liquidity is concentrated on the listing exchange in such securities, the listing exchange may have flexibility to innovate with alternative market structures, such as variable tick sizes or periodic batch auctions that are not currently possible under Regulation NMS when multiple exchanges are quoting and trading the securities, and which may further enhance the market quality of the effected illiquid securities.[10]

The proposed rule change promotes just and equitable principles of trade because it will provide certainty and transparency to members and investors with respect to which securities the Exchange will or will not designate for quoting and trading on the Exchange, thereby avoiding confusion.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that nothing in its rules or any applicable securities regulation require it to designate for trading any class of securities listed or admitted to unlisted trading privileges on the Exchange pursuant to Chapter XIV of the Exchange's rules. The Exchange believes enacting such a provision in its rules would not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. While the Exchange will be voluntarily foregoing potential market share by not quoting and trading securities subject to the rule, the Exchange believes the proposal will enhance market quality in such securities by increasing quoting competition among liquidity providers on the listing exchange, which will result in better prices at the NBBO and greater depth of book. The Exchange further believes these enhancements in market quality may increase investor interest in trading such securities, which in turn would improve competition by generating increased volume which would also ultimately benefit the Exchange once such securities become eligible for trading on the Exchange under the rule in the future.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule changes.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, 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 email to *rule-comments@sec.gov.* Please include File Number SR–BYX–2015–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BYX–2015–25. This file number should be included on the subject line if email 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 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BYX–2015–25 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12415 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

[9] *See supra* note 6.

[10] The Exchange is not proposing or advocating any form of trade-at prohibition, which, depending on its various iterations, would generally act to prevent trading off-exchange without first executing against all equal or better priced protected quotations. Rather, the Exchange is proposing and advocating a reduction in the number of displayed venues on which certain illiquid securities will be quoted and traded, which the Exchange believes will concentrate the quoting activity serving to enhance quote competition and thereby increase market quality by narrowing the NBBO and increasing the quoted depth of book for effected securities, without regard to off-exchange trading.

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74966; File No. SR–OCC–2015–010]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of a Proposed Rule Change Concerning the Implementation of New Risk Models in Order To Support the Clearance and Settlement of Asian-Style Flexibly Structured Options and Flexibly Structured Cliquet Options

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 1, 2015, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change by OCC concerns the implementation of new risk models in order to support the clearance and settlement of Asian-style flexibly structured options (''Asian Options'') and flexibly structured Cliquet options (''Cliquet Options'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. OCC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of these statements.

A. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to describe the risk models that OCC proposes to add to its STANS methodology in order to support the clearance and settlement of Asian Options and Cliquet Options.

Background

OCC currently clears flexibly structured options on various securities indices (''Current Index Flex Options'').[3] Current Index Flex Options permit the buyer and seller to negotiate certain variable terms, pursuant to exchange rules,[4] in order to customize such terms. For example, the parties may select from a variety of underlying indices, pick a strike price and expiration date as well as pick the exercise-style of the option—*i.e.*, American or European exercise.[5] Current Index Flex Options are cash settled options for which the exercise settlement amount is determined based entirely on the strike price of a given option and the current underlying interest value on the day of exercise, in the case of American style Current Index Flex Options, or final day of trading, in the case of European style Current Index Flex Options. For risk modeling purposes, OCC computes clearing member margin requirements on Current Index Flex Options through pricing models within its STANS[6] methodology that derive prices from the implied volatility of index options with the same tenor, strike price and underlying interest.

Asian Options are European style options that use an ''Asian-style'' methodology for determining the exercise settlement amount of an option, which is the difference between the aggregate exercise price and the aggregate current underlying interest value, which is based on the average of twelve monthly price ''observations.'' Traders of Asian Options would select an observation date as well as an expiration date for the contract approximately twelve months following the contract's creation.[7] Consequently, all Asian Options for which OCC would provide clearance and settlement services would have a term of approximately one year.[8]

Cliquet Options are European style options that use a cliquet[9] method for determining the exercise settlement amount of the option, which is the greater of: (i) Zero (*i.e.*, the underlying index had negative returns during the option's tenor); and, (ii) the difference between the aggregate exercise price and the aggregate current underlying interest value, which is based on the sum of the Capped Returns (defined below) of the underlying index on 12 predetermined ''observation dates'' (each an ''Observation Date,'' and the computed value an ''Observation''). The parties to a Cliquet Option would designate a set of Observation Dates for each contract as well as an expiration date.[10] On each Observation Date, the exchange on which the Cliquet Options is listed would determine the actual return of the underlying index from observation period-to-observation period, which would be compared to the observation cap, which is an amount designated the parties to the Cliquet Option.[11] The lesser of the actual observation period-to-observation period return or the observation cap would be the Capped Return for a given Observation Date.[12]

Both Asian Options and Cliquet Options would be only available in European style exercises, and would be subject to OCC's expiration exercise procedures set forth in OCC Rule 805, as supplemented by OCC Rule 1804. In addition, OCC would initially clear Asian Options and Cliquet Options on the S&P 500 Index, Nasdaq100 Index, Russell 2000 Index and the Dow Jones Industrial Average Index and may clear Asian Options and Cliquet Options on other indices in the future.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] OCC clears Current Index Flex Options on the S&P 500® Index, S&P 100® Index, Nasdaq 100® Index and the Russell 2000® Index, among other underlying indexes.

[4] *See* OCC By-Laws Article 1, Section 1(F)(5).

[5] Options with an American style exercise may be exercised at any time prior to, and including, expiration. Options with a European style exercise may only be exercised at expiration.

[6] *See http://www.theocc.com/risk-management/margins/* for a description of OCC's margin methodology. *See also* OCC Rule 601.

[7] Expiration dates must be within 50 to 53 calendar weeks from the date of listing.

[8] If the expiration date precedes the observation date in the final month, then the final ''observation'' would be the current underlying interest value on expiration date and not the observation date. If one of the observation dates falls on a weekend or holiday, the value used would be from the previous business day.

[9] Cliquet style settlement provides for payout based on the (positive) sum of ''capped'' returns of an index on pre-determined dates over a specified period of time.

[10] Observations Dates would generally be a given date each month for the twelve months preceding the expiration date, with the last Observation Date being the expiration date. If the Observation Date chosen by the parties to a Cliquet Option precedes the expiration date then there would be two Observation Dates in the final month (*i.e.*, the expiration date would always be an Observation Date) and ten other Observation Dates; one date in each of the ten months preceding the expiration month that would coincide with the Observation Date that was chosen by the parties to a Cliquet Option (not the expiration date). Expiration dates must be within 50 to 53 calendar weeks from the date of listing. If one of the Observation Dates falls on a weekend or holiday, the previous business day would be deemed to be the Observation Date.

[11] *Id.*

[12] For example, if the actual return of the underlying index was 1.75% and the designated capped return for a Cliquet Option was 2%, the 1.75% value would be included (and not the 2%) as the value for the Observation Date. Using this same example, if the actual return of the underlying index was 3.30%, the 2% value would be included (and not the 3.30%) as the value for the Observation Date.

New Risk Models

OCC would compute clearing member margin requirements on Asian Options and Cliquet Options using its STANS methodology. Since STANS uses option prices to compute clearing member margin charges, the risk model changes necessary to accommodate the clearance and settlement of Asian Options and Cliquet Options concern the addition of appropriate price models for Asian Options and Cliquet Options. Both Asian Options and Cliquet Options are index options, and while OCC computes the price of Current Index Flex Options on indices through standard pricing models (*i.e.*, the Black-Scholes pricing model) that consider: (i) The value of the option's underlying index, (ii) the implied volatility of an option's underlying index, (iii) time until expiration, (iv) risk-free interest rate, and (v) the strike price of the option, certain modifications to OCC's existing pricing models for Current Index Flex Options are necessary in order to account for certain features of Asian Options and Cliquet Options, as described below, so that clearing member margin on such options may be computed through STANS. Accordingly, OCC proposes to implement the new pricing models described below in order to compute prices for Asian Options and Cliquet Options thereby allowing for the computation of clearing member margin requirements for such options through the STANS methodology.

Asian Options

Asian Options differ from the Current Index Flex Options currently cleared by OCC due to the option's exercise settlement amount being a function of the arithmetic average of the underlying index on certain observation dates. (In comparison, and in the case Current Index Flex Options, the exercise settlement amount of the option is a function of the value of underlying index of a given option on the exercise date or expiration date, as applicable.) Based on this phenomenon, OCC proposes to add a new pricing model for Asian Options that would be a shifted lognormal model [13] to accommodate the fact that Asian Options would have an arithmetic average value of the underlying index within the final exercise settlement amount calculation. The shifted lognormal model would account for the fact that the current underlying interest value on the expiration date of an Asian Option is based on an arithmetic average of prices, and not the value of the underlying index on the option's expiration date, which introduces non-normality into the probability distribution of contract payoffs.

With respect to the Asian Option shifted lognormal pricing model, OCC proposes to utilize a modified Black-Scholes pricing model with a shift parameter that employs the first three statistical ''moments.'' In accordance with such model, the first moment is the expected value of an Asian Option's value based on the option's implied volatility. The second moment accounts for the statistical volatility of the option's value. The third moment accounts for the statistical skewness of the option's value. The moments are intended to account for variability in the arithmetic average value of an Asian Option's underlying index. The shifted lognormal distribution (*i.e.*, the lognormal probability distribution derived using the first through third moments above) is then priced through the standard Black-Scholes equation.[14] The shift parameters are then adjusted out of the Black-Scholes price in order to derive a price for a given Asian Option that is appropriate to be utilized within the STANS methodology for the purposes of computing clearing member margin on Asian Options.

Cliquet Options

Similar to Asian Options, the price of a given Cliquet Options is based on monthly Observations of an underlying index. While a shifted lognormal model is an appropriate pricing model for Asian Options, the capped return feature of Cliquet Options makes the numerical solution to the Black-Scholes Partial Differential Equation [15] the appropriate pricing model for Cliquet Options.[16] OCC therefore proposes to add a Cliquet Option pricing model to its STANS methodology that would compute the numerical solution to the Black-Scholes Partial Differential Equation. Such a solution would provide OCC with the price of a given Cliquet Option that would be utilized within the STANS methodology for the purposes of computing clearing member margin requirements.

With respect to the pricing of a given Cliquet Option, and based on the capped return feature of Cliquet Options, OCC would identify the known implied volatility skew of standard options with the same underlying interest, a similar tenor and a similar amount of forward moneyness [17] of the given Cliquet Option. OCC's calculation of forward moneyness would include an adjustment to account for any known Observations of the underlying interest for a given Cliquet Option. The known implied volatility skew would subsequently be utilized within the Black-Scholes Partial Differential Equation so that OCC would be able to derive the price of a given Cliquet Option, which would then be utilized within the STANS methodology for purposes of computing clearing member margin requirements on a Cliquet Options.

2. Statutory Basis

OCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act [18] because it would assure the safeguarding of securities and funds which are in the custody and control of OCC. OCC believes that the proposed rule change assures the safeguarding of securities and funds in the custody and control of OCC because it would permit OCC to modify its risk models to accommodate the manner in which the exercise settlement amount for Asian Options and Cliquet Options is determined thereby permitting OCC to risk manage Asian Options and Cliquet Options through appropriate risk models. Such risk models would reduce the risk that clearing member margin assets would be insufficient should OCC need to use such assets to close-out the positions of a defaulted clearing member. In addition, the proposed rule change is consistent with Rule 17Ad–22(b)(2)

[13] *See* Andreasen, J., ''The pricing of discretely sampled Asian and lookback options: A change of numeraire approach,'' Journal of Computational Finance, September 2000. *See also* Brigo, D., Mercurio, F., Rapidsarda, F., Scotti, R., ''Approximated moment- matching dynamics for basket-options simulation,'' EFMA Lugano meetings, November 2001. *See also* Haug, E.G. and Margrabe, W., ''Asian Pyramid Power,'' Wilmott Magazine, March 2003.

[14] In connection with using the standard Black-Sholes equation, OCC would also compute each of the three moments using a random shifted lognormal variable.

[15] The differential equation model incorporates boundary conditions that ensure that the value of a given Cliquet Option is consistent throughout the equation. (Boundary conditions are necessary in order to solve differential equations.)

[16] *See* Andreasen, J., ''The pricing of discretely sampled Asian and lookback options: A change of numeraire approach.'' Journal of Computational Finance (2000). *See also* Bernard, C., & Li, W.V., ''Pricing and Hedging of Cliquet Options and Locally Capped Contracts.'' SIAM Journal on Financial Mathematics, 353–371 (2013). *See also* Hagan, P.S., Kumar, D., & Lesniewski, A.S., ''Managing Smile Risk.'' Wilmott Magazine, 84–108 (2002). *See also* Hull, John C., ''Options Futures and other Derivatives.'' McGraw Hill (2000). *See also* Kjaer, M., ''Fast pricing of cliquet options with global floor.'' Journal of Derivatives, 14(2), 47–60 (2006).

[17] Forward moneyness is the ratio of the strike to the current value of the implied forward for the index.

[18] 15 U.S.C. 78q–1(b)(3)(F).

under the Act,[19] because the proposed rule change because [sic] would allow OCC to implement risk-based models and parameters, as described above, to set margin requirements for clearing members who trade Asian Options and Cliquet Options. The proposed rule change is not inconsistent with any existing OCC By-Laws or Rules, including any rules proposed to be amended.

B. Clearing Agency's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose a burden on competition.[20] As described above, the proposed rule change concerns implementation of certain pricing models in to the STANS methodology in order to facilitate the margining of clearing member positions in Asian Options and Cliquet Options. The proposed rule change would uniformly affect all clearing members who trade Asian Options and Cliquet Options and therefore OCC does not believe that proposed rule change would impose a burden on competition.

C. Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change; or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–OCC–2015–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2015–010. This file number should be included on the subject line if email 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 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.theocc.com/components/docs/legal/rules_and_bylaws/sr_occ_15_010.pdf*.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–OCC–2015–010 and should be submitted on or before June 12, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12636 Filed 5–20–15; 4:15 pm]

BILLING CODE 8011–01–P

[19] 17 CFR 240.17Ad–22(b)(2).

[20] 15 U.S.C. 78q–1(b)(3)(I).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–9774; 34–74984; File No. 265–27]

SEC Advisory Committee on Small and Emerging Companies

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting.

SUMMARY: The Securities and Exchange Commission Advisory Committee on Small and Emerging Companies is providing notice that it will hold a public meeting on Wednesday, June 3, 2015, in Multi-Purpose Room LL–006 at the Commission's headquarters, 100 F Street NE., Washington, DC. The meeting will begin at 9:30 a.m. (EST) and will be open to the public. The meeting will be webcast on the Commission's Web site at *www.sec.gov*. Persons needing special accommodations to take part because of a disability should notify the contact person listed below. The public is invited to submit written statements to the Committee. The agenda for the meeting includes matters relating to rules and regulations affecting small and emerging companies under the federal securities laws. Notice of this meeting is less than fifteen days prior to the meeting due to an administrative delay.

DATES: The public meeting will be held on Wednesday, June 3, 2015. Written statements should be received on or before June 1, 2015.

ADDRESSES: The meeting will be held at the Commission's headquarters, 100 F Street NE., Washington, DC. Written statements may be submitted by any of the following methods:

Electronic Statements

- Use the Commission's Internet submission form (*http://www.sec.gov/spotlight/acsec-spotlight.shtml*); or
- Send an email message to *rule-comments@sec.gov*. Please include File Number 265–27 on the subject line; or

Paper Statements

- Send paper statements in triplicate to Brent J. Fields, Federal Advisory Committee Management Officer, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. 265–27. This file number should be included on the subject line if email is used. To help us process and review your statement more efficiently, please use only one method. The Commission will post all statements on the Advisory

Committee's Web site (*http://www.sec.gov/spotlight/acsec-spotlight.shtml*).

Statements also will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Room 1580, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All statements received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Julie Z. Davis, Senior Special Counsel, at (202) 551–3460, Office of Small Business Policy, Division of Corporation Finance, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: In accordance with Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C.-App. 1, and the regulations thereunder, Keith Higgins, Designated Federal Officer of the Committee, has ordered publication of this notice.

Dated: May 18, 2015.

Brent J. Fields,

Committee Management Officer.

[FR Doc. 2015–12379 Filed 5–21–15; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14312]

MASSACHUSETTS Disaster #MA–00064 Declaration of Economic Injury

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the Commonwealth of Massachusetts, dated 05/15/2015.

Incident: Record-breaking Snowfall and Extreme Cold Temperatures.

Incident Period: 01/26/2015 through 02/22/2015.

DATES: *Effective Date:* 05/15/2015.

EIDL Loan Application Deadline Date: 02/15/2016.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Middlesex, Norfolk, Plymouth

Contiguous Counties:

Massachusetts: Barnstable, Bristol, Essex, Suffolk, Worcester

New Hampshire: Hillsborough

Rhode Island: Providence

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.625

The number assigned to this disaster for economic injury is 143120.

The States which received an EIDL Declaration # are: Massachusetts, New Hampshire, Rhode Island.

(Catalog of Federal Domestic Assistance Number 59002)

Dated: May 15, 2015.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2015–12370 Filed 5–21–15; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2015–0030]

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections, and reinstatements of previously OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.* Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2015–0029].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than July 21, 2015. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Statement of Funds You Provided to Another and Statement of Funds You Received—20 CFR 404.1520(b), 404.1571–404.1576, 404.1584–404.1593 and 416.971–416.976—0960–0059. SSA uses Form SSA–821–BK to collect recipient employment information to determine whether recipients worked after becoming disabled and, if so, whether the work is substantial gainful activity. SSA's field offices use Form SSA–821–BK to obtain work information during the initial claims process, the continuing disability review process, and for Supplemental Security Income (SSI) claims involving work issues. SSA's processing centers and the Office of Disability and International Operations use the form to obtain post-adjudicative work issue from recipients. SSA reviews and evaluates the data to determine if the applicant or recipient meets the disability requirements of the law. The respondents are applicants and recipients of Title II Social Security and SSI disability payments.

Type of Request: Reinstatement with change of a previous OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–821–BK	300,000	1	30	150,000

2. Coverage of Employees of State and Local Governments—20 CFR 404, Subpart M—0960–0425. The Code of Federal Regulations at 20 CFR 404, Subpart M, prescribes the rules for States submitting reports of deposits and recordkeeping to SSA. States (and interstate instrumentalities) are required to provide wage and deposit contribution information for pre-1987 periods. Not all states have completely satisfied their pending wage report and contribution liability with SSA for pre-1987 tax years. These regulations are needed until all pending items with all states are closed out, and to provide for collection of this information in the future, if necessary. The respondents are State and local governments or interstate instrumentalities.

Type of Request: Reinstatement without change of a previously approved collection.

Regulation section	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
404.1204 (a) & (b)	52	1	30	26
404.1215	52	1	60	52
404.1216 (a) & (b)	52	1	60	52
Total	156			130

3. Credit Card Payment Form—0960–0648. SSA uses Form SSA–1414 to process: (1) Credit card payments from former employees and vendors with outstanding debts to the agency; (2) advance payments for reimbursable agreements; and (3) credit card payments for all Freedom of Information Act (FOIA) requests requiring payment. The respondents are former employees and vendors who have outstanding debts to the agency, entities who have reimbursable agreements with SSA, and individuals who request information through FOIA.

Type of Request: Reinstatement without change of a previous OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1414	6,000	1	2	200

4. Social Security Administration Health IT Partner Program Assessment—Participating Facilities and Available Content Form—20 CFR 404.1614, 416.1014, 24 CFR 495.300–495.370—0960–0798. The Health Information Technology for Economic and Clinical Health (HITECH) Act promotes the adoption and meaningful use of health information technology (IT), particularly in the context of working with government agencies. Similarly, section 3004 of the Public Health Service Act requires health care providers or health insurance issuers with government contracts to implement, acquire, or upgrade their health IT systems and products to meet adopted standards and implementation specifications. To support expansion of SSA's health IT initiative as defined under HITECH, SSA developed Form SSA–680, the Health IT Partner Program Assessment—Participating Facilities and Available Content Form. The SSA–680 allows healthcare providers to provide the information SSA needs to determine their ability to exchange health information with us electronically. We evaluate potential partners (*i.e.,* healthcare providers and organizations) on (1) the accessibility of health information they possess, and (2) the content value of their electronic health records' systems for our disability adjudication processes. SSA reviews the completeness of organizations' SSA–680 responses as one part of our careful analysis of their readiness to enter into a health IT partnership with us. The respondents are healthcare providers and organizations exchanging information with the agency.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (hours)	Estimated total annual burden (hours)
SSA–680	30	1	5	150

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding the information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication.

To be sure we consider your comments, we must receive them no later than June 22, 2015. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

1. Application for Supplemental Security Income—20 CFR 416.305–416.335, Subpart C—0960–0444. SSA uses Form SSA–8001–BK to determine an applicant's eligibility for SSI and SSI payment amounts. SSA employees also collect this information during interviews with members of the public who wish to file for SSI. SSA uses the information for two purposes: (1) Formally deny SSI for non-medical reasons when information the applicant provides results in ineligibility; or (2) establish a disability claim, but defer the complete development of non-medical issues until SSA approves the disability. The respondents are applicants for SSI.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
MSSICS/Signature Proxy	1,195,521	1	20	398,507
Non-MSSICS (Paper)	140,145	1	20	46,715
Totals	1,335,666			445,222

2. Statement of Reclamation Action—31 CFR 210—0960–0734. Regulations governing the Federal Government Participation in the Automated Clearing House (1) allow SSA to send Social Security payments to Canada, and (2) mandate the reclamation of funds paid erroneously to a Canadian bank or financial institution after the death of a Social Security beneficiary. SSA uses Form SSA–1713, Notice of Reclamation Action, to determine if, how, and when the Canadian bank or financial institution is going to return erroneous payments after the death of a Social Security beneficiary who elected to have payments sent to Canada. Form SSA–1712 (or SSA–1712 CN), Notice of Reclamation-Canada Payment Made in the United States, is the cover sheet SSA prepares to request return of the payment. The respondents are Canadian banks and financial institutions who erroneously received Social Security payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–1713	15	1	5	1

Dated: May 19, 2015.

Faye I. Lipsky,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2015–12454 Filed 5–21–15; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Fifteenth Meeting: RTCA NextGen Advisory Committee (NAC)

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

ACTION: Fifteenth Meeting Notice of RTCA NextGen Advisory Committee.

SUMMARY: The FAA is issuing this notice to advise the public of the fifteenth meeting of the RTCA NextGen Advisory Committee.

DATES: The meeting will be held June 5, 2015 from 9 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at RTCA Headquarters, NBAA/Colson Conference Rooms 1150, 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.* Andy Cebula, NAC Secretary can also be contacted at *acebula@rtca.org* or 202–330–0652.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of Special Committee 224. The agenda will include the following:

June 5th

- Opening of Meeting/Introduction of NAC Members—Chairman Richard Anderson, Chief Executive Officer, Delta Air Lines, Inc.
- Official Statement of Designated Federal Official—The Honorable Mike Whitaker, FAA Deputy Administrator
- Review and Approval of February 26, 2015 Meeting Summary
- Chairman's Report—Chairman Anderson
- FAA Report—Mr. Whitaker
- NextGen Integration Working Group (NIWG) Reports—Surface, Performance Based Navigation, Multiple Runway Operations, DataComm
- Harmonization of DataComm
- NACSC Metrics AdHoc Group Report
- NAC ADS–B AdHoc Group Report
- FAA Response to RTCA ''Blueprint for Success to Implementing Performance Based Navigation'' Recommendation
- Summary of meeting and next steps—DFO and NAC Chairman Closing Comments
- Other business
- Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on May 19th 2015.

Mohannad Dawoud,

Management Analyst, NextGen, Program Oversight and Administration, Federal Aviation Administration.

[FR Doc. 2015–12517 Filed 5–19–15; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate for the use of non-domestic Cargo Cranes with minimum capacity of 92.5 US tons for Cleveland-Cuyahoga Ports Authority in the State of Ohio.

DATES: The effective date of the waiver is May 26, 2015.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366–1562, or via email at *gerald.yakowenko@dot.gov.* For legal questions, please contact Mr. Jomar Maldonado, FHWA Office of the Chief Counsel, (202) 366–1373, or via email at *Jomar.Maldonado@dot.gov.* Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Publishing Office's database at: *http://www.access.gpo.gov/nara.*

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate for use of non-domestic Cargo Cranes with minimum capacity of 92.5 US tons for Cleveland-Cuyahoga Ports Authority in the State of Ohio.

In accordance with Division K, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2015'' (Pub. L. 113–235), the FHWA published a notice of intent to issue a waiver on its Web site for non-domestic Cargo Cranes (*http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=105*) on March 11. The FHWA received no comments in response to the publication. During the 15-day comment period, FHWA conducted additional review to locate potential domestic manufacturers of Cargo Cranes that meet the project specifications. Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers of the Cargo Cranes that meet the specifications for Cleveland-Cuyahoga Ports Authority.

In accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), FHWA is providing this notice as its finding that a waiver of Buy America requirements is appropriate. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to the FHWA's Web site via the link provided to the Ohio waiver page noted above.

(Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410)

Issued on: May 8, 2015.

Gregory G. Nadeau,

Acting Administrator, Federal Highway Administration.

[FR Doc. 2015–12456 Filed 5–21–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0047]

Public Hearing To Determine Whether Fiat Chrysler Has Reasonably Met Its Obligations To Remedy Recalled Vehicles and To Notify NHTSA, Owners, and Purchasers of Recalls

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of public hearing.

SUMMARY: NHTSA will hold a public hearing on whether Fiat Chrysler Automobiles US LLC (Fiat Chrysler) has reasonably met its obligations to remedy recalled vehicles and to notify NHTSA, owners, and purchasers of recalls.

DATES: The public hearing will be held beginning at 10 a.m. ET on July 2, 2015, at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. If you wish to attend or speak at the hearing, you must register in advance no later than June 30, 2015 (and June 26, 2015, for non-U.S. citizens), by following the instructions in the *Procedural Matters* section of this notice. NHTSA will consider late registrants to the extent time and space allows, but cannot ensure that late registrants will be able to attend or speak at the hearing. To ensure that NHTSA has an opportunity to consider comments, NHTSA must receive written comments by June 23, 2015.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *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 a.m. and 5 p.m. ET, 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 office at 202–366–9324.

Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: For registration to attend or speak at the public hearing: Carla Bridges, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (Telephone: 202–366–2992) (Fax: 202–366–3820). For hearing procedures: Justine Casselle, Office of the Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (Telephone: 202–366–2992) (Fax: 202–366–3820). Information regarding recalls is available on NHTSA's Web site: *http://www.safercar.gov.* To find recalls by NHTSA Recall Number: (1) In the drop-down menu in the lower right-hand corner for ''Shortcut search for a recall,''

select ''by Campaign ID Number''; (2) click ''Go''; (3) select the box for ''Recalls''; (3) enter the recall number; and (4) click ''GO.''

SUPPLEMENTARY INFORMATION: NHTSA has substantial concerns about the significant safety hazards posed to consumers in connection with Fiat Chrysler's administration and execution of its recalls. Pursuant to 49 U.S.C. 30118(e) and 30120(e), and 49 CFR 557.6(d) and 557.7, NHTSA has decided to hold a public hearing on whether Fiat Chrysler has reasonably met its obligations under the National Traffic and Motor Vehicle Safety Act, as amended (Safety Act), to remedy recalled vehicles and to provide notifications regarding its recalls.

The public hearing may address recalls including NHTSA Recall Nos. 13V–038, 13V–252, 13V–527, 13V–528, 13V–529, 14V–373, 14V–391, 14V–438, 14V–567, 14V–634, 14V–749, 14V–795, 14V–796, 14V–817, 15V–041, 15V–046, 15V–090, 15V–114, 15V–115, and 15V–178. The recall campaigns are to address the following:

1. Loosening of the rear axle pinion nut causing loss of vehicle control (13V–038);
2. Rear fuel tank structure's risk of failure (13V–252);
3. Failure of the left tie rod assembly resulting in loss of steering control (13V–527);
4. Failure of the left tie rod assembly resulting in loss of steering control (13V–528);
5. Failure of the left tie rod assembly resulting in loss of steering control (13V–529);
6. Inadvertent ignition switch movement turning off the engine (14V–373);
7. Vanity lamp wiring shortages resulting in fire (14V–391);
8. Inadvertent ignition switch movement turning off the engine (14V–438);
9. Inadvertent ignition switch movement turning off the engine (14V–567);
10. Sudden failure of the alternator (14V–634);
11. Inoperative instrument cluster causing vehicle failure (14V–749);
12. Broken springs in the clutch ignition interlock switch (14V–795);
13. Loosening of the rear axle pinion nut causing loss of vehicle control (14V–796);
14. Potential air bag inflator rupture with metal fragments causing serious injury (14V–817);
15. Unintended air bag deployment during vehicle operation (15V–041);
16. Unintended air bag deployment during vehicle operation (15V–046);
17. Contaminated, dislodged or broken parking pawl or park rod (15V–090);
18. Fuel leak near an ignition source (15V–114);
19. Fuel pump relay causing a vehicle to stall without warning (15V–115); and,
20. Driver and passenger side door latch failure (15V–178).

Based on information presented at the public hearing and other available information, NHTSA may issue an order that could include a finding that Fiat Chrysler failed to carry out its recall requirements under the Safety Act and requiring Fiat Chrysler to take specific actions to comply with the law.

Any interested person may make written and/or oral presentations of information, views, and arguments on whether Fiat Chrysler has reasonably met the remedy and/or notification requirements. There will be no cross-examination of witnesses. 49 CFR 557.7.

NHTSA will consider the views of participants in deciding whether Fiat Chrysler has reasonably met the notification and/or remedy requirements under 49 U.S.C. 30118 and 30120, and in developing the terms of an order (if any) requiring Fiat Chrysler to take specified action as the remedy for the recalls and/or take other action. 49 U.S.C. 30118(e), 30120(e); 49 CFR 557.8.

Procedural Matters: Interested persons may participate in these proceedings through written and/or oral presentations. Persons wishing to attend must notify Carla Bridges, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (Telephone: 202–366–2992) (Fax: 202–366–3820), before the close of business on June 30, 2015 (and June 26, 2015, for non-U.S. citizens). Each person wishing to attend must provide his or her name and country of citizenship. Non-U.S. citizens must also provide date of birth, title or position, and passport or diplomatic ID number, along with expiration date. Each person wishing to make an oral presentation must also specify the amount of time that the presentation is expected to last, his or her organizational affiliation, phone number, and email address. NHTSA will prepare a schedule of presentations. Depending upon the number of persons who wish to make oral presentations and the anticipated length of those presentations, NHTSA may limit the length of oral presentations.

For security purposes, photo identification is required to enter the U.S. Department of Transportation building. To allow sufficient time to clear security and enter the building, NHTSA recommends that hearing participants arrive 30 to 60 minutes prior to the start of the public hearing.

The hearing will be held at a site accessible to individuals with disabilities. Individuals who require accommodations, such as sign language interpreters, should contact Ms. Justine Casselle using the contact information in the **FOR FURTHER INFORMATION CONTACT** section above no later than June 24, 2015. A transcript of the proceedings will be placed in the docket for this notice at a later date.

Persons who wish to file written comments should submit them so that they are received by NHTSA no later than June 23, 2015. Instructions on how to submit written comments to the docket is located under the **ADDRESSES** section of this notice.

Authority: 49 U.S.C. 30118(e), 30120(e); 49 CFR 557.6(d), 557.7; delegations of authority at 49 CFR 1.95(a) and 501.2(a)(1).

Dated: May 18, 2015.

Mark R. Rosekind,

Administrator.

[FR Doc. 2015–12386 Filed 5–21–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Notice of Intent To Open a Coordinated Remedy Program Proceeding for the Replacement of Certain Takata Air Bag Inflators

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of intent to open a coordinated remedy program proceeding for the replacement of certain Takata air bag inflators pursuant to 49 U.S.C. 30120(c)(3) and other authority.

SUMMARY: In order to organize and prioritize vehicle manufacturer's recall and remedy programs to address defective Takata frontal air bag inflators, the National Highway Traffic Safety Administration (''NHTSA'') is providing notice of NHTSA's intent to open proceedings pursuant to its authority under 49 U.S.C. 30120(c)(3) and other authority. NHTSA is considering implementing these remedy programs for all manufacturers and suppliers involved in the recalls of defective Takata air bag inflators. This notice explains NHTSA's authority to open such a proceeding and describes some of the issues that the agency would consider, and information the agency

would request from commenters, as part of such a proceeding.

FOR FURTHER INFORMATION CONTACT: Arija Flowers, Trial Attorney, Office of the Chief Counsel, NCC–111, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590 (telephone: 202–366–8714).

SUPPLEMENTARY INFORMATION: In order to ensure that all vehicles in the United States are equipped with safe air bags as quickly as possible and to reduce the risk of serious injury or death due to an inflator rupture, NHTSA is considering exercising its authority under the National Traffic and Motor Vehicle Safety Act of 1966, as amended and recodified (the ''Safety Act''), 49 U.S.C. 30101, *et seq.,* to organize and prioritize the remedy programs of BMW of North America, LLC (''BMW''), Chrysler Group, LLC (''Chrysler''), Daimler Trucks North America, LLC (''DTNA''), Ford Motor Company (''Ford''), General Motors, LLC (''GM''), American Honda Motor Company (''Honda''), Mazda North American Operations (''Mazda''), Mitsubishi Motors North America, Inc. (''Mitsubishi''), Nissan North America, Inc. (''Nissan''), Subaru of America, Inc. (''Subaru''), and Toyota Motor Engineering and Manufacturing (''Toyota'') (collectively, the ''Manufacturers''), and TK Holdings, Inc. (''Takata'') to address Takata frontal air bag inflators. Specifically, NHTSA is issuing this notice pursuant to its authority under the Safety Act to ''accelerate'' a remedy program, 49 U.S.C. 30120(c)(3) and 49 CFR 573.14, as delegated by the Secretary of Transportation, 49 CFR 1.95, 501.2(a)(1), to inspect and investigate, 49 U.S.C. 30166(b)(1), and to ensure that defective vehicles and equipment are recalled, 49 U.S.C. 30118–30119.

On May 18, 2015, Takata filed four Defect Information Reports (''DIR's'') pursuant to 49 CFR 573.6. In those DIR's, Takata determined that a defect exists in certain models of frontal air bag inflators (PSDI, PSDI–4, PSDI–4K, SPI, PSPI and PSPI–L).

The Safety Act requires manufacturers to remedy safety-related defects in motor vehicles. 49 U.S.C. 30120(a). If the Secretary of Transportation determines that a manufacturer's remedy program is not likely to be capable of completion within a reasonable time, the Secretary may require the manufacturer to ''accelerate'' the remedy program if the Secretary finds that there is a risk of serious injury or death if the remedy program is not accelerated and that acceleration of the remedy program can be reasonably achieved by expanding the sources of replacement parts, expanding the number of authorized repair facilities, or both. *Id.* § 30120(c)(3). The Secretary has delegated his authorities under the Safety Act to the NHTSA Administrator, 49 CFR 1.95(a), 501.2(a)(1). Each of the Manufacturers has elected a remedy program of repair of the affected vehicles. *See* 49 U.S.C. 30120(a)(1)(A). These remedy programs are individual to each of the Manufacturers, creating a patch-work solution that NHTSA believes may not adequately address the safety risks presented by the defective Takata inflators within a reasonable time. Regardless of root cause, these recalls involve the same safety risk: The risk of the air bag inflator rupturing when the air bag is inflated, which may result in serious injury or death to vehicle occupants without any prior warning.

The number of impacted vehicles and manufacturers in combination with the supply issues related to these air bag recalls adds a previously unprecedented level of complexity to this recall and remedy process. Given the number of manufacturers (11) and the technical complexity of the issues involved, NHTSA intends to open a Section 30120(c)(3) proceeding, and has therefore issued this Notice of Intent to inform the public.

The goal of a Section 30120(c)(3) proceeding is for the agency to consider whether (and if so, how) to organize and prioritize the recall and remedy programs of the Manufacturers, in order to aid the Manufacturers in accomplishing their significant task of replacing all defective Takata air bag inflators.

As part of a Section 30120(c)(3) proceeding, NHTSA plans to consider the views of commenters regarding NHTSA's exercising its authority with respect to recall and remedy programs involving certain defective Takata frontal air bag inflators, including, but not limited whether it should, and on what terms, issue an order to ''accelerate'' all applicable recall remedy programs, which could include, but not be limited to, provisions regarding sourcing, production, allocation, delivery, installation, and adequacy of the remedy.

Further, as part of a Section 30120(c)(3) proceeding, NHTSA would specifically request comments on how the Manufacturers would comply with an organization and prioritization of remedy directive, the possible terms of any such order and, in particular, how NHTSA should order the sourcing of the replacement parts for Manufacturers, whether NHTSA should issue the remedy order to some but not all Manufacturers, whether NHTSA should order the Manufacturers to prioritize certain vehicles or certain regions in its allocation of replacement parts and how, and whether NHTSA should order a re-replacement schedule for replacement frontal inflators if Takata cannot provide assurances for the ongoing safety of the inflators.

Upon NHTSA's opening of a Section 30120(c)(3) proceeding, additional information, including how to comment, will be published in a supplemental **Federal Register** Notice.

Authority: 49 U.S.C. 30101, *et seq.,* 30118–30119, 30120(c)(3), 30166(b)(1); 49 CFR 573.6, 573. 14; delegations of authority at 49 CFR 1.95(a), 501.2(a)(1).

Issued: May 18, 2015.

Mark R. Rosekind,

Administrator

[FR Doc. 2015–12449 Filed 5–21–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[OCC Charter Number 706335]

St. James Federal Savings and Loan Association, St. James, Minnesota; Approval of Conversion Application

Notice is hereby given that on May 14, 2015, the Office of the Comptroller of the Currency (OCC) approved the application of St. James Federal Savings and Loan Association, St. James, Minnesota, to convert to the stock form of organization. Copies of the application are available for inspection on the OCC Web site at the FOIA Electronic Reading Room *https://foia-pal.occ.gov/palMain.aspx.* If you have any questions, please call OCC Licensing Activities at (202) 649–6260.

Dated: May 14, 2014.

By the Office of the Comptroller of the Currency.

Stephen A. Lybarger,

Deputy Comptroller for Licensing.

[FR Doc. 2015–12395 Filed 5–21–15; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0085]

Agency Information Collection (Appeal to Board of Veterans' Appeals) Activity Under OMB Review

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

ACTION: Notice; correction

SUMMARY: The Department of Veterans Affairs (VA) published a collection of information notice in a **Federal Register** February 19, 2015, that contained an error. The notice incorrectly stated the agency as ''Office of Acquisition, Logistics and Construction, Department of Veterans Affairs.'' This document corrects the error by correcting the name of the agency.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at 202–632–7492.

Correction

In FR Doc. 2015–03425, published on February 19, 2015, at 80 FR 8952 make the following correction. On page 8952, at the top of the page, the name of the agency should read as follows:

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015–12369 Filed 5–21–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Research Advisory Committee on Gulf War Veterans' Illnesses; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2 that the Research Advisory Committee on Gulf War Veterans' Illnesses will meet on June 23, 2015, in Washington, DC. The meeting will be held in Room 230, 810 Vermont Avenue NW., Washington, DC, from 9:00 a.m. until 5:30 p.m. All sessions will be open to the public. Interested persons who cannot attend the meeting may use this toll-free telephone number (800) 767–1750; access code 56978# to listen to the meeting.

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on proposed research studies, research plans, and research strategies relating to the health consequences of military service in the Southwest Asia Theater of operations during the Gulf War in 1990–1991.

The Committee will review VA program activities related to Gulf War Veterans' Illnesses, and receive updates on relevant scientific research published since the last Committee meeting. Presentations will include updates on the VA Gulf War Research Program, followed by research presentations describing treatments and treatment research involving Gulf War Veterans. There will also be a discussion of Committee business and activities.

The meeting will include time reserved for public comments in the afternoon. A sign-up sheet for 5-minute comments will be available at the meeting. Individuals who wish to address the Committee may submit a 1–2 page summary of their comments for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Dr. Roberta White at *rwhite@bu.edu.*

Because the meeting is being held in a Government building, a photo I.D. must be presented as part of the clearance process; therefore, any person attending should allow an additional 15 minutes before the meeting begins. Any member of the public seeking additional information should contact Dr. White, Scientific Director, at (617) 638–4620 or Dr. Victor Kalasinsky, Designated Federal Officer, at (202) 443–5682.

Dated: May 19, 2015.

Rebecca Schiller,

Advisory Committee Management Officer.

[FR Doc. 2015–12428 Filed 5–21–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Genomic Medicine Program Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Genomic Medicine Program Advisory Committee will meet on June 30, 2015, at the Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, Room 230 (Sonny Montgomery Room). The meeting will convene at 9:00 a.m. and adjourn at 5:00 p.m. The meeting is open to the public.

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Veterans Affairs on using genetic information to optimize medical care for Veterans and to enhance development of tests and treatments for diseases particularly relevant to Veterans.

The Committee will receive program updates and continue to provide insight into optimal ways for VA to incorporate genomic information into its health care program while applying appropriate ethical oversight and protecting the privacy of Veterans. The meeting focus will be on developing and implementing phenotyping and computational requirements for the Million Veteran Program. Public comments will be received at 3:30 p.m. and are limited to 5 minutes each. Individuals who speak are invited to submit a 1–2 page summary of their comments for inclusion in the official meeting record to Dr. Sumitra Muralidhar, Designated Federal Officer, 810 Vermont Avenue NW., Washington, DC 20420, or by email at *sumitra.muralidhar@va.gov.* Any member of the public seeking additional information should contact Dr. Muralidhar at (202) 443–5679.

Dated: May 19, 2015.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2015–12511 Filed 5–21–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 80 Friday,

No. 99 May 22, 2015

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 401, 488 and 489

Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 488 and 489

[CMS–3255–F]

RIN 0938–AQ33

Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the survey, certification, and enforcement procedures related to CMS oversight of national accrediting organizations (AOs). The revisions implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The revisions also clarify and strengthen our oversight of AOs that apply for, and are granted, recognition and approval of an accreditation program in accordance with the statute. The rule also extends some provisions, which are applicable to Medicare-participating providers, to Medicare-participating suppliers subject to certification requirements, and clarifies the definition of ''immediate jeopardy.''

DATES: This final rule is effective on July 21, 2015.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310 or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Acronyms

ADI Advanced Diagnostic Imaging Services
AO Accrediting Organization
ASC Ambulatory Surgical Center
CAH Critical Access Hospital
CfC Condition for coverage
CFR Code of Federal Regulations
CMHC Community Mental Health Center
CMS Center for Medicare & Medicaid Services
CoP Condition of Participation
CORF Comprehensive Outpatient Rehabilitation Facility
EMTALA Emergency Medical Treatment and Labor Act
GAO Government Accountability Office
HHA Home Health Agency
HHS [Department of] Health and Human Services
LSC Life Safety Code
MIPPA Medicare Improvements for Patients and Providers Act of 2008
NF Nursing Facility
OIG Office of the Inspector General
OPT Provider of outpatient physical therapy and speech language pathology services
RHC Rural Health Clinic
SA State Survey Agency
SNF Skilled Nursing Facility
SOM State Operations Manual
The Act Social Security Act
TJC The Joint Commission

I. Background

To participate in the Medicare program, providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Social Security Act (the Act), as well as any additional regulatory requirements specified by the Secretary of the Department of Health and Human Services (HHS). These requirements are generally called ''conditions of participation'' (CoPs) for most providers, ''requirements'' for skilled nursing facilities (SNFs), ''conditions for coverage'' (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and ''conditions for certification'' for rural health clinics (RHCs). A provider or supplier that does not substantially comply with the applicable requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey institutional health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements (as applicable), and certify their findings to us. Based on these state survey agency (SA) certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows ''provider entities'' which include all types of providers and suppliers subject to certification, with the exception of kidney transplant programs and end stage renal dialysis facilities, to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accrediting organization (AO). If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed all applicable Medicare CoPs, requirements, CfCs, or conditions for certification, then any provider or supplier accredited by the AO's CMS-approved Medicare accreditation program may be deemed by us to meet the Medicare requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring that providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS, for a period not to exceed 6 years. The AO must reapply for renewed CMS approval of an accreditation program before the date that its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at §§ 488.1 through 488.9.

In accordance with § 488.8(f), if we determine that an AO's accreditation program requirements are no longer comparable to Medicare requirements we may open a deeming authority review and give the AO up to 180 days to adopt comparable requirements. If at the end of the deeming authority review period, the AO's accreditation program has failed to adopt comparable requirements, we may give the AO conditional approval with a probationary period for up to one year. Within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice (including reasons for the determination) to the AO and, in the case of a decision to terminate approval, to affected providers or suppliers.

In addition, section 1834(e) of the Act requires that, beginning January 1, 2012, Medicare payment may only be made for the technical component of advanced diagnostic imaging (ADI) services paid under the physician fee schedule to a supplier who is accredited by an AO designated by the Secretary. Oversight of these AOs is limited to the requirements at § 414.68, rather than those for accreditation programs based on section 1865 of the Act, codified at 42 CFR part 488, subpart A.

Section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008), entitled ''Revocation of Unique Deeming Authority of The Joint Commission,'' removed prior subsection (a) of section 1865 of the Act and redesignated the remaining subsections. The effect of this removal was to give the Joint

Commission's (TJC) hospital accreditation program the same regulatory status as all other accreditation programs, that is, subject to CMS approval, in accordance with section 1865 of the Act. It also removed from section 1861(e) of the Act, which provides the definition of a hospital for Medicare purposes, references to TJC's hospital accreditation program and replaced them with references to accreditation programs recognized by the Secretary in accordance with section 1865(a) of the Act. Similar revisions were made to section 1875(b) of the Act, which had the effect of expanding the requirement for us to report annually to Congress on the performance of TJC's hospital program to a requirement to report on all accreditation programs approved in accordance with section 1865 of the Act.

Previously, in response to recommendations of the HHS Office of Inspector General (OIG) and the Government Accountability Office (GAO) to strengthen our oversight and ensure greater accountability of AOs, particularly for hospitals, the Secretary instructed CMS to respond appropriately.[1] AOs and their CMS-approved Medicare accreditation programs significantly impact the health and safety of patients and the quality of care provided in Medicare-participating facilities across the country. We currently have 21 approved accreditation programs offered by nine national AOs. In fiscal year 2013, accredited facilities deemed to meet Medicare standards accounted for over 13,000 Medicare-participating facilities (not including accredited clinical laboratories). With the MIPPA statutory amendments Congress provided us with additional authority to strengthen our oversight.

Part 489 consists of regulations codifying Medicare provider agreement requirements found in section 1866 of the Act. Currently, certain provisions of part 489, such as the regulation governing the effective date of a Medicare agreement at § 489.13, apply to both providers, as well as to supplier types that are subject to certification requirements. However, other provisions pertinent to termination of such Medicare agreements apply only to providers. Part 489 also contains a definition of ''immediate jeopardy'', which applies to all types of certified providers and suppliers, but which employs terminology pertinent only to residential healthcare facilities.

In the April 5, 2013 **Federal Register**, we published the proposed rule ''Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures'', and provided for a 60-day public comment period (78 FR 20564). In the May 24, 2013 **Federal Register**, we published a notice extending the deadline for the comment period from June 4, 2013, to July 5, 2013 (78 FR 31472).

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Summary of the Proposed Rule

To conform our regulations to the MIPPA revisions to section 1865 of the Act, we proposed to eliminate the requirements at current § 488.5. That regulation currently addresses hospital accreditation by TJC (previously known as JCAHO) and AOA separately. The regulation also fails to reflect the statutory requirement at section 1865(a)(1) of the Act (as revised by MIPPA) that an AO's Medicare accreditation program meet or exceed all, that is, each, applicable requirement separately.

We also proposed numerous revisions to clarify and reorganize the existing regulations, to eliminate potentially confusing and unnecessary duplication, as well as to strengthen our ongoing oversight processes, consistent with the recommendations of the OIG, and the GAO. All 21 CMS-approved AO Medicare accreditation programs have received extensive reviews in accordance with the application and reapplication processes described at part 488 in recent years. The high volume of comprehensive AO application and reapplication reviews that we conducted has provided us with an abundance of opportunities to apply the existing AO oversight regulations in a variety of circumstances. This experience has helped us to identify areas of our regulations that need revision to more clearly articulate our intentions. Furthermore, we have become aware of the need to clarify, reorganize, and amend our regulations to support a more efficient and effective oversight process. In several situations, we had to require an AO to implement corrective action(s) to ensure comparability with the Medicare requirements. We have also opened deeming reviews outside the normal reapplication process, and issued conditional approvals with a probationary period. We believe it is necessary to revise and expand our enforcement tools to strengthen our ability to address serious and pervasive areas of AO non-compliance with the Medicare requirements; ensure that the AO takes the necessary corrective actions to address areas of non-compliance; and ensure continuing compliance and comparability with Medicare requirements.

To ensure that AOs are enforcing Medicare standards adequately, SAs, under the authority of section 1864 of the Act, often perform additional follow-up surveys on CMS' behalf to ensure that AOs are holding provider entities accountable for compliance with Medicare requirements. These Medicare validation surveys are of two types. The first is a comprehensive survey of a representative sample of provider entities' operations. The second is a ''substantial allegation validation survey'', carried out in response to an allegation from an outside party that a specific provider entity is in violation of Medicare CoPs, CfCs, or requirements. The scope of these surveys is limited to the matter that was the subject of the complaint.

Currently, when a ''substantial allegation validation survey'' of an accredited provider or supplier finds substantial non-compliance with one or more of Medicare's conditions or requirements, we have limited flexibility in terms of our next steps. We may either proceed immediately to enforcement action based on that substantial allegation validation survey, or may require the SA to conduct another, full survey which assesses compliance with all of the CoPs or CfCs for that type of provider or supplier. We proposed to expand our flexibility to provide a third option for a SA to conduct another, more comprehensive survey, but not a full survey. This would allow us to make efficient use of survey resources while maintaining an effective enforcement process that is appropriate for each specific case.

We also proposed to expand the scope of the AO oversight regulations at part 488, subpart A to include AOs with CMS-approved Medicare accreditation programs for ADI services. This proposed expansion was part of our initiative to broaden our quality oversight of both the CMS-approved

[1] HCFA's Approval and Oversight of Private Accreditation Organizations (HEHS–99–197R), September 30, 1999. *http://www.gao.gov/products/HEHS-99-197R.*

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals (GAO–04–850) July 20, 2004. *http://www.gao.gov/new.items/d04850.pdf.*

Hospital Oversight in Medicare: Accreditation and Deeming Authority. May 6, 2005. *http://www.nhpf.org/library/issue-briefs/IB802_Accreditation_05-06-05.pdf.*

Moffett, M. & Bohara, A. Hospital Quality Oversight by the Joint Commission on Accreditation of Healthcare Organizations. Vol.31, No.4 (Fall 2005) pp 629–647.

AOs, as well as the suppliers of ADI services, which would include future rulemaking to develop and implement more detailed Medicare health and safety standards which the designated AOs must incorporate into their accreditation programs for suppliers of these services.

We proposed to amend part 489 to use more appropriate terminology in the definition of ''immediate jeopardy'' and to extend certain of the provisions governing termination of provider agreements to certified suppliers.

B. Public Comments Received

We received 50 timely pieces of correspondence in response to the April 5, 2013 proposed rule. Most of the comments came from AOs and hospital associations or individual hospitals, with a few comments from practitioner organizations and from groups of patient/resident advocates. This final rule discusses the provisions of the April 5, 2013 proposed rule, summarizes the public comments received on each provision, sets out our response to those comments, and sets forth the provisions of our final rule.

1. General Comments

Many commenters presented brief comments expressing opposition to the proposed rule, but their comments were so vague that we are unable to provide specific responses to them.

Comment: Several commenters stated that the framework for oversight of hospital accreditation established with the creation of Medicare in 1965 was a public-private partnership. One commenter stated that this ''partnership'' presumed that TJC applied higher standards than the Medicare standards, and that SA surveys and certification were never intended to supplant accreditation or become the national benchmark for assessing the quality of care in accredited health care organizations. The commenter stated that the original partnership premise has been replaced by a contractor type of arrangement whereby government sets the terms for AOs at all levels of their processes, standards and functioning, replacing professionally recognized standards as the driver/gold standard. The commenter also stated that there are adverse consequences to the quality of care from CMS' enforcement approach to AO oversight. They stated that: AOs feared to make changes to their programs for fear of being out of step with the State Operations Manual; consistency among AOs was preferred to celebrating their differences that would lead to positive results; excessive CMS focus on too many unimportant issues would result in lost opportunities to work with AOs collaboratively on important quality and safety issues; increased consumption of government and private sector resources on administrative issues brought no value to health care; CMS's methodology was an implicit rejection of AOs' quality improvement since CMS expected accrediting organizations to cite any provider's deviation from a standard, no matter how small or infrequent. The commenter stated that the current scheme caused providers to drop accreditation because of frustration at being held to standards that mimic government standards or because accreditation did not protect them from being surveyed by an SA; that CMS had an inordinate focus on administrative metrics in the performance evaluation of AOs; that there was excess government spending on state investigation of complaints rather than trusting AOs to handle complaints; and that the system resulted in enormous spending by providers to address non-value driven or inappropriate State Operations Manual requirements. The commenter objected to CMS's refusal to allow AOs to provide Life Safety Code (LSC) waivers or equivalencies; to the general atmosphere of distrust between CMS and AOs; and to CMS's disproportionate emphasis on the results of validation surveys, which should be conducted by CMS staff rather than SA surveyors, who, they asserted, were often biased against AOs.

Response: We disagree with the commenter. The statutory framework established in section 1865 of the Act, both before and after the MIPPA amendments, prescribes neither a ''partnership'' nor a ''contractor'' relationship between CMS and AOs. Instead, section 1865 of the Act establishes the criteria for our approval of a national AO's Medicare accreditation program(s), and provides specifically for SAs to conduct validation surveys to validate the oversight by AOs of certified providers and suppliers which they accredit. Section 1875(b) of the Act requires us to report to Congress annually on the operation and administration of AOs, explicitly including the validation surveys specified in section 1865 of the Act. Moreover, the MIPPA amendments of 2008 clearly establish that all accreditation programs, including TJC's hospital accreditation program, are subject to the same CMS oversight. Furthermore, section 1864 of the Act establishes that surveys by SAs are the method by which CMS establishes a provider's or supplier's compliance with the applicable Medicare statutory definition and implementing regulations, with section 1865 of the Act creating a voluntary alternative option for providers or suppliers to substitute accreditation for a state survey in those cases where CMS has approved a national AO's Medicare accreditation program. There is no basis in the statute for the commenter's assertion that SA surveys and certification were never intended to ''supplant'' accreditation. Surveys conducted by SAs on our behalf assess compliance with the applicable Medicare requirements. While an AO's survey may also assess compliance with their own additional, more stringent standards, there cannot be any conflict between the standards of a Medicare accreditation program and those applied by state surveyors, since the express language of section 1865(a)(1) of the Act requires that we find that an AO's program meets or exceeds all applicable Medicare requirements.

Likewise, the commenter's concern that an AO cannot issue waivers to the LSC requirements adopted in various CoPs or CfCs reflects a misunderstanding of our policy. We are not delegating this authority to either the SAs or AOs. The commenter's references to the State Operations Manual (SOM) also appear to be inappropriate, since this manual provides interpretive guidance for the certification regulations at part 488, as well as for the provider-specific CoPs, CfCs, requirements or conditions for certification. If the commenter believes that any particular provider/supplier-specific regulations are in need of revision, there are appropriate avenues outside the AO oversight process for pursuing those changes. In fact, we have published three regulations since 2012 with the express purpose of reducing unnecessary burdens on certified providers and suppliers (''Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation'' published in the **Federal Register** on May 16, 2012 (77 FR 29034); ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction'' published in the **Federal Register** on May 16, 2012 (77 FR 29002); and ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'' published in the **Federal Register** on May 12, 2014 (79 FR 27106), and many of the ideas for changes made via those regulations came from AOs, as well as regulated

providers and suppliers. Most importantly, the commenters' objections to the regulatory framework for our oversight of providers or suppliers seem to focus on the current substantive regulatory requirements for those specific providers or suppliers, and they are not suggesting that our proposed revisions created these issues.

We did not propose to change the current regulatory framework to create a ''partnership'' relationship such as the one that the commenters would prefer, nor are we amending our proposal to do so in this final rule, because we believe a ''partnership'' approach would be inconsistent with the statutory requirements, as well as with the recommendations of both GAO and OIG to strengthen our oversight of AOs.

Comment: Some commenters expressed general opposition to the regulation on the basis that it would subject AOs to standards and survey processes that can be out-of-date, ineffective or inappropriate to the delivery of high quality care. Commenters stated that the delivery of sophisticated, rapidly evolving, and technologically intensive services needs to be evaluated using state-of-the art knowledge and standards. Some of these commenters objected to AOs being held to requirements of the SOM, which is not subject to public notice or comment.

Response: We believe the commenters' concerns appear to be with the substantive regulations underlying the SOM, since the manual does not by itself create requirements for Medicare providers and suppliers. The SOM provides interpretive guidance on the requirements established under the provider- and supplier-specific CoPs, requirements, CfCs or conditions for certification, as well as under part 488, governing survey, certification, and accreditation processes in general. These underlying regulations are subject to notice and public comment. Moreover, the provider- and supplier-specific regulations are often written in broad terms that require adherence to generally accepted standards of practice, to enable updates to guidance via the SOM that reflect changes in such standards of practice, without having to go through the more time-consuming process of revising regulations. All SOM revisions are subject to review to ensure that they do not exceed the authority of our regulations, and are guidance, not legal requirements in and of themselves. We occasionally may solicit input from members of the general public before we finalize such guidance. Further, as previously stated, we have over the past 2 years proposed and adopted numerous changes to the CoPs, requirements, CfCs, and conditions for certification to remove outdated and unnecessary requirements, and the SOM is generally revised to reflect these changes. It should be noted that we never object to an AO establishing accreditation requirements that exceed Medicare's requirements; problems arise only when an AO's standards are more permissive than, or in conflict with, the Medicare requirements. Since section 1865 of the Act requires an AO's program to meet or exceed all Medicare requirements, we are obligated either to not approve that program or to require changes to the program as a condition of approval or continued approval. To the extent that the commenters' concerns are with the underlying substantive Medicare requirements that an AO's standards must meet or exceed, it is beyond the scope of this regulation to address those concerns.

Comment: One commenter stated support for the proposed rule, which he found reasonable. The commenter believes the proposed rule provided clarity and direction to AOs on a variety of issues.

Response: We appreciate the commenter's support.

Comment: One commenter stated that a historical anomaly gave a single hospital accreditor statutory recognition and allowed it to avoid many of the requirements imposed on other hospital accreditors that were subject to CMS oversight. As a result, the commenter, a different AO, stated, this made its own hospital accreditation program more rigorous, but also gave it a more burdensome, less flexible appearance. The commenter stated that health care systems with hospitals accredited under both AOs found it difficult to harmonize their processes due to these differences. The commenter stated it had expected that when the statute was changed in 2008 and all AOs came under CMS oversight that this problem would be corrected. However, the commenter stated that this was not the case, and that so-called legacy issues remain 5 years later. For this reason the commenter indicated its reluctance to unconditionally endorse the more demanding oversight requirements embodied in the proposed regulation until CMS demonstrates its willingness and ability to apply its requirements across the board to all AOs.

Response: We are committed to treating all AOs subject to our oversight in the same manner. The commenter is correct that a number of legacy issues came to light that we had not identified during the initial application review process for the AO program affected by the MIPPA amendments, given the complexity of that hospital accreditation program. As legacy issues have been identified we have and will continue to work diligently to assure that all AOs are treated equitably and fairly.

Comment: One commenter called the proposed rule a reflection of CMS's commitment to continuously improve its regulations so that they effective promote accountability, protect public health and safety, and improve operational efficiency. The commenter indicated their understanding of the need for tighter controls and strict application of standards and their appreciation of how this will effectuate the safe and consistent delivery of quality care to patients. The commenter also stated that the challenge is to understand how to preserve the innovative aspects of quality by balancing the necessarily prescriptive characteristics of accreditation with the ability to promote quality using multiple techniques, and expressed his hope that the proposed rule would leave room for some degree of flexibility as AOs continue to navigate this inherent and dynamic tension.

Response: We appreciate the commenter's statements about the regulation. It is our intention to provide AOs the flexibility to innovate within the framework of assuring that the statutory requirements to meet or exceed the Medicare requirements are met.

Comment: A group of commenters expressed concern that the proposed rule left open the possibility that CMS could potentially approve an AO's application for a Medicare-approved accreditation program for Medicare skilled nursing facilities. The commenters noted that section 1865(a) of the Act exempts nursing homes from the categories of providers that are automatically afforded deemed status via Medicare-approved accreditation programs, and sets a higher bar for deeming SNFs because of strong public sentiment that SNF/NF residents should be protected by a publicly accountable federal and state survey and enforcement system. The commenters cite the objections of TJC and the healthcare industry to the proposed rule as evidence why they do not believe we should allow powerful private entities to become entrenched in LTC facility certification. They further state that while the federal/state survey and certification system has not achieved its supporters' expectations, it is still a transparent system whose activities are visible to the public and accountable to beneficiaries, taxpayers and Congress. In the view of these commenters, deemed status promotes secrecy and prohibits

disclosure of information, involves an inherent conflict of interest for AOs, involves an inappropriate consultative, collaborative approach to surveys, lacks accountability to the public, and inappropriately separates the survey process from enforcement, since AOs must refer cases to CMS for enforcement. The commenters indicated their support of our intent to issue regulations to clarify and strengthen our oversight of AOs, but believe that the proposed regulations do not, and probably could not, address what they view are the inherent flaws in the structure, which favors resolution of compliance problems in a non-public process after evaluation by private organizations that maintain a fiduciary relationship with providers. Another group of organizations representing long term care advocacy groups expressed similar concerns, and urged CMS to continue to refuse to permit deemed status for long term care facilities. This group also noted that AOs would be unable to comply with requirements under the Nursing Home Reform Law and the Nursing Home Transparency and Improvement provisions of the Affordable Care Act (Title VI, Subtitle B, sections 6101 through 6121), which among other things, establish a resident's right to examine the results of the most recent survey, and require states to post the survey reports of long term care facilities on the states' Web sites. They also suggest CMS could not maintain Nursing Home Compare without submission of survey report data and categorization of some long term care facilities as special focus facilities. This group also asserted that AOs miss serious problems, noting that research by another commenter on the proposed rule stated that four ''special focus facilities,'' that is, SNFs/NFs whose citation history has led CMS to identify them as having serious, systemic noncompliance issues warranting heightened attention and enforcement action, were currently accredited by an AO, suggesting that there is a serious discrepancy between the standards/survey process used by CMS and those of AOs.

Response: We thank the commenters for their support of our effort to clarify and strengthen our oversight of AOs. The commenters' remarks about the inherent problems they see in permitting a role for private AOs in the Medicare certification process are outside the scope of this proposal, since the statute specifically permits AOs to play such a role. The primary purpose of our proposed revisions to part 488 was to ensure that the regulations are consistent with the statutory provisions at section 1865 of the Act.

The statute distinguishes AO programs for skilled nursing facilities (SNFs) from other accreditation programs for which AOs seek CMS approval in two respects: (1) The statutory timeframe for completing our review of an AO's application for our approval does not apply to accreditation programs for SNFs (section 1865(a)(3)(B) of the Act); and (2) even if we find that an AO's SNF accreditation program meets or exceeds all applicable requirements, we nevertheless have the discretion to not approve that accreditation program. Unlike the situation with kidney transplant and end stage renal dialysis programs, which, in accordance with the provisions at section 1865(a)(1) of the Act, we may not consider for deemed status, the statute does not permit us to refuse to accept for review an AO's application for approval of a Medicare SNF accreditation program. Accordingly, we proposed revisions to the regulations to recognize the technical possibility that at some future date an AO may choose to submit an application for our approval of a Medicare SNF accreditation program.

However, we emphasize that it was not the intent of our proposed revisions to signal any interest on our part in receiving AO applications for approval of a Medicare long term care facility accreditation program. We are on record in an earlier report to Congress as observing:

> ''A fundamental question is the appropriateness of allowing a private entity to perform an important public function. In some sense, Congress has already decided the ''appropriateness'' issue for skilled nursing facilities (SNFs) by granting the Secretary ''discretion'' to grant deemed status provided that accreditation offers a reasonable assurance that Medicare conditions of participation or, for SNFs, requirements, are met. In another sense, probably due to the concerns expressed by deeming's opponents, Congress has circumscribed the ''appropriateness'' issue by exempting SNFs from those accredited provider types for which the Secretary ''must'' accord deemed status if it is found that private accreditation demonstrates compliance with Medicare conditions of participation or requirements. . . . Given that the studies produced overwhelming evidence that the [private AO] surveyors often miss serious deficiencies, in some cases even apparently unjustified deaths, the potential cost savings to deeming would not appear to justify the risk to the health and safety of the vulnerable nursing home population. . . . If future empirical studies produce convincing evidence that LEAP, other accrediting organizations, or a revised JCAHO survey meets all the criteria for comparability with the HCFA survey discussed in this report, then it might be time to revisit the issue of deeming.'' (Executive summary, *HCFA Report to Congress: Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System,* July 1, 1998, accessed on line at *https://archive.org/stream/reporttocongress00unit_11/reporttocongress00unit_11_djvu.txt* 8/6/2014).

There has been no evidence since we issued that report that convinces us that we should reconsider our position. To the contrary, in our recent annual reports to Congress on the performance of AOs with CMS-approved accreditation programs we have continued to identify persistent disparities in identification of significant deficient practices by AOs when compared to SAs through the validation survey program. We continue to work with the AOs through our oversight activities to identify and address the sources of these disparities, but this more recent evidence is consistent with the position that we adopted in 1998.

Further, the commenters raise important issues about the apparent contradictions between section 1865 of the Act's prohibition on disclosure of most accreditation surveys and other statutory provisions that require disclosure of all long term care facility surveys. Should we ever receive an application from an AO seeking our approval of a Medicare SNF accreditation program, these and other similar issues would weigh very heavily in any decision on our part whether to exercise our discretion to disapprove a Medicare SNF accreditation program, regardless of whether the AO's application suggested that its requirements met or exceeded the Medicare SNF requirements.

Upon closer review we also acknowledge that the wording of one proposed provision did not adequately reflect the special statutory status of SNFs at section 1865(a)(3)(B) of the Act. Proposed § 488.5(f)(2) indicated that we would publish a final notice of our decision on an AO's application within 210 calendar days from the date we determined the application to be complete, and proposed § 488.5(f)(2)(ii) would require us to describe, if denying approval, how an organization failed to provide reasonable assurance that its accredited providers or suppliers meet the applicable Medicare requirements. However, section 1865(a)(3)(B) of the Act excepts SNFs from this process. Accordingly, in response to comments, we are revising the proposed provision at § 488.5(e)(2) to indicate that the 210

day period to publish a final notice does not apply when the application is for a SNF accreditation program, and that we may disapprove a SNF accreditation application based either on its failure to provide reasonable assurances to CMS regarding the equivalence of its accreditation program, or based on our decision to exercise our discretion to not approve the AO's application for any other reason, in accordance with section 1865(a)(1)(B) of the Act.

2. Accreditation of Advanced Diagnostic Imaging Suppliers

Comment: One commenter indicated concern for our proposal to include oversight of the accreditors of the technical component of ADI services under part 488. The commenter noted that ADI AOs are currently subject to oversight regulations at § 414.68, which were only adopted in 2010 and which physician suppliers of ADI have been gaining familiarity. The commenter further noted that CMS proposed to retain those regulations in addition to applying the proposed regulations at part 488. The commenter indicated concern that the part 488 requirements, which heretofore only applied to AOs for hospitals and other specified providers and suppliers, would significantly expand the rules applying to ADI accreditation, thus imposing undue burdens on both ADI physician suppliers and their patients. The commenter noted that physician practices are already struggling to keep up with numerous new federal rules and stated they should not be subjected to yet another swath of new requirements and/or increased fees via the accreditation process. The commenter objected to the following proposals: The disclosure of accreditation survey information in connection with a CMS enforcement action; loss of accredited status by physician ADI suppliers if CMS withdraws its approval of the ADI accrediting program without any assurance that the supplier would have enough time to obtain timely accreditation elsewhere, unlike the arrangement under § 414.68; the requirement to notify of an SA that it has submitted an application for accreditation when SAs play no role in oversight of ADI suppliers; requirements for ADI suppliers to submit to validation surveys, permit photocopying of any records and grant immediate access to state survey entities or face termination of their Medicare participation, again when SAs have no role to play. The commenter urged us to carefully consider the inconsistencies between our 2010 rulemaking for ADI accreditation and this proposed rule, and to rescind our proposal in light of the practical difficulties of applying the standards of hospital accreditation to physician office-based suppliers of ADI.

Response: We do not agree that individual elements of increased AO oversight are inappropriate or overly burdensome for suppliers of the technical component of ADI services. We discussed in the proposed rule our initiative to broaden our quality oversight of both the CMS-approved AOs, as well as suppliers of ADI services, indicating we anticipated future rulemaking to develop and implement Medicare health and safety standards for suppliers of ADI services that must be incorporated into all ADI accreditation programs. This initiative is consistent with the GAO's recommendations in its May, 2013 report, ''Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services.'' However, we agree with the commenter that it is not appropriate to include ADI AOs and suppliers of the technical component of ADI services in the framework of part 488, which was designed to address issues related to SA surveys and voluntary accreditation of providers and suppliers that are subject to CoPs, CfCs, conditions for certification or long term care requirements to participate in the Medicare or Medicaid programs. Additionally the commenter is correct in noting that we did not propose to rescind § 414.68, so that adoption of our proposed rule would leave ADI AOs subject to two different set of requirements. In light of these considerations, we are removing from this final rule all provisions that would have the effect of subjecting accreditors of suppliers of the technical component of ADI services to the provisions of part 488. At a future date we expect to propose Medicare health and safety standards for suppliers of ADI services that must be incorporated into all ADI accreditation programs, and also to propose revisions to § 414.68 which we believe necessary to strengthen our oversight of ADI accreditors.

In response to comments, we also note that our proposed definition did not clearly exclude physician practices, and it was never our intent to imply that they might be subject to the provisions of parts 488 and 489. Also, the proposed definition incorrectly referred to transplant centers as a type of supplier when in fact they are neither a discrete provider or supplier type, but rather a part of a certified hospital that is subject to additional conditions. The proposed definition also excluded from the definition end stage renal dialysis facilities, which are subject to many of the provisions of part 488, even though they are not eligible by statute to participate in Medicare via deemed status.

We have also had questions about what categories of supplier are subject to accreditation requirements. We believe that to ensure an accurate definition of the suppliers to which part 488 applies, it would be better to enumerate the covered supplier types. Accordingly, in this final rule we are withdrawing our proposed revision to the definition of ''supplier'' at § 488.1 and will continue to rely upon the current definition.

We are also removing the reference to ''1843(e) [sic]—Requirements for Advanced Diagnostic Imaging (ADI) Services'' at § 488.2, Statutory basis.

3. Definitions (§ 488.1)

Section 488.1 sets forth definitions for terms used in part 488. We proposed revisions at § 488.1 as follows:

- We proposed deleting the definition of ''accredited provider or supplier.'' Use of this language has caused confusion both internally and externally. National AOs offer a variety of accreditation programs. However, not all programs are CMS-approved accreditation programs for the purpose of Medicare participation. We received no comments on this proposed revision.
- We proposed deleting the language, ''AOA stands for the American Osteopathic Association.'' The proposed revisions to subpart A would no longer refer to any specific AO. The proposed revisions instead are broader, referencing national AOs generically. We received no comments on this proposed revision.
- We proposed expanding the definition of ''certification'' to include the rural health clinic (RHC) conditions for certification; clarifying that each provider or supplier must meet its respective conditions or requirements to be certified; and deleting the language ''for SNFs and NFs'' to eliminate redundancy. We received no comments on this proposed revision.
- We proposed adding a definition of ''conditions for certification'' to include the terminology for standards that RHCs must meet to participate in the Medicare program. We received no comments on this proposed revision.
- We proposed adding a definition of ''deemed status'' to increase clarity and reduce ambiguity when referring to the status of providers and suppliers accredited under a CMS-approved accreditation program and who are

participating in Medicare via this accreditation.

Comment: One commenter found the following statement within the definition of ''deemed status'' confusing. The proposed definition reads: ''Deemed status is an alternative to regular surveys by the SA to determine whether or not it continues to meet the Medicare requirements.'' The commenter believes this might be especially confusing for health care organizations that might not be familiar with the deeming ''partnership.'' This commenter suggested instead including a statement in the definition saying that voluntary accreditation by a CMS-approved AO is an alternative to regular surveys by the SA.

Response: We agree with the commenter that the definition could be clearer and are revising it in this final rule to indicate that it means that we have certified a provider or supplier for Medicare participation based on its having been accredited under an approved, applicable Medicare accreditation program, the AO has recommended it for certification based on its accreditation, and we have accepted this recommendation and found that all other participation requirements have been met.

• We proposed revising the definition of ''full review'' to clarify that the regulations at part 488 apply to all providers and suppliers, not just hospitals. We received no comments on this proposed revision.

• We proposed adding a definition of ''immediate jeopardy'' at § 488.1 that would apply generically to all providers and suppliers subject to the certification requirements at part 488. The proposed definition matched the revision we proposed to the definition of ''immediate jeopardy'' at § 489.3. Comments we received are included in our discussion of the part 489 proposed amendments.

• We proposed deleting the language, ''JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations,'' since the proposed revisions to subpart A do not refer to any specific AO. We received no comments on this proposed revision.

• We proposed adding a definition of ''national accreditation organization'' to specify that CMS requires a program for which an AO is seeking initial approval to already be fully implemented and operational nationally.

Comment: We received several comments on this proposal. One commenter proposed that we modify that part of the definition that describes the providers and suppliers accredited by national AOs by replacing the phrase ''healthcare facility'' with ''healthcare organization''. The commenter stated this modification better describes organizations that are ''entities'' which may not be traditional bricks & mortar establishments with a physical building at which services are provided. Several commenters proposed modifying the definition to include a minimum quantitative threshold for accredited facilities to be considered ''national.'' Another commenter stated that CMS should not exceed the existing criteria that an accreditation program includes at least one facility in each of at least five states to be considered national.

Response: We agree that the term ''health care facility'' could be misconstrued to refer only to providers or certified suppliers who provide their services in traditional bricks and mortar settings, rather than to those which provide services in the patient's home, such as home health agencies or hospices. To address this ambiguity, we believe it would be more precise to use the term ''provider entity,'' which is used in section 1865 of the Act, rather than the commenter's suggested term, ''healthcare organization.'' Section 1865(a)(4) of the Act defines a ''provider entity'' as ''a provider of services, supplier, facility, clinic, agency, or laboratory.'' Therefore, we are, in this final rule, revising the definition to replace the term ''health care facility'' with ''provider entity.''

We note that once an AO has a CMS-approved Medicare accreditation program for a specific type of provider or supplier, it must only accredit provider entities consistent with the organization's description as set out in its Medicare provider agreement. For example, a Medicare hospital accreditation program may not award one accreditation to two hospitals that each have a separate Medicare agreement (and thus are two provider entities), nor can it award two accreditations, one for each campus, of a two-campus hospital that participates in Medicare under one Medicare agreement (and thus is one provider entity).

We do not require an AO seeking initial CMS approval of a new Medicare accreditation program to have already accredited at least one provider entity in at least five states, as the commenter suggested, for us to approve it. Not only do we not employ such an inflexible quantitative approach now, we do not agree with the commenters who recommended that we incorporate such an approach in the regulatory definition of a national AO. We require a program seeking initial approval to already be fully implemented, operational, and widely dispersed geographically throughout the country, but we do not establish a minimum or a specific geographic distribution for provider entities that the program must have already accredited. We expect an initial application to demonstrate that the AO is capable of scaling up over time to handle additional facilities. To avoid creating artificial barriers to entry by new AO programs, we believe there should be flexibility for us to review the application submitted by an applicant against these criteria, without our prescribing a more detailed and uniform formula that every applicant must satisfy.

• We proposed expanding the definition of ''provider of services or provider'' to include a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech language pathology services. This proposed change is consistent with the language at section 1861(p)(4) of the Act. We received no comments on this proposal.

• We proposed revising the definition of ''reasonable assurance'' by deleting the language ''taken as a whole.'' This proposed change would clarify the requirement that an AO's CMS-approved accreditation program has standards that meet or exceed all applicable Medicare conditions or requirements, consistent with language at section 1865(a)(1) of the Act.

Comment: A number of commenters expressed concern with removing the language, ''taken as a whole,'' from the definition of ''reasonable assurance.'' The commenters interpreted the intent of the proposed definition to be a requirement for an exact, one-one correlation of the AO's standards and survey processes with those utilized by SAs in the SOM. Another commenter suggested that we add to the definition the following wording to indicate that requirements which are not identical may achieve the same patient safety goals: ''. . .although AO standards and Medicare requirements need not be identical.'' Still another commenter stated it opposes a requirement for a one-to-one match between AO requirements and the CoPs, and requests we modify the definition to clarify that AO requirements need not be identical to Medicare requirements but would be acceptable if they achieve the same patient safety.

Response: We believe that the language, ''taken as a whole,'' is not consistent with section 1865(a)(1) of the Act, which requires that a national AO demonstrate that its Medicare accreditation program meets or exceeds all, that is, each, of the conditions or

requirements applicable under the Act. The same objection applies to the alternate language proposed by the commenters related to AO standards being acceptable if they achieve the same ''patient safety'' or ''patient safety goals.'' In fact, the CoPs, requirements, CfCs and conditions for certification applicable to the various types of providers and certified suppliers are generally referred to as the Medicare ''health and safety standards'' that we have determined to be necessary for the health, safety and well-being of patients and residents (see, for example, the terminology in section 1861(e)(9) of the Act, related to hospitals). Therefore, we believe that the statutory requirement for AOs to demonstrate that they meet or exceed each of the applicable Medicare requirements is the manner in which AOs demonstrate that their accreditation programs achieve patient safety goals.

Further, when determining if all requirements are met or exceeded in an AO's program, we are required under section 1865(a)(2) of the Act to consider the AO's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance and its ability to provide us with necessary information for validation. Our primary purpose for proposing to revise part 488 was to align our regulatory requirements with the revised statutory requirements.

We also note that the language, ''taken as a whole,'' in the current definition of ''reasonable assurance'' also contradicts the current § 488.8(a)(1), which requires us, when reviewing an AO's application, to review and evaluate the ''equivalency'' of an AO's accreditation requirements to the comparable Medicare requirements. Likewise, the current regulation at § 488.8(d)(1) requires us to compare the ''equivalency'' of an AO's accreditation requirements to the comparable Medicare requirements when we impose new requirements or change our survey process; when an AO proposes to adopt new requirements or change its survey process; or when our approval of the AO's program has been in effect for the maximum term specified in the final approval notice. In our review of an AO's standards, we have adhered to the requirements at § 488.8, which we believe are consistent with the statutory requirements. Finally, even though an AO must demonstrate that its program meets or exceeds all applicable requirements, it is not our practice to insist that the AO's program exactly replicate the wording or organization of our regulations, or the procedures we establish for SAs. We require AOs to include in their applications a crosswalk in which they identify which of their requirements are comparable to each Medicare requirement. We then evaluate on a case-by-case basis whether accreditation program standards, survey and enforcement processes substantively are equivalent to or exceed the identified comparable Medicare standards, survey and enforcement procedures. We also review the submitted crosswalk to ensure that the AO has identified comparable requirements for every Medicare requirement. After due consideration of the comments, we are adopting in this final rule the definition of ''reasonable assurance'' as proposed.

- We proposed updating the definition of ''SA'' for added clarity and precision. We received no comments on this proposal.
- We proposed revising the definition of ''substantial allegation of non-compliance'' to correct a previous error.

Comment: One commenter suggested, for the definition of ''substantial allegation of noncompliance'', that complaints only be submitted in writing and that they not be permitted to be anonymous, to allow an AO to gather and verify all necessary data and avoid spending resources on an unfounded allegation. Another commenter suggested revising the definition to include the following language: ''could or may *materially* affect the health and safety of patients . . .'' This commenter stated that the language in the current definition is so broad and vague that SAs conduct about 4000 complaint surveys annually in accredited hospitals, but over the past decade only 5 or 6 percent of these surveys have resulted in condition-level deficiency citations.

Response: Part 488 establishes definitions and requirements that are applicable, depending on the context, to actions taken by an SA, AOs or CMS. The term ''substantial allegation of noncompliance'' is used in the current regulations at § 488.7(a) (and in the final rule we are adopting at § 488.9(a)) to describe one circumstance in which we may require an SA to conduct a validation survey of a deemed status provider entity. Validation surveys may be authorized either on a representative sample basis or in response to substantial allegations of noncompliance. We apply the term ''substantial allegation of noncompliance'' to describe the complaints we or SAs receive regarding a deemed status provider entity that are of a serious nature and which, if found to be true, would mean that the provider entity failed to comply with at least one of the Medicare conditions or requirements applicable to it. Such substantial noncompliance may be grounds for terminating the provider entity's Medicare agreement and participation in the Medicare program (with the exception of long-term care facilities, whose standards are enforced under sections 1819(h)(2) and 1919(h)(2) of the Act). Section 1864(c) of the Act authorizes us to use SAs to investigate substantial allegations of noncompliance concerning a deemed status provider entity.

It is our longstanding policy, reflected in the current definition of this term, that we and SAs accept complaints from a variety of sources, including anonymous sources, communicated in any of a wide variety of methods, not just in writing. It has been our experience that complaints can be a very effective means to focus survey activity to identify serious noncompliance by a provider or supplier. The definition for a substantial allegation of noncompliance is used to establish a threshold for us to authorize an SA investigation of a complaint concerning a deemed status provider entity. Thus, we believe the commenter who suggested that all complaints be in writing and that anonymous complaints not be accepted is misunderstanding the context in which this definition is used, given that the commenter's rationale for the suggested changes is that they would make it easier for AOs to gather and validate data related to complaints the AO investigates.

For the suggestion that the word ''materially'' be added to the definition, we do not believe that this would add any more specificity or clarity. We believe that the language about the complaint raising doubts as to a provider's or supplier's compliance with any Medicare CoP, CfC, condition for certification, or other requirement is sufficiently clear. In recent years, we have provided additional guidance and training on the appropriate triage categories for complaints to both our regional offices, and to SAs, which receive most of the complaints. The fact that only 7.4 percent of complaint surveys (based on FY 2012 and FY 2013 data) resulted in citations of condition-level noncompliance does not necessarily mean that the other complaints were not credible allegations that warranted further investigation.

In the course of reviewing the comments on this definition we reviewed not only the current definition

found at § 488.1 but also the statutory basis for a complaint-driven validation survey in section 1864(c) of the Act. Section 1864(c) of the Act permits us to authorize a state to conduct a validation survey of a deemed status provider entity because of a ''substantial allegation of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients.'' We believe that our proposed definition should adhere more closely to this language by using the term ''would'', as does the definition currently found at § 488.1, instead of ''could or may'' and are therefore reverting to the terminology found in the current rule. Further, since a provider entity could include providers that have ''residents'' instead of ''patients'', in the interest of clarity we believe the definition should also refer to ''residents,'' and are therefore revising the definition upon adoption to refer to both residents and patients We are also changing the phrase ''that is,'' when referring to sources of complaints, to ''such as,'' since the brief list that follows the phrase is clearly intended to provide examples and not be an all-inclusive list.

- We proposed modifying the definition of ''supplier'' to make it consistent with the definition of supplier as amended by section 901 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) and to add a clarification that for the purposes of part 488 the term ''supplier'' does not include suppliers of durable medical equipment and supplies, kidney transplant centers, or end stage renal dialysis facilities. As indicated in our earlier response to comments about the inclusion of suppliers of the technical component of ADI services, we are in this final rule withdrawing our proposal to revise the definition of ''supplier'' and reverting to the current definition, which enumerates the types of certified suppliers covered by part 488. There were no comments on this.
- We proposed deleting the definition of ''validation review period.'' The concept of a fixed review period would not be used in the proposed revisions at § 488.8.

Comment: One commenter objected to our proposal to delete the definition of the term ''validation review period,'' stating that it will be difficult to validate the AO survey if significant time has passed, since the provider may have undergone significant changes in practice, policies, procedures and processes.

Response: We believe the commenter misunderstood the way in which the term ''validation review period'' is used in the current regulations, and thus the effect of our proposal to delete this term. The term ''validation review period'' under the current regulation refers to the 1 year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by an accrediting organization. After a ''validation review period,'' as set out in the current regulation at § 488.8(d)(2), CMS will conduct a ''validation review'' if an AO has a disparity rate greater than 20 percent; CMS may also conduct a validation review if survey results suggest systemic problems in an AO's accreditation process. As discussed concerning our proposal for revisions at § 488.8, we proposed to replace the concept of a ''validation review'' with the broader concept of a ''performance'' review, making the definition of a ''validation review period'' unnecessary.

However, we believe the commenter is referring, instead, to a maximum length for the time interval between an AO's survey of a provider or supplier and the SA's conduct of a representative sample validation survey of that provider or supplier. We are retaining our current policy, which permits us to use, when calculating the validation survey disparity rate for our annual report required under section 1875 of the Act, only those validation surveys conducted by SAs no more than 60 days after the conclusion of the AO's survey. We note that section 3242 of the SOM articulates the requirement for SAs to adhere to the 60-day timeframe for conducting a representative sample validation survey. After due consideration of these comments, we are, in this final rule, not incorporating a definition of a ''validation review period.''

4. Conditions of Participation; Conditions for Coverage; Conditions for Certification; and Long-Term Care Requirements (§ 488.3).

Section 488.3 sets forth the conditions or requirements that a prospective provider or supplier must meet to be approved for participation in or coverage under the Medicare program. We proposed revising § 488.3 to include the statutory citations and/or regulatory references for CAHs, RHCs, hospitals that provide extended care services, hospices, CORFs, CMHCs, OPTs, and ADIs. In addition, we proposed to revise § 488.3(b) to address all providers as well as suppliers of services subject to certification. This proposal would also authorize the Secretary to consult with SAs and other organizations, which would include all AOs and other national standard-setting organizations to develop CoPs.

Comment: Many commenters expressed concerns that the proposed revisions to § 488.3(b) reflect a change in policy that is inconsistent with the requirements under section 1863 of the Act for us to consult with appropriate SAs and national accrediting bodies when determining CoPs. One commenter stated that AOs have rigorous standards development processes and the ability to stay current with standards of medical practice in a way that the CoPs do not. Another commenter indicated that making consultation optional could lead to development of regulations that are not best practices and therefore negatively impact patient care.

Response: Section 1863 of the Act requires us to consult with appropriate SAs and national accrediting bodies when determining CoPs for hospitals, psychiatric hospitals, SNFs, HHAs, CORFs, hospices and ASCs. By contrast, the current language at § 488.3(b)(1) states, the Secretary, after consultation with the JCAHO or AOA, may issue Conditions of Participation for hospitals higher or more precise than those of either those accrediting bodies. This language was related to the now-deleted provision of section 1865 of the Act which concerned hospital accreditation by TJC, rather than to section 1863 of the Act. We note that it has been our longstanding position that the consultation required under section 1863 of the Act is adequately addressed through the public notice and comment process for adopting new or revised CoPs. It was our intent to broaden the option for consultation provided in § 488.3(b) beyond the hospital CoPs, to include the regulations governing all providers, as well as those for suppliers of services subject to certification, not just hospitals. Additionally, we proposed to remove reference to specific AOs found in the current regulatory language, consistent with our policy of referring to national AOs generically throughout the proposed rule to reflect changes made by MIPPA. However, given that § 488.3(b)(1) and (2) include provisions that clearly implement requirements under section 1863 of the Act, we agree with the commenters that § 488.3(b) should also be worded in a manner consistent with this section. We are, therefore revising, § 488.3(b) to state under ''Special conditions'' that there shall be consultation with SAs and national AOs.

5. CMS-Approved National Accreditation Programs for Providers and Suppliers (§ 488.4)

We proposed to revise § 488.4 as part of our effort to reorganize the application and reapplication process, delete redundancy, and reorganize the accreditation requirements in a more logical sequence as follows:

• We proposed at § 488.4(a) to replace the requirements currently set out at § 488.6(a), with some modifications. The current regulation specifically lists the eligible provider and supplier accreditation programs under which AOs may provide us with reasonable assurance that the AO's requirements are at least as stringent as the Medicare conditions or requirements. We proposed eliminating references to specific types of provider and supplier accreditation programs by simply stating that CMS-approved accreditation program for providers and suppliers with the exception of kidney transplant centers, end stage renal dialysis facilities, and suppliers of medical equipment and supplies may provide reasonable assurance to CMS that it requires providers and suppliers it accredits to meet the requirements that are at least as stringent as the Medicare conditions or requirements. Also, since this section addresses national accreditation programs for hospitals other than those offered by TJC and AOA, as well as accreditation programs for other types of providers and suppliers, we proposed deleting the reference to ''requirements concerning hospitals accredited by the JCAHO or AOA.''

• We stated in the preamble that we were proposing at § 488.4(b) a new provision, making it explicit that an AO's CMS-approved accreditation program would be approved in its entirety, and that an AO would not be permitted to make a recommendation to us for deemed status for a provider or supplier unless that provider or supplier satisfied all of the AO's requirements for accreditation. This would include both the AO accreditation program standards that may exceed the Medicare standards, as well as those that meet the Medicare standards.

Comment: Several commenters indicated the provision described at § 488.4(b) in the preamble of the proposed rule did not have any corresponding regulatory text. The regulatory text at § 488.4(b) of the proposed rule indicates ''Reserved.''

Response: The commenters are correct that we proposed to reserve § 488.4(b). The discussion in the preamble was meant to describe the changes we proposed at § 488.4(a)(1).

Comment: Several commenters objected to our statement in the preamble that we were making explicit in proposed § 488.4(a)(1) that an AO's CMS-approved accreditation program is approved in its entirety. Many commenters submitted similar comments stating that reviewing accreditation programs in their entirety represents an overreach of federal authority. The commenters also indicated their belief that if an AO finds that a provider or supplier meets all of its accreditation standards that correspond to Medicare conditions, it should be able to recommend deemed status even if the provider or supplier fails to meet other requirements of the accreditation program which exceed the Medicare requirements. One commenter indicated that this provision would set up a dual standard for non-accredited providers and suppliers, which only have to meet the Medicare conditions, and deemed status providers and suppliers that would have to meet the higher accreditation standards.

Response: Section 1865(a)(1) of the Act refers to ''accreditation of a provider entity'' and authorizes us to accept such accreditation as demonstrating the provider's or supplier's compliance with Medicare conditions or requirements, if we find that the AO's accreditation program meets or exceeds all applicable requirements. If a provider or supplier fails to meet the standards for accreditation, then it does not satisfy the statutory requirement for deemed status. It does not matter which of the accreditation program standards the provider or supplier has failed to satisfy.

We also note that it is a voluntary decision on the part of an AO whether it includes standards that exceed the Medicare requirements in the accreditation program that it submits to us for review when seeking approval as a Medicare accreditation program. We review the program that an AO submits to us, and when we approve a program for purposes of our granting Medicare deemed status to providers or supplier accredited under it, we approve it in its entirety. We do not take any position regarding whether standards exceeding CMS's are necessary or advisable, but likewise, we do not insist that they be removed so that the accreditation program is purely Medicare-specific. We believe the statutory language in section 1865 of the Act, which requires us to find that an accreditation program ''meets or exceeds'' all applicable Medicare standards, indicates an expectation that a program submitted for our review might contain elements that are not required under the Medicare standards.

It would be contrary to the statute if CMS accepted deemed status based on satisfaction of only some of the accreditation requirements in its CMS-approved Medicare accreditation program, because the statute only allows us to recognize those facilities that have received accreditation. If a provider or supplier meets Medicare standards but fails to receive accreditation, it can ask for a state survey instead. Likewise, it would be arbitrary and contrary to our regulations at § 488.8(d)(1)(ii) if an AO modified portions of a CMS-approved Medicare accreditation program subsequent to our approval without informing us. Although the AO may believe that its changes would not affect any accreditation provisions related to Medicare requirements, the determination of whether a revised program continues to meet or exceed Medicare standards is CMS's, rather than the AO's, to make. We have not delegated to the AO itself our responsibility under the statute to ensure that an accreditation program's standards, including any changes to them, continue to meet or exceed Medicare requirements. This is not a new policy on our part, because we believe it is required by our current regulations. We have only proposed to make this policy more explicit in our proposed regulations (at § 488.5(a)(18)) due to the confusion experienced by a few AOs regarding this issue. Our role is to determine if the AO's standards meet or exceed all applicable Medicare requirements. On that basis we determine whether to approve the AO's program for Medicare deeming purposes, and, in the case of an AO's proposal to revise standards within its CMS-approved Medicare accreditation program, whether a program with the proposed revisions would continue to meet or exceed the substantive Medicare facility standards.

In our view, this does not create a double standard with deemed status providers and suppliers having to satisfy higher standards to participate in Medicare. We note that the decision on the part of a provider or supplier to seek to demonstrate compliance with Medicare requirements through accreditation rather than survey by an SA is voluntary. We welcome the decision by many providers and suppliers to seek accreditation under programs that have requirements that exceed the Medicare standards, but this does not change the statutory requirement that they must be

accredited to be recommended for deemed status.

In view of the changes we made to the definition of ''supplier,'' as discussed above, we are making conforming changes in this final rule to § 488.4(a), indicating that we will not accept applications for approval of accreditation programs for kidney transplant centers within hospitals or for end stage renal dialysis facilities. We are also making a technical correction to replace potentially ambiguous language stating that AOs apply for our approval to accredit providers or suppliers with more precise language indicating that they apply for our approval of their accreditation programs.

6. Application and Reapplication Procedures for National Accreditation Organizations (§ 488.5).

We proposed to revise § 488.5 to clarify the requirement that an AO seeking our approval of a Medicare accreditation program be national in scope. We also proposed moving the regulatory language currently at § 488.4 to § 488.5, with modifications, as part of our effort to reorganize the accreditation requirements in a more logical sequence.

Specifically, we proposed the following revisions:

- We proposed at § 488.5(a) to replace the requirement currently set out at § 488.4(a) concerning the application and reapplication procedures for an AO seeking our initial or continued approval of a Medicare accreditation program. We further proposed revising the current language to clarify that all of these provisions would apply to both initial applications for new accreditation programs, as well as reapprovals of existing CMS-approved accreditation programs, and to clarify that each application for approval would pertain to a single provider/supplier-specific accreditation program. We received no comments on the above proposed changes and are adopting them as proposed in this final rule.
- We proposed at § 488.5(a)(1) to require an AO seeking either our initial approval of a new Medicare accreditation program or renewed approval of an existing program to demonstrate for that program that the organization meets the definition of a ''national AO.'' Section 1865 of the Act applies only to programs of national accreditation bodies. We stated in our proposal that this demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. We indicated as an example that an AO which has one or more existing CMS-approved programs and which seeks our initial approval of a new accreditation program must demonstrate that the new program has been implemented nationally. Several commenters addressed this provision in terms of the definition of a ''national AO'' and we addressed their comments in our discussion of § 488.1 above. We are adopting this provision in this final rule without change.
- We proposed at § 488.5(a)(1) to require an AO seeking either our initial approval of a new Medicare accreditation program or renewed approval of an existing program to demonstrate for that program that the organization meets the definition of a ''national AO.'' Section 1865 of the Act applies only to programs of national accreditation bodies. We stated in our proposal that this demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. We indicated as an example that an AO which has one or more existing CMS-approved programs and which seeks our initial approval of a new accreditation program must demonstrate that the new program has been implemented nationally. Several commenters addressed this provision in terms of the definition of a ''national AO'' and we addressed their comments in our discussion of § 488.1 above. We are adopting this provision in this final rule without change.
- We proposed at § 488.5(a)(2) to replace the requirement currently set out at § 488.4(a)(1), concerning the AO's identification of the types of provider or supplier for which it is seeking approval. We indicated that this revision would clarify that each application for our approval must be specific to a particular type of provider or supplier and would be separate and distinct from applications for our approval of accreditation programs for other types of providers or suppliers. We received no comments on this proposed revision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(3) to replace the requirement, currently set out at § 488.4(a)(2), concerning the requirement that an AO submit a detailed comparison of its standards to Medicare requirements, and set out the components of an acceptable crosswalk. We received no comments on this proposed revision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4) to replace the requirement currently set out at § 488.4(a)(3), which addresses the requirement that the AO must provide us a detailed description of its survey process in its application for our approval of an accreditation program. We proposed to leave the language of this provision unchanged. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(i) to replace the requirement currently set out at § 488.4(a)(3)(i), concerning the frequency of surveys. We stated that the proposed revisions reflect existing policy requiring re-survey of an accredited provider or supplier no later than 36 months after the previous accreditation survey, and thus would not impose any new requirements. We indicated that we were proposing the revision to clarify the existing requirements.

Comment: A commenter proposed expanding the definition of ''survey'' to include a ''desk review'' for suppliers of advanced diagnostic imaging.

Response: Since we are rescinding our proposal to apply the provisions of part 488 to accreditors of suppliers of the technical component of advanced diagnostic imaging services, it is not necessary to address in this final rule issues that are specific to such accreditation. For deemed status providers and suppliers, as defined in this final rule, a reaccreditation survey assessing compliance with all accreditation program standards must be conducted via an on-site survey.

Comment: One commenter indicated that the current AO performance measure used by CMS to assess if triennial surveys are timely requires that, for ASCs surveyed for first-time participation in an AO's Medicare accreditation program, the start date [for accreditation] is the date an acceptable plan of correction has been received, and therefore the end date of the accreditation term and deemed status term is no later than 36 months after that date. The commenter notes the proposal would change the requirement to 36 months from the initial survey date. The commenter suggested this would result in an inconsistency with the current performance measures and will lead to unnecessary changes in the current AO reporting structure.

Response: We proposed a maximum interval of 36 months from the ''previous accreditation survey,'' which could encompass more than the last date the AO was on-site as part of its reaccreditation survey. The commenter may be confusing the special requirements that apply to accreditation surveys of initial applicants for Medicare participation for determining a participation effective date with the way in which we calculate the timeframe for when a triennial survey is due. However, in response to this

comment, we believe it would more accurately reflect our current practice and reduce confusion to use the phrase ''prior accreditation effective date'' and are making this revision in this final rule.

Comment: One commenter proposed that we require that a minimum percentage of surveys commence during off-business hours, to further reduce the predictability of surveys.

Response: We do not impose such an obligation on SAs, except in the case of long term care facilities, and we see no compelling reasons why we should do so for AOs for non-long term care provider or supplier types. While it might be possible to conduct a survey outside typical ''business hours'' in health care facilities that provide care on a 24 hours per day/7 days per week basis, such surveys in ambulatory care settings would generally eliminate the possibility of surveyors being able to observe how care is actually provided by the facility. Even in the case of other types of acute care facilities operating on a 24/7 basis, there would be fewer opportunities to observe the wide range of health care services furnished than during daytime hours. If an AO has received a credible allegation of serious deficiencies that occur only during specific time periods, then it would be logical to conduct a survey during such periods, but we are not aware of such complaints specific to off-hours operations. We are making no changes in response to this comment.

- We proposed at § 488.5(a)(4)(ii) a new provision to ensure surveys conducted by AOs were comparable to the Medicare requirements, consistent with section 1865(a)(2) of the Act. Specifically, we proposed that an AO be required to demonstrate the comparability of its survey process and guidance to the process and guidance that we require for SAs conducting a Federal survey for the same provider or supplier type; the operative guidance for each provider and supplier type is specified in our Publication 100–07, the SOM.

Comment: One commenter representing health care services consumers indicated its support for requiring comparability of the survey process, to ensure surveys meet Medicare requirements. By contrast, a number of other commenters representing hospitals or AOs expressed their opposition to this proposal. Several of these commenters said that the SOM is outdated, and often includes language and practices that do not reflect the best practice in quality and safety standards. A number of these commenters also noted that the SOM represents subregulatory guidance and is not open for public comment and review, with one commenter expressing concern about the precedent set by holding private entities to sub-regulatory guidance they had no voice in creating. The commenter further expressed concerns that the proposed provision would require AOs to have comparably-sized survey teams and survey duration, which would greatly increase the cost of an accreditation survey. This commenter suggested that SAs typically maintain much larger survey teams and conduct longer surveys to meet the requirements set out in the SOM, and urged us to remove this requirement and continue to place the authority with AOs to use state-of-the-art survey processes to evaluate compliance with Federal requirements. Another commenter suggested we follow the best practices established by AOs and not hold the latter to the SOM, instead letting them survey at greater detail and test innovative approaches. This commenter urged us to clarify that the term ''demonstrating comparability'' does not mean identical standards and survey processes related to the SOM. This commenter also expressed concerns that requiring comparably sized survey teams and survey duration would increase costs. Another commenter expressed similar cost-based concerns, and also was concerned about an adverse impact on current AO survey processes, such as tracer methodology, complaint surveys, frequency, and costs. Another commenter suggested that we establish a comment process for the SOM prior to final publication and a process for distributing the responses to the AOs. One commenter requested that we make it clear that we do not require one-to-one comparability between the SOM and AO procedures.

Response: The SOM is a complex document that provides guidance for a number of different Medicare regulations. The commenters' references to what they view as outdated quality and safety standards seem to be referring to those parts of the SOM that provide our official policy interpreting the various provider/supplier-specific CoPs, CfCs, conditions for certification or requirements. Thus, this aspect of the objection to the proposed provision at § 488.5(a)(4)(ii) concerning comparability of survey processes appears to be misplaced. We also note for the record that the SOM does not establish but instead implements existing regulatory requirements, and thus is subregulatory guidance that is not subject to the requirements for public notice and comment. Nevertheless, we often confer informally with AOs and other members of the general public when we revise our interpretive guidance for the applicable conditions, and have found their input to be invaluable in helping us develop and update such guidance.

We also have noted that it is not uncommon for objections to be raised about ''the SOM'' which are really objections to the underlying regulatory requirements found in the various conditions or requirements. We take such concerns seriously and have made a number of regulatory changes to various providers and suppliers in recent years, to revise outdated regulations and remove unduly burdensome requirements that do not contribute to increased patient or resident quality and safety. However, we emphasize that an AO does not have the authority to modify in its Medicare accreditation program Medicare requirements that it disagrees with, nor is the AO application review process the appropriate venue for an AO to air, or us to resolve, its complaints about substantive provider/supplier-specific Medicare conditions of participation, conditions for coverage, conditions for certification, or long term care requirements. The purpose of the application review is to determine whether the applicant's accreditation program meets or exceeds existing Medicare standards.

For the commenters' objections to survey process issues, such as survey team composition, survey frequency and duration, how complaints are handled, etc., we note that Section 1865(a)(1) of the Act requires us to make a finding that the AO's accreditation program meets or exceeds all applicable Medicare conditions or requirements, and section 1865(a)(2) of the Act requires us, when making this finding, to consider a national AOs ''survey procedures'' and ''. . . its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements. . . .'' The longstanding requirements under the existing regulations at § 488.4(a)(3) implemented this statutory provision by requiring AOs to provide us with detailed information on their survey processes, including their forms, guidelines and instructions to surveyors, frequency of their surveys, the size and composition of their survey teams, the qualifications of their surveys, the way in which they train their surveyors, etc. Moreover, the existing regulations at § 488.8(a)(2)(ii)

require us, when reviewing an application, to determine ''the comparability of survey procedures to those of SAs, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.'' It has been our practice to assess comparability by reviewing the information in the AO's application in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements. Our proposal was only intended to make the role of the SOM in articulating and implementing the regulatory requirements for survey process more explicit. We believe commenters' concerns about our imposing survey processes that inhibit use of best, most efficient survey practices that are efficient are unfounded. In fact, it has been our practice to allow both SAs and AOs flexibility in determining the size and composition of their survey teams and the duration of their surveys, and considerable variation exists among both SAs and AOs in this regard. We not only have no objection to an AO's use of a tracer methodology, but we also have developed tools for state surveyors to employ tracers as one component of their surveys. We note, further, that many of the commenters represent hospital organizations that are accredited by TJC, whose hospital program was not subject to the comparability requirements of section 1865 of the Act prior to July 15, 2010. This may account for their erroneous perception that our proposal represented a significant departure from current requirements and practices. Nevertheless, in consideration of the above comments, we are revising this provision upon adoption to require an AO to provide documentation demonstrating the comparability of its survey process and surveyor guidance to those required for SAs conducting federal surveys for the same provider or supplier type, in accordance with the applicable regulations. We are removing the explicit reference in this provision to the SOM as unnecessary, but this will not change our practice of assessing comparability in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements.

Comment: One commenter expressed concern this provision would conflict with recent legislation in its State recognizing national AO accreditation in place of a State hospital licensure survey, recognizing that an AO can be more nimble in updating its accreditation standards than the State can in updating its licensure standards. The commenter stated the provisions of this rule would be a step back by forcing AOs to rely on outdated provisions that are part of the SOM.

Response: We do not establish state licensure requirements. We believe this comment also is referring primarily to provider/supplier-specific conditions or requirements rather than to survey process requirements. However, for both accreditation standards and survey processes, we are compelled by section 1865 of the Act to determine whether an AO's requirements meet or exceed all applicable Medicare requirements. It is not within our authority to consider the impact our determinations may have directly or indirectly on a state's licensure requirements.

- We proposed at § 488.5(a)(4)(iii) to redesignate the requirement currently set out at § 488.4(a)(3)(ii). This provision requires an accreditation organization to provide us with information on the content and frequency of survey personnel training. We proposed to leave unchanged the current language of this requirement. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(iv), consistent with the requirement currently set out at § 488.4(a)(3), to require an AO to provide us a copy of its most recent survey report and any other survey-related information we require. We proposed to require documentation that the AO's survey reports identify for each accreditation deficiency cited the applicable Medicare requirement. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(v) to replace the requirement currently set out at § 488.4(a)(3)(iii), concerning the survey review and accreditation decision-making process. We proposed to delete language that would be redundant with language being incorporated into the proposed revised regulatory language at § 488.5(a)(8). We received no comments on this provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(vi) to replace the requirement currently at § 488.4(a)(3)(iv) and to revise the existing language to specify that the AO must provide us a description of its provider or supplier notification procedures as well as its timelines for notifying surveyed facilities of noncompliance with accreditation program standards. We received no comments on this provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(vii) a provision similar to the current requirement at § 488.4(a)(3)(iv), regarding providing us information on the AO's procedures for monitoring the facilities found to be out of compliance. In our proposal, we added a requirement to provide information on timelines for monitoring corrections, and revised the provision to clarify the requirement and provide more specific and precise language. We indicated that the proposal was consistent with our longstanding practice and thus imposed no new burdens.

Comment: One commenter expressed support for this provision, saying it would allow CMS to better monitor an AO and its actions.

Response: We thank the commenter for their support. We are adopting this provision without change in this final rule.

- We proposed at § 488.5(a)(4)(viii) to replace the requirement currently set out at § 488.8(a)(3), which requires the AO to provide us a copy of its most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey that we may require. We proposed modifying the language of this provision for consistency and clarity.

Comment: One commenter requested clarification whether the proposed requirement would change the current process for providing survey information to CMS. Several commenters responded to this provision expressing concerns about disclosing survey and survey-related information to CMS. One commenter indicated that the proposed provision would provide CMS with broad authority to collect information related to a survey, including patient safety work product (PSWP) protected under the Federal Patient Safety and Quality Improvement Act (PSQIA). The commenter suggested CMS add clarifying language acknowledging that it may not be feasible for the AO to provide some information obtained from an accredited entity during a survey. The commenter also requested that we add the language ''when specifically requested by CMS'' since it does not believe routine submission of information to CMS is needed. Another commenter expressed concern that certain information protected from disclosure by federal standards would lose its protected

status if shared, and requested we add clarification that information required would only be related to the deemed status accreditation survey. By contrast, other commenters stated that CMS cannot monitor the work of AOs without seeing their most recent surveys for a provider and indicated the proposed provision would improve CMS's ability to obtain this information. The commenters suggested that failure of an AO to furnish us with copy of an accreditation survey be grounds for withdrawing deeming authority for that organization.

Response: Consistent with the existing requirement at § 488.8(a)(3) we have, since 2009, required AOs to routinely submit information to us electronically, including survey information extracted from their survey reports. Since 2013, we have asked for these submissions to be made to us monthly. We have also required that AOs routinely submit to us, for initial surveys only, a copy of the actual survey report. In addition to this routine electronic submission of data from every survey report and survey reports for initial surveys, we also request, from time to time, a copy of the actual survey report, as well as additional supporting information, such as plans of correction for reaccreditation or complaint investigation surveys. The proposed revision to the regulation was not intended to alter current practice. Section 1865(b) of the Act prohibits us from disclosing accreditation surveys, except for home health surveys, but permits us to disclose surveys to the extent that they related to an enforcement action we take. With the exception of denials of certification to applicants for initial enrollment in the Medicare program, we generally use our enforcement discretion to not take enforcement action based solely on an accreditation survey. For example, if an AO notifies us that it has terminated accreditation due to a provider's or supplier's inability to demonstrate compliance, we instruct the SA to survey that provider or supplier as soon as possible, and use the results of the SA's survey to make enforcement decisions. Accordingly, with the exception of home health agency surveys, generally most accreditation surveys may not be disclosed by us to any third parties.

For an AO not being permitted to disclose to CMS patient safety work product protected under the Patient Safety and Quality Improvement Act (PSQIA) (Public Law 109–41), we do not believe that the PSQIA was intended to inhibit our legitimate AO approval, validation and other oversight activities under part 488. Additionally, providers/suppliers cannot unilaterally declare the factual information used in developing a ''patient safety work product'' (PSWP) to be itself non-disclosable. Indeed, the Department's final rule implementing PSQIA, ''Patient Safety and Quality Improvement; Final Rule'' states explicitly that ''nothing in the final rule or the statute relieves a provider from his or her obligation to disclose information from such original records or other information that is not patient safety work product to comply with state reporting or other laws.'' (73 FR 70732, 70786, November 21, 2008.) An AO's survey report must include the factual evidence that supports the citations the AO makes for violations of its accreditation standards. Accordingly, we find it unlikely that AO survey reports or other material we might request would contain PSWP. We agree that the PSQIA does not permit an AO to re-disclose to us PSWP disclosed to the AO by a ''provider,'' as that term is defined in the PSQIA and its implementation regulation, and which encompasses both providers and suppliers that are certified for Medicare participation on the basis of their accreditation by the AO. We expect that accrediting organizations, in carrying out their surveys and appropriately documenting their findings, will generate survey reports that do not contain PSWP, and thus may be provided to us, as required under section 1865 of the Act.

For the commenter's suggestion that we add language, ''when specifically requested by CMS,'' we believe that our proposal could more effectively differentiate between the routine electronic submission we require of information extracted from each survey report from copies of the survey report, as well as other information related to the survey report which we request routinely in the case of surveys of initial applicants for Medicare participation, from case-specific circumstances where we request additional information. Accordingly, in this final rule we are revising this provision to state that an AO agrees, as a condition of CMS approval of its accreditation program, to provide us with information extracted from each accreditation survey as part of its data submissions required under § 488.5(a)(11)(ii) and, upon request from us, a copy of the most recent AO survey tougher we any other information related to the survey that we may require.

- We proposed at § 488.5(a)(4)(ix) to replace the requirement currently found at § 488.4(b)(3)(vii), requiring an AO to notify us when it identifies an immediate threat to the health and safety of patients, that is, a situation that constitutes an ''immediate jeopardy'' as that term is defined at § 489.3. We proposed to revise the timeframe for notifying us from the current requirement of ten days to within one business day from the date the immediate jeopardy is identified. We indicated this proposed provision would ensure that we are notified of situations that may put the health and safety of patients receiving care in Medicare-participating facilities at serious risk of harm, and which would require us to take immediate action to enforce the Medicare requirements applicable to these facilities.

Comment: One commenter noted a contradiction between our proposed requirement and the requirement for AOs accrediting suppliers of the technical component of advanced diagnostic imaging services at § 414.68(g)(14)(vi), which requires notification to CMS of an immediate jeopardy within 2 business days.

Response: We agree that there was a conflict between our proposal and § 414.68(g)(14)(vi). However, since we have removed all reference to accreditation of suppliers of the technical component of ADI services from part 488 in this final rule, there is no longer a conflict. AOs that accredit such suppliers continue to be subject to the requirement at § 414.68(g)(14)(vi). We expect to propose changes to § 414.68 in future rulemaking, to strengthen our oversight of AOs that accredit suppliers of the technical component of ADI services, making such oversight more consistent with part 488.

Comment: Several commenters found the proposed shortening of the timeframe from 10 days to 1 business day problematic. One commenter suggested 2 days as an alternative. Another commenter said a one-day notification is feasible, but may result in omission of important information or details pertaining to the case, which could lead CMS to make uninformed decisions or conclusions. This commenter also suggested that CMS Regional Offices be held to the same requirement and should notify the pertinent AO when the SA or Regional Office declares an immediate jeopardy situation. Another commenter also suggested that its experience with follow-up requests from us for more detailed information calls into question the utility of requiring faster, but less detailed notification. On the other hand, another commenter applauded us for reducing the notification time, but believed that 1 business day was too

long, given the possibility of greater harm to patients occurring. This group suggested we revise our proposal to require immediate notification.

Response: We believe that once an immediate jeopardy has been determined by an AO to be present, regardless of whether or not the AO survey team also finds that the immediate jeopardy was removed while the team was on site, there is sufficient information within one business day for AOs to provide notification to CMS. As previously indicated, we generally exercise our enforcement discretion to require an SA survey before taking official enforcement action against a provider or supplier, and to arrange a timely state survey to determine whether there continues to be either an immediate jeopardy or even lower-level but substantial noncompliance requiring our enforcement action, we need prompt notice from an AO. We also note that since the original provision was adopted, email has generally replaced hard-copy mail as the primary means of communication between AOs and ourselves, and thus an extended 10-day time frame is no longer necessary. We do recognize that we frequently ask an AO to provide us with more detail about an immediate jeopardy after its initial notice to us before we authorize a state survey, and thus we believe it would be appropriate to extend the notification timeframe to 2 business days. For the comment calling for us to shorten the timeframe to immediate notification, we believe that this affords the AO too little time to complete its internal notification and decision-making processes. Since we expect that the AO will be taking appropriate action to require prompt correction of any immediate jeopardy situation, we believe that a small delay does not increase the risk of harm. Accordingly, we are revising the proposed provision in this final rule to require notice to us about an immediate jeopardy situation within two business days. This policy is consistent with the policy we have adopted for the technical component of advanced diagnostic imaging services.

- We proposed at § 488.5(a)(5) to replace the requirement currently set out at § 488.4(a)(4)(i), which requires AO applicants to provide us information on the size and composition of their survey teams for each type of accredited provider or supplier. We proposed to add to the existing provision language requiring the AO to furnish us information on its criteria for determining survey team size and composition, including variations for individual provider or supplier surveys. We stated that, within a given accreditation program there can be great variation in the size and complexity of individual health care facilities, and that we believe a uniform size and composition for the AO's survey teams would not be appropriate.
- We also proposed at § 488.5(a)(6) a new provision that would help ensure that an AO maintains an adequate number of trained surveyors to meet the demand for surveys, both initial and re-accreditation surveys. We reported that there have been instances where an AO could not maintain the required re-accreditation survey schedule interval for its existing accredited deemed status facilities because it was focusing its limited resources on meeting the demand of new customers for initial Medicare accreditation surveys. These AOs lacked sufficient personnel resources to handle both existing and new workloads.

Comment: Several commenters objected to both of these proposed provisions, expressing concerns they would prescribe the size and composition of survey teams, thereby increasing the costs to facilities, which could cause more facilities to seek Medicare participation through SAs and thereby increase costs to the government. One commenter stated that CMS should evaluate AOs on the basis of their performance and not dictate processes used by the AOs. The commenter also stated its formula for determining survey team size is proprietary, and that increasing the survey team size will increase costs to providers/suppliers and the government. Another commenter said it would oppose this provision if CMS intends to prescribe a specific ratio of surveyors to accredited facilities, saying AOs vary greatly in their business operations and therefore may also vary in the number of facilities that can be supported by surveyors. This commenter suggested it should be sufficient for each AO to provider its rationale.

Response: Section 1865(a)(2) of the Act requires us, when determining whether an AO meets or exceeds all applicable Medicare requirements, to consider, among other things, an AO's ''ability to provide adequate resources for conducting the required surveys . . .''. Under the existing requirement at § 488.4(a)(4)(i), AOs are already required to furnish us information about the size and composition of their survey teams. In our proposed revisions, we refined these requirements to obtain information that would better enable us to assess an AO's ability to provide adequate resources, recognizing that variations in the size and complexity of facilities necessarily impact an AO's survey process, and that growth in an AO's accreditation program may require an adjustment in the overall number of surveyors the AO utilizes to accomplish its surveys. For example, the resources required to evaluate compliance in a 50-bed rural hospital are considerably different than those required to accomplish the same evaluation in a 600-bed urban academic medical center. Likewise, the overall survey resources required by an accreditation program which is increasing the number of facilities it accredits will be different than those required by an AO whose program is relatively static in size. Accordingly, the final rule will require AOs to give us information on how they adjust survey teams and composition to account for facility differences, and how they adjust the overall size of their survey staff to account for growth in their accreditation program and still fulfill their survey obligations. This information will enable us to evaluate more effectively the AO's ability to provide adequate resources, as required by the statute. The final rule does not mandate specific survey team sizes or composition which AOs must use, and thus we do not agree with those commenters who stated that it would increase costs to the facilities surveyed by AOs. We do not intend to impose a specific ratio of surveyors to accredited facilities on AOs by policy. However, we will review the information and rationale provided us by an AO in its application; if the rationale is not supported by the information in the provider's application or by performance data we have collected, in the case of a renewal application, we reserve the right to withhold our approval until the AO either provides us a more convincing rationale or revises its approach to assuring adequate survey resources.

For the comment about focusing on AO performance rather than dictating internal AO processes, we note that it was through our ongoing evaluation of AO performance that we identified problems with several AOs, such as failure to identify serious noncompliance with the LSC requirements, or inability to perform timely reaccreditation surveys, which may be related to the survey resources the AO makes available to accomplish its required survey work. Therefore, we believe it is incumbent upon us to obtain more information from AO applicants for new or renewed approval about the way in which they assure adequate survey resources. We are making no changes in this final rule in

response to these comments and are adopting § 488.5(a)(5) and (6) as proposed.

• We proposed at § 488.5(a)(7) to replace the requirement currently set out at § 488.4(a)(4)(ii) concerning furnishing us with information on the AO's education and experience requirements for its surveyors.

Comment: We received one comment asking for clarification of the difference between ''surveyors'' and ''AO staff'' and also recommending that surveyors for ADI have experience in diagnostic imaging.

Response: We consider ''surveyors'' to include all individuals who conduct on-site surveys, or inspections, of providers and suppliers seeking new or continued deemed status. Surveyors typically also have additional off-site responsibilities established by the AO. We believe the commenter's question relates to some of the unique circumstances pertaining to accreditation of suppliers of the technical component of ADI services. Given our decision to remove all reference to ADI services and their accreditation from part 488 in this final rule, we believe that it is not necessary to address the commenter's recommendation for ADI surveyor qualifications. We are not making any changes in response to this comment and are adopting this provision in this final rule as proposed.

• We proposed at § 488.5(a)(8) to replace the requirement currently set out at § 488.4(a)(4)(iii), which requires an AO applicant to provide us information concerning the content and frequency of in-service training of AO survey personnel. We received no comments on this proposed revision and are adopting it without change in this final rule.

• We proposed at § 488.5(a)(9) to replace the requirement currently set out at § 488.4(a)(4)(iv), which requires an AO applicant to provide us information concerning evaluation systems it uses to monitor the performance of individual surveyors and survey teams.

Comment: One commenter expressed its opposition to the proposal since it believes it implies that the AO's surveyor evaluation system would require prior approval, which would restrict the AO's flexibility in adjusting evaluation processes to emerging trends and impair the evaluation of quality assurance processes.

Response: This requirement is unchanged from the existing requirement at § 488.4(a)(4)(iv), and thus we proposed no change from our current practice. We do not micromanage the process by which AOs review their surveyors' performance, but we must evaluate whether an AO has a credible process for evaluating on an ongoing basis the performance of its surveyors and survey teams. We are making no changes in response to this comment and are adopting the provision in this final rule as proposed.

• We proposed § 488.5(a)(10*)* to replace the requirement currently set out at § 488.4(a)(4)(v), which requires an AO to provide us detailed information its policies and procedures concerning the involvement of personnel in the survey or accreditation decision process who may have a financial or professional affiliation with the provider or supplier. We proposed to modify the provision to state more clearly that we expect an AO to have policies and procedures to avoid potential conflicts of interest by precluding the participation of individuals who have a professional or financial affiliation with a provider or supplier from participating in the survey or accreditation decision.

Comment: Some commenters proposed adding a minimum timeframe of 2 years after termination of a surveyor's affiliation with a provider or supplier during which the surveyor would be precluded from participating in a survey or accreditation decision for that provider or supplier. The commenters also proposed we require an AO to have different personnel on a survey team from that which previously surveyed the provider or supplier.

Response: The commenters are focusing on prior affiliations and seems to presume that an AO's surveyors are full-time staff. Our proposal was focused on avoiding conflicts of interest where AO staff has current affiliations with providers or suppliers, since it is our understanding that few AOs employ full-time surveyors, but instead rely upon contracted surveyors who often have ongoing relationships with some providers and suppliers. However, we agree that it could also create the appearance of a conflict of interest for an individual to participate in a survey of a provider or supplier with which he or she was previously affiliated and that such appearance should also be avoided as much as possible. Nevertheless, we do not specifically mandate in regulation or policy that SAs preclude newly-hired staff from engaging in surveys or decisions affecting a prior employer for a specified period of time. In section 4008 of the SOM we establish a policy for conflicts of interest of SA employees engaged in federal survey and certification work, indicating that such conflicts may arise when public employees utilize their position for private gain or to secure unfair advantages for outside associates. We specifically state that it is not possible to list all situations that could be construed as potential conflicts of interest, but do provide some examples of potential conflicts, including having various relationships with a health care facility in the employing state. We also indicate in section 4008B of the SOM that state codes provide judicial or administrative remedies for abuses of influence and that employee actions would be handled in accordance with the applicable State procedures. Thus we do not prescribe uniform limitations or prohibitions that all states must incorporate. AOs might not be as likely as states to have conflict of interest policies absent our requirement that they do so, but this does not necessarily mean that we should specify in regulation the detailed content of such policies. We also believe that a 2-year ban on a surveyor's participation is excessive and might unduly limit an AO's (or state's) ability to use its staff resources effectively. Within CMS, for example, a newly-hired employee is precluded from participating in matters concerning a prior employer for one year. In summary, while we believe it is prudent for both AOs and states to avoid conflicts of interest involving previous as well as current affiliations, we believe we should not in this regulation specify in detail how to avoid such conflicts.

We also do not require SAs to use different personnel for successive surveys of a provider or supplier; in fact, we believe it is more likely that SAs would have the same personnel conducting successive surveys than would AOs, given the national scope of an AO's operations. We also see no particular value to such a requirement; one might argue that familiarity of a surveyor with a facility might enhance their ability to identify deficient practices. In fact, some AOs have suggested that SAs tend to be more successful in identifying LSC deficiencies in providers or suppliers precisely because they have long-standing familiarity with the physical plants of facilities in their states.

Comment: Commenters stated that the ''business-client relationship'' that exists between AOs and the facilities they survey creates an inherent conflict of interest and expressed concern that this provision does not address this more generic type of conflict of interest.

Response: Section 1865 of the Act specifically allows for us to certify providers or suppliers as meeting the applicable conditions or requirements on the basis of accreditation of

providers or suppliers by private AOs. Thus, under the law the business-client relationship is not prohibited in those cases where we have reviewed the AO's Medicare accreditation program and found that it meets or exceeds all applicable requirements. We also note that we exercise continuing oversight over AOs, including making the determination whether or not to accept an AO's recommendation of a provider or supplier for deemed status.

Comment: Several commenters proposed that we also preclude surveyors from participating in a survey or accreditation decision when they have a financial or professional affiliation with a competitor of the provider or supplier being surveyed.

Response: We believe there is merit to the commenters' concerns, particularly given that few AOs employ full-time surveyors but instead rely upon contracted surveyors who often have ongoing relationships with some providers and suppliers. We expect AOs to be careful to avoid the appearance of conflicts of interest that could compromise confidence in the objectivity of their survey findings or accreditation decisions. At the same time, we are reluctant to attempt to specify in regulation a definition or methodology for determining which providers or suppliers are ''competitors'' of a provider or supplier being surveyed, since there are many varying factors that could influence whether there is a competitive relationship among providers and suppliers and to what extent that would deleteriously impact surveyors' objectivity.

In light of the various commenters' concerns about potential conflicts of interest scenarios that go beyond the situation of a surveyor being involved in a survey or accreditation decision of a facility with which he or she has a current professional or financial affiliation, as well as our intent to not micro-manage the way in which either states or AOs avoid conflicts of interest, we are in this final rule revising this provision to state more generically that an AO must provide us its policies and procedures for avoiding conflicts of interest, including the appearance of conflicts of interest.

• We proposed at § 488.5(a)(11) to replace the requirement currently set out at § 488.4(a)(5), which addresses the requirement that the AO provide information on its data management system in its application. We proposed at § 488.5(a)(11) to retain the existing language at § 488.4(a)(5). In addition, we proposed a new provision at § 488.5(a)(11)(i) to require submission of a detailed description of how the AO uses its data system to assure compliance of its accreditation program with the Medicare requirements.

• We also proposed at § 488.4(a)(11)(ii) requirements replacing those at current § 488.4(a)(9), which requires the AO to furnish us a list of all currently accredited facilities including type of accreditation and expiration date, and at § 488.8(a)(2)(v), requiring us to determine the AO's ability to provide us electronic data in ACSII comparable code and reports necessary for effective validation and assessment of the AO's survey process. We indicated the regulatory text currently at § 488.8(a)(2)(v) which requires an AO to include in its application a written presentation of its ability to submit information electronically ''in ASCII comparable code,'' is outdated and insufficient. We stated that the proposed modifications are necessary to ensure that we have the required data to provide effective oversight of an approved accreditation program.

Comment: One commenter indicated its support for these provisions, while another indicated it appreciated that this provision would require AOs to devote more resources to articulating their plans for data use.

Response: We thank the commenters for their support.

Comment: One commenter proposed we add language indicating CMS will be judicious and prudent with its requests for data, acknowledging that each demand for data is resource intensive and can be costly.

Response: We agree that we should not require AOs to submit data that are not necessary for us to support our evaluation of an AO's performance, and that we should be mindful of the need to avoid undue burdens on AOs. However, we do not agree that the regulations need further revisions to reflect this principle, since it already clearly links the data to be submitted to our evaluation of an AO's performance. Upon adoption we are, however, making non-substantive stylistic edits and changing the order of the last two sentences of this provision.

• We proposed at § 488.5(a)(12) to replace the requirement currently set out at § 488.4(a)(6), which requires an AO to provide us information on its procedures for responding to and investigating complaints, including coordination with appropriate licensing bodies and ombudsmen programs.

Comment: One commenter proposed we mandate that AO procedures for investigating complaints, include timeframes for resolution and a process to communicate the results to the complainant. The commenter also proposed that complaint resolution timeframes be consistent with those utilized by SAs and the complaint procedures be made publicly available upon request.

Response: We require in this provision that AOs seeking CMS-approval of their accreditation program provide us information on their processes for responding to, and investigating complaints, including grievances, against accredited facilities. We compare their policies and procedures to those we require for SAs during the application process and determine whether all applicable Medicare requirements are met or exceeded.

Comment: One commenter asked us to identify ombudsmen programs for advanced diagnostic imaging.

Response: We are not aware of ADI ombudsmen programs, and since we have rescinded our proposal to apply part 488 to accreditors of suppliers of the technical component of ADI services, the question is largely moot. However, we are taking this opportunity to note that we believe the language of the regulation makes it clear that we expect AOs to coordinate with licensing bodies and ombudsman programs in their investigation of complaints when it is appropriate to do so. For example, if in the course of an investigation an AO identifies a matter that appears to warrant separate investigation and action by the state authority responsible for licensing health care professionals, we would expect the AO to make an appropriate referral. Likewise, if there is an ombudsman program for the type of provider or supplier the AO accredits, we would also expect it to make appropriate referrals to such ombudsman programs. To make our intent clearer we are revising this provision in this final rule to require referrals, when applicable, to appropriate licensing bodies and ombudsman programs.

• We proposed at § 488.5(a)(13) to replace requirements currently set out at § 488.4(a)(7) and (a)(8), with modifications. The current provision at § 488.4(a)(8) require AOs to provide us a description of all types and categories of accreditation offered, including duration, etc. We proposed to modify this provision by deleting language and terminology specific to one particular AO. Furthermore, the current provision seems to require the AO to submit information on its accreditation programs that fall outside the parameters of its Medicare accreditation programs. Since we do not approve accreditation programs unrelated to

Medicare, we indicated that we believed that there was no reason to require AOs to submit such information to us, nor for us to have and review this non-relevant information.

The current provision at § 488.4(a)(7) requires an AO to submit information to us regarding its policies and procedures for withholding, or removing accreditation status or taking any other actions related to noncompliance with its standards. Since the granting of full or less than full accreditation status is an essential component of an AO's accreditation decision process, we stated it is necessary for us to receive information on the policies and procedures pertaining to these types of decisions.

We also proposed to include within § 488.5(a)(13), with modification, the requirement currently set out at § 488.4(b)(3)(i), which requires an AO to commit to notifying us of any facility that has had its accreditation revoked, withdrawn, or revised or that has had any other remedial or adverse action taken against its accreditation within 30 days of such action. We proposed to change the notification period to within three business days of the date of action. We proposed to reduce this timeframe since AOs transmit such information to us electronically. The 30-day timeframe was based on information being sent to us via hard copy mail. Given the instantaneous nature of the electronic notification, as well as our need to learn of such adverse actions in a timely manner so that, when applicable, we may initiate enforcement action, we indicated we believe it would be reasonable to require that the AO provide notice to us within three business days of its having taken the adverse action.

Comment: We received no comments on proposed § 488.5(a)(13) and § 488.5(a)(13)(i). Several commenters made comments related to the proposal at § 488.5(a)(13)(ii) to require notice to us within 3 business days of any adverse action. Most of these commenters indicated that this proposal would not allow sufficient time for AOs to process appeals of its decisions by its accredited providers and suppliers and suggested that notice not be required until after appeals are completed and final decisions made. One commenter suggested that we clarify our use of the term ''withdrawal.'' This commenter indicated that if the term refers to involuntary withdrawal from accreditation, then the timeframe is appropriate. If the term includes a voluntary withdrawal from accreditation, then the timeframe is not appropriate, since the AO takes a number of steps, including attempting to change the organization's mind about remaining accredited. In this case the commenter proposed we set different reporting timeframes for involuntary versus voluntary withdrawals of accreditation. One commenter noted that ADI AOs currently provide only weekly reports to CMS and said CMS would need to increase the frequency of data transmissions for them to comply. By contrast another commenter suggested that the notification deadline be one day, noting that 3 business days could be a total of 5 days, and that this delays CMS action against these agencies, leaving home health patients in situations where their health and safety might be seriously jeopardized.

Response: By ''withdrawal'' we mean a voluntary decision on the part of the accredited provider or supplier to end its participation in the accreditation program. This is in contrast to an AO's revocation of accreditation, which we view as including both an action taken when an AO concludes that a provider or supplier is substantially noncompliant with accreditation standards and has not corrected its deficient practices within the timeframe specified by the AO, as well as an action taken by an AO to revoke a provider's or supplier's accreditation due to the provider's or supplier's nonpayment of accreditation fees. By ''revised'' we mean a change in a provider's or supplier's accreditation status, based on the formal accreditation status categories the AO employs. We intended this latter term to include both adverse changes that fall short of revocation, as well as positive changes reflecting a provider's or supplier's improved compliance. Reflecting upon the commenters' comments, we believe that our additional language ''any remedial or adverse action taken against it'' is vague and potentially duplicative, and thus should be removed. Our intent was for AOs to notify us when they have taken a final action concerning a change in the accreditation status of a deemed status provider or supplier. If an action is not final until after an appeals process, then notice would not be required until three business days after that process has concluded and a final AO determination has been made. If a voluntary withdrawal from accreditation is not effected until an AO completes a number of steps to try to reverse the provider's or supplier's decision, and the AO continues to accredit the provider/supplier during this process, then notice would not be required until 3 business days after the effective date that the AO ultimately processes the provider's or supplier's voluntary withdrawal. In this latter case we would expect that the AO's timeframe for pursuing a revised decision from its customer would not be unreasonably long, so as to call into question whether the provider/supplier continued to meet the AO's accreditation standards. For example, we anticipate that a provider/supplier might notify an AO of its intent to withdraw shortly before its next payment is due, which might also be shortly before its current 3-year accreditation expires. We believe it is important to have these providers/suppliers recertified via another survey, either by another AO the provider or supplier has concurrently chosen or, in the alternative, by an SA in a timely manner. In the case of an HHA, we must ensure that the statutorily-mandated maximum survey interval of no more than 36 months is maintained, and that SAs are afforded as much advance notice of their need to conduct a survey as possible.

We do not believe that it would be reasonable to shorten this timeframe further, to 1 day. We note that the separate requirement at § 488.4(a)(4)(ix) for AOs to notify us of any immediate jeopardy they identify should permit us to take prompt action when the health and safety of patients are threatened.

For ADI AOs, this comment was one of the many that made us conclude that this type of accreditation could not reasonably be accommodated within the framework of part 488 and that we needed to remove ADI accreditation from this final rule. We have already established a weekly data submission schedule for ADI AOs to identify all suppliers of the technical components of ADI services that they accredit as of that week, to ensure that their Medicare claims can be appropriately and timely paid. We need to explore further with ADI AOs how best to incorporate into future rulemaking modifications of this process that include notice to us of the nature of the accreditation decisions underlying the week-to-week changes.

In light of these clarifications, we are revising the provision to clarify that notice is required for any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier within 3 business days' of the effective date the AO takes action.

- We proposed at § 488.5(a)(14) to replace the requirement currently set out at § 488.4(a)(9) concerning submission of information on currently accredited facilities as part of the AO's application. We proposed to modify the current language for clarity. We received

no comments on this proposal and are adopting it without change in this final rule.

• We proposed at § 488.5(a)(15) to create a new requirement for an AO seeking renewed approval for a current CMS-approved Medicare accreditation program. We proposed that the AO seeking renewed approval must demonstrate, as a condition of our acceptance of its application for renewal, that it demonstrated growth from its initial approval, as evidenced by there being at the time of its renewal application at least 50 health care facilities with deemed status based on the AO's CMS-approved Medicare accreditation program. We stated that we believe that an established AO accreditation program that has not been able to accredit a minimum of 50 health care facilities under its Medicare accreditation program since receiving initial CMS approval has failed to demonstrate sufficient infrastructure and scale to be sustained over time. Although we indicated we were willing to be flexible in accepting applications for initial approval from new national accreditation programs that were comparatively small, we stated we believe that an established CMS-approved Medicare accreditation program that was not able to accredit at least 50 healthcare facilities during the period since its initial approval would have failed to demonstrate long-term national viability. Further, we indicated that we have limited resources available to conduct the detailed, comprehensive review of an AO's application required under section 1865(a)(2) of the Act. We indicated we believe these limited federal resources are best focused on those larger accreditation programs responsible for oversight of the quality of care provided in hundreds of accredited healthcare facilities, serving millions of patients, rather than on an accreditation program connected with a relatively small number of Medicare providers or suppliers.

Comment: One commenter suggested that if an AO is truly national in scope, then it should be accrediting significantly more than 50 facilities. This commenter also suggested the final rule should make clear the time interval for reaching the threshold. By contrast, all of the other commenters on this provision opposed this proposal. One commenter found the number to be both too large and arbitrary. Several commenters suggested that we consider all of an AO's approved programs when assessing its infrastructure and sustainability, rather than each individual Medicare accreditation program in isolation. They indicated that an AO with a small program could rely upon the infrastructure and capabilities of larger, similar types of programs. Another commenter noted that the pool of potential facility applicants for some accreditation programs might be limited, giving as an example psychiatric hospitals. One commenter noted that the provision could present a barrier for an AO to maintain approval of a program that focuses on rural areas or markets with fewer resources to support their health care facilities. Another indicated that introduction of a minimum number of facilities an AO must accredit would create a significant barrier for entry for AOs seeking to gain or retain deeming authority and is on its face anti-competitive. This commenter pointed out that, since accreditation is typically for 3 years, the opportunity to convert a facility from one AO to another is infrequent, so that it can take years for an AO to grow. The commenter also noted that sometimes health care systems seek a single AO for all of their facilities, making it vital for an AO to provide comprehensive services, even if one of their programs does not meet an arbitrary number that CMS has set. Another commenter indicated that requiring an AO to achieve a minimum of 50 accredited facilities during its initial approval period for an accreditation program is acceptable, but that thereafter the AO should be considered to have met the criteria even if its program falls below 50 facilities. This commenter mentioned that some facilities may flock to an AO to obtain initial deemed status only to drop accreditation in favor of the state agency when it is time for them to be recertified. The commenter indicated this might be an unlikely scenario, but could not be ruled out, given the economic realities for some providers, and AOs should not be disqualified due to temporary fluctuations.

Response: We do not agree that our proposal would have created a significant barrier to entry for AO's seeking our initial approval. Our proposal would have established a minimum of 50 accredited facilities for each Medicare accreditation program for which an AO was seeking renewed approval. AOs seeking their first approval from us would not have been subject to this provision. When we approve an initial applicant, we typically provide a four-year approval and expect to see the AO's program grow during that first 4 years, to be sustainable over the longer term. Since accreditation programs typically provide a three-year accreditation, a program with fewer than 50 facilities might be conducting 16 or fewer surveys per year, making it difficult to ensure surveyor teams maintain their skill levels in conducting surveys for that type of provider or supplier.

On the other hand, we recognize the merit of those commenters who pointed out that the market for a particular program might be more limited, as is the case with psychiatric hospitals or for programs focused on rural areas. We also agree that smaller AOs seeking to compete with larger AOs have a legitimate interest in providing ''one-stop shopping'' for health care systems seeking deemed status for all the various types of providers and suppliers in their system. Finally, we acknowledge that the overall surveyor and administrative infrastructure of an AO that has several CMS-approved Medicare accreditation programs should be considered when assessing a given program's long-term sustainability. This does not entirely mitigate our concern about surveyors having more limited experience in understanding and applying the accreditation standards and survey methods for a small individual program. However, we agree that through the application review process for a renewal application we should be able to determine whether, all things considered, a program lacks adequate infrastructure and/or capabilities to warrant our renewed approval. Therefore we are not adopting the proposed provision at § 488.5(a)(15) in this final rule. We are renumbering all of the subsequent provisions of § 488.5(a) accordingly.

• We proposed at § 488.5(a)(16) to replace the requirement currently set out at § 488.4(a)(10), which addresses the requirement for AOs to provide us with a list of accreditation surveys scheduled to be performed. We proposed to revise this requirement to state that the AO would need to provide us only its survey schedule for the 6-month period following submission of an application for CMS approval. Since we must complete the entire application review and publish a final notice announcing our decision within a 210-day statutory timeframe, we indicated that it would not be useful for a survey schedule to be submitted for a longer timeframe. We stated that we use this survey schedule to plan our survey observation as part of our review of the AO's application. We indicated that this requirement would apply to both initial and renewal applications and would be distinct from the requirement proposed at § 488.5(a)(11) that an AO to submit survey schedules on a regular basis as

part of the data it agrees to provide us for our ongoing oversight.

Comment: We received one comment suggesting that we include the phrase ''deemed status'' in front of ''accreditation'' in the phrase ''all accreditation surveys.''

Response: For an accreditation program for which an AO is seeking our initial approval, addition of the suggested phrase would not be appropriate, since none of the facilities accredited by the AO under that not-yet-approved program would have deemed status based on that accreditation program. Even for a renewal application, an AO might include a survey scheduled for a provider or supplier that does not have deemed status, either because it is seeking initial enrollment and certification in the Medicare program, or because it is already enrolled as a non-accredited provider or supplier, or with deemed status based on another AO's program. However, upon adoption as § 488.5(a)(15), we are revising this provision to make clear our intent that an AO applicant provide us a survey schedule only for surveys for the accreditation program under our review.

• We proposed at § 488.5(a)(17) to replace the requirement currently set out at § 488.4(b)(2), which requires an AO to provide a resource analysis demonstrating that it has the resources to support its accreditation program. We stated that our proposed modifications of the current language would more clearly identify the type of documentation an AO must provide to demonstrate the adequacy of its resources. We received no comments on our proposal, and other than renumbering this provision to be § 488.5(a)(16), we are adopting this provision in this final rule as proposed.

• We proposed at § 488.5(a)(18) a new provision that would address requirements related to AO providing written notification at least 90 days in advance to its currently deemed providers or suppliers when the AO elected to terminate its CMS-approved accreditation program voluntarily. We stated that the affected providers or suppliers would subsequently need to be surveyed by SAs, unless they sought and received accreditation from another CMS-approved Medicare accreditation program.

Comment: One commenter indicated that an AO should be required to provide written notice to all patients or assure that the providers they accredit provide patients written notice, saying that patients have a right to know of any change in oversight of the provider.

Response: We believe that it is both unnecessary and unduly burdensome to require written notification of each patient when there is a change in their provider's oversight, whether from one AO to another, or from an AO to SA supervision, or from SA supervision to an AO, regardless of whether the change is due to decisions in individual cases on the part of the provider/supplier or AO, or if it is due to a voluntary or involuntary termination of an AO accreditation program's approval for Medicare deemed status. We believe that for patients and residents of Medicare-participating providers and suppliers, the specific nature of the oversight of their participation in Medicare is not pertinent, since our approval of an AO's accreditation program indicates that it meets or exceeds all Medicare requirements. By contrast, we do believe it is important for patients to know whether a provider's participation in Medicare has been terminated, whether voluntarily or involuntarily. However, even in this case we do not require individual patient notifications. Particularly for acute care providers and suppliers that have rapid turnover in patients from day to day, an individual notice requirement would be impractical. In the case of a voluntary termination of a provider, we require at § 489.52(c) that the provider must provide notice to the public through a local newspaper at least 15 days before the voluntary termination is effective; and in the case of an involuntary termination of a provider, in accordance with the provisions at § 489.53(d)(5), we similarly provide notice to the public.

Comment: One commenter noted a contradiction between this provision and the one we proposed at § 488.8(e), which would require an AO to give written notice to its accredited providers and suppliers in the event either of a voluntary or involuntary termination of its CMS-approved accreditation program no later than 30 days after publication of the termination notice in the **Federal Register**. The commenter noted that the timeframes may be compatible, but questioned why there needed to be two different provisions. The commenter also urged that hospitals be provided as much notice as possible, at least 90 days, and to simplify the notice requirement so that providers know what to expect.

Response: We agree that the interaction between proposed § 488.5(a)(18) and proposed § 488.8(e) is confusing. We are, therefore, revising this provision to distinguish between notice requirements for voluntary and involuntary terminations and to make explicit that notice of a voluntary termination must be given to us as well. In the revised provision in this final rule an AO would agree to provide written notice to us and its accredited providers or suppliers at least 90 calendar days in advance of the effective date of its voluntary termination of its CMS-approved accreditation program, and in the case of an involuntary termination action by us, to give notice to its accredited providers or suppliers as required by § 488.8(e). We are also requiring the AO to include in its notice the implications for the deemed status of its accredited providers or suppliers, in accordance with § 488.8(g)(2). We are also making conforming changes at § 488.8(e) to remove all reference to voluntary termination of a CMS-approved Medicare accreditation program by an AO.

• We proposed at § 488.5(a)(19) to replace the requirements currently set out at § 488.4(b)(3)(iii), which addresses the timeframe for AO notification to us regarding proposed changes in accreditation requirements. We indicated that we proposed to modify the current requirement by lengthening the advance notice period from 30 to 60 days, to provide adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. We also proposed language clarifying that any proposed changes in a CMS-approved accreditation program could not be implemented by the AO before we approved such changes. We stated that this policy would ensure that the accreditation program continued to meet or exceed the Medicare requirements.

Comment: Numerous commenters expressed concerns with or opposition to our proposed changes. Some of the commenters made objections similar to those they raised about our proposal at § 488.4(a)(1), concerning our approval of a program in its entirety. Various commenters suggested that an AO only be required to submit to us only those proposed standard changes related directly to the CoP; or be required to submit only ''proposed material changes''; other commenters expressed concerns that this provision would give us authority over ''non-deeming aspects'' of an accreditation program's standards; or that this requirement would be ''contrary to the very essence of the originally-intended deeming relationship.''

One commenter referenced our preamble statement, with regard to proposed § 488.5(a)(13)(i), that we were revising the current language to clarify that there would be no requirement for an AO to submit information on its

accreditation programs that fell outside the parameters of its Medicare accreditation programs, and indicated that it agreed it would be inappropriate to require an AO to submit changes to their programs that were unrelated to Medicare deeming status. The commenter suggested we amend our proposal to require advance submission only of ''Medicare-related standards.'' Another commenter indicated its support for the previous commenter's proposal.

Several commenters indicated that not allowing an AO to adopt revised standards prior to our approval would slow down implementation of changes needed to meet an ever-changing health care environment and advances in the oversight of quality and safety.

One commenter indicated that 60 days was a reasonable amount of time for an AO to prepare and CMS to review proposed changes, but expressed concern about the uncertainty created for the AO if it was prohibited from implementing its proposed changes until we gave our approval. This commenter indicated there could be potentially damaging and costly implementation effects if CMS did not give its approval in a timely fashion and noted that there was nothing in the proposed rule to hold us accountable for rendering timely decisions. The commenter suggested that we revise the proposal to state that unless we affirmatively rejected an AO's proposed changes within 60 days, the changes would be deemed approved and would take effect. The commenter also proposed as an alternative that we eliminate the 60 day advance notice requirement and replace it with a requirement that an AO submit proposed changes prior to implementation and not implement the changes until 30 days after receiving approval from CMS. The commenter stated that this would give CMS an open-ended review period, prevent implementation prior to approval, and not interfere with AOs' plans to roll-out a change. Another commenter requested that we establish a timeframe by which CMS would have to give its response to a proposed change.

Response: We find many of the comments surprising, since we do not believe our proposal differs substantively, beyond the change from 30 to 60 days, from the requirements under the current regulations, which are found at § 488.4(b)(3)(iii) and § 488.8(d)(1)(ii). Taken together, these provisions oblige an AO to submit its proposed changes to us 30 days in advance and oblige us to conduct a comparability review of the proposed changes to determine the equivalency of the AO's proposed revised requirements to the Medicare requirements. As we stated in our response to comments on proposed § 488.4(a)(1), it would be arbitrary and contrary to the statute if, under the theory that its changes would not affect any accreditation provisions related to Medicare requirements, an AO modified portions of a CMS-approved Medicare accreditation program without providing us prior notice and our determination of whether the revised program continued to meet or exceed the Medicare standards, and could continue to be approved. We may not delegate to an AO our responsibility under the statute to determine whether an accreditation program, including any changes to it, meets or exceeds all Medicare requirements. This is not new policy on our part, because we believe it is required by the statute and our current regulations. We proposed to make this policy more explicit in our proposed regulations due to confusion a few AOs have had around this issue.

The commenter who noted our preamble statement in reference to our proposal at § 488.5(a)(13)(i) misunderstood our statement, or misapplied it in the context of proposed § 488.5(a)(19). We are aware that some AOs offer multiple types of accreditation programs, and that CMS-approved Medicare accreditation programs may be a subset of their overall accreditation program offerings. Our preamble statement related to proposed § 488.5(a)(13)(i) was intended to clarify that we do not require an AO to submit information to us on any accreditation program it offers which is not a Medicare accreditation program for which it is seeking our initial or renewed approval. Our statement was not intended to imply that an AO does not have to submit proposed changes within its CMS-approved Medicare accreditation program, and the express language of our proposal at § 488.5(a)(19) makes clear that, in fact, we expect all proposed changes to a CMS-approved Medicare accreditation program to be submitted to us in advance.

We find merit in those comments that expressed concern about undue delays if our reviews are not timely. We believe that we should be accountable to AOs just as we expect them to be accountable to us. We also agree that the language of both the current and proposed regulations, by specifying a notice requirement tied to the effective date of an AO's proposed changes, can be a source of confusion. Accordingly, in this final rule we are revising this provision to: change the number to § 488.4(a)(18), reflecting the prior revision; remove reference to the effective date of the changes; and indicate that the AO agrees to not implement the changes before receiving CMS approval, unless 60 calendar days after submission of the proposal has passed and CMS has not responded. We are also making conforming changes to § 488.8(b)(1)(iv) to state that an AO may implement a change in its standards without jeopardizing its Medicare accreditation program if we do not notify the AO within 60 calendar days after receipt of their proposed revisions of the results of our comparability review, including whether or not the AO's Medicare accreditation program, as revised, would continue to have CMS approval.

- We proposed at § 488.5(a)(20) to replace the requirement, currently set out at § 488.4(b)(3)(iv), concerning AO submission of changes to its standards within 30 days of a change in our requirements. We proposed modifying the regulation text by deleting references to specific timeframes. We indicated this would provide us the flexibility to consider other factors when determining an appropriate timeframe for AOs to revise their program and submit their conforming changes to us. We stated these factors may include: the effective date of the applicable final rule, the effective date of our revised interpretive guidance or survey process, and the scope and magnitude of our changes that require corresponding AO changes. We further stated that AOs would benefit from our having the flexibility to provide them longer timeframes for response, when appropriate. In addition, we proposed adding language to ensure the AO program continues to meet or exceed the Medicare requirements, and specify the consequences for an AO's failure to submit timely comparable changes.

Comment: One commenter requested clarification on how CMS will communicate these changes, asking if they would be published in the **Federal Register** as notices of proposed and final rules.

Response: Our reference to changes to the ''applicable Medicare conditions or requirements'' refers both to changes in our regulations governing the various types of providers or suppliers, including applicable changes in our regulations at parts 488 and 489, as well as substantial revisions to our official interpretation of applicable regulatory requirements. All regulation changes are accomplished through **Federal Register** notices of proposed rulemaking and notice of adoption of a final rule. All changes to our official interpretation of

applicable regulatory requirements are distributed to SAs via Survey and Certification Policy memoranda, which are also distributed to affected AOs and are published online. These changes are then subsequently incorporated into our online SOM, Publication 100–07. Our proposal called for an AO to submit its proposed conforming changes to us within 30 calendar days or by the date specified in the CMS notice to the AO, whichever is later. We recognize, however, that the proposed regulatory language, by using the term ''notice,'' appears to have led some commenters to believe we were referring to **Federal Register** notices. To avoid future confusion we will revise the regulatory text to state: ''in response to a written notice from CMS to the organization of a change. The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization, or by the date specified in the notice, whichever is later.''

Comment: Several commenters requested that the provision be modified to include a mechanism for AOs to request additional time in implementing changes to their programs in response to CMS-initiated changes. These commenters also proposed that we include a timeframe to complete our review of the AO's changes, with one commenter suggesting 30 days.

Response: We agree and are modifying our proposal in this final rule to indicate we will give due consideration to an AO's request for extension submitted prior to the deadline. We also are revising the final rule to indicate that the AO agrees not to implement its proposed changes without our prior written notice of continued program approval, except as provided for at § 488.8(b)(1)(iv). That provision will state that an accreditation program's proposed changes in its standards will be deemed approved unless we provide the AO with a written notice of the results of our review no later than 60 days after receipt of the proposed changes.

Comment: One commenter opposed our requiring AOs to obtain CMS approval prior to implementing any changes to a CMS-approved program, indicating this would cause delays in implementation and limit flexibility.

Response: Section 1865 of the Act requires us to determine whether an AO's Medicare accreditation program meets or exceeds all applicable Medicare requirements. When those requirements change, it is necessary for us to determine whether the AO's program continues to meet or exceed the applicable Medicare requirements. We believe it would be even more time-consuming and disruptive if an AO were to implement changes that we subsequently determined no longer met Medicare standards. The AO would be faced, in this case, with then having to make and implement further program changes or else undergo a deeming review that could result in our terminating our approval of its program as a Medicare accreditation program. Accordingly we believe it is prudent for all parties if the AO agrees in its application to not implement changes that have neither been found nor deemed to warrant our continued program approval.

In this final, rule we are adopting this provision revised to reflect the numbering change referenced above, to make clearer that the purpose of our review is to determine whether the proposed revised accreditation program meets the standards for our continued approval, to make explicit that we will give due consideration to timely requests for an extension of the deadline for submitting proposed revisions to us; and to cross-reference § 488.8(b)(1)(iv), that permits a revised program to be deemed to have our continued approval if we do not issue a written determination within 60 days of receipt of notification.

- We proposed at § 488.5(a)(21) to modify the requirement currently set out at § 488.4(b)(3)(v), which requires the AO to permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We proposed modifying the regulation by adding language to clarify the scope of the requirement.

Comment: Two commenters expressed concerns with our proposal to change the current requirement for an AO to ''permit'' its surveyors to act as witnesses to a requirement for its surveyors to serve as witnesses. One indicated a surveyor should be able to refuse to be a witness. The other indicated that this provision would force an employer to condition an employee's hire on compelled speech, which could impact an individual's First Amendment rights. This commenter suggested the current provision could be strengthened without impacting an individual's rights, and proposed we used language such as ''make surveyors available'' or have CMS serve an AO with an administrative subpoena if a surveyor is reluctant to serve as a witness.

Response: Although section 1865(b) of the Act clearly authorizes us to take enforcement action on the basis of a survey conducted by an AO with an approved Medicare accreditation program, in practice we generally exercise our enforcement discretion to take enforcement action based on SA surveys conducted for us. That is why we typically require an SA survey, when an AO reports an adverse accreditation action on its part, or when it reports finding an immediate jeopardy situation. However, one standard exception to this practice concerns AO surveys of prospective providers or suppliers seeking initial certification to participate in Medicare. Since we have for a number of years, in an effort to make efficient use of federal resources, established initial surveys for prospective providers and suppliers that have an accreditation option as the lowest work priority for SAs, we usually make initial certification decisions involving applicants who seek deemed status after reviewing AO survey reports. These initial certification decisions include denials of certification and determination of the effective date of the Medicare provider agreement or supplier approval, and both of these types of decisions may be appealed by the applicant at the administrative level. Generally such appeals actions do not require an AO's surveyors to appear as a witness, but we cannot exclude this as a possibility. Thus we proposed that an AO require its surveyors to be available to serve as a witness. Therefore, we are revising this provision to require an AO to permit surveyors to serve as witnesses, and to cooperate with CMS to make surveyors available when needed as witnesses. We are also renumbering this provision, consistent with our revisions above.

- We proposed at § 488.5(b) to revise the requirement currently set out at § 488.4(c), which provides that if we need additional information to make a determination for approval or denial of an AO's application for deeming authority, the AO will be notified and afforded the opportunity to provide such information. We stated that we proposed deleting the language, ''deeming authority,'' which has been a source of confusion both internally and externally. It has led healthcare facilities and others to mistakenly believe that the AO awards deemed status and participation in Medicare. We stated that this proposed removal clarifies that only CMS has the authority to grant ''deemed status,'' not the AO. We received no comments on this proposal and are adopting it in this final rule without change.

We proposed at § 488.5(c)(1) to replace the requirement currently set out at § 488.4(f), which addresses the provision that an AO may withdraw its application at any time before the final

notice is published in the **Federal Register**. We also proposed a new requirement at § 488.5(c)(2) to address situations where an AO wishes to voluntarily terminate its CMS-approved Medicare accreditation program. We stated that in such case, the AO must notify us of its decision and provide an effective date of termination. We proposed that we would publish in the **Federal Register** a notice that includes the reason for the termination and the effective date. We stated that, in accordance with the requirements we proposed at § 488.8(e), the AOs would have to notify, in writing, each of its providers or suppliers of its decision no later than 30 calendar days after the notice was published in the **Federal Register**. We received no public comments on these proposed revisions, but are making conforming changes to reflect the changes we are making in response to public comments to § 488.4(a)(17) and § 488.8(e), to remove any reference to publishing a notice in the **Federal Register**.

• We proposed at § 488.5(d) and § 488.5(e) to replace the requirements currently set out at § 488.4(h), which addresses requests for reconsideration, as well as those occasions when we permit an AO whose request for approval of an accreditation program has been denied to resubmit its application, including certain requirements to be met. Specifically, we proposed at § 488.5(d) that if an AO has requested, in accordance with part 488 subpart D, a reconsideration of a disapproval, it may not submit an initial application for an accreditation program for another type of provider or supplier until the hearing officer's final decision has been rendered. We proposed at § 488.5(e) to allow an AO to resubmit its application for an accreditation program after our initial denial if the AO revises its program to address the issues related to the previous denial, demonstrates that it can provide reasonable assurance that its accredited facilities meet the applicable Medicare program requirements, and resubmits the application in its entirety.

Comment: We received no comments on our proposed § 488.5(e), but did receive a comment on proposed § 488.5(d) which requested that we remove it as contrary to the principle set out in the rest of the rule that each accreditation program is independent of other programs of an AO. The commenter stated that reconsideration of a denial should not be tied to an AO's ability to submit an initial application for a different program.

Response: We agree with the commenter that an AO's ability to request a reconsideration of a denial should not be conditioned upon precluding that AO's submission of an initial application for a different program. As we indicated in the preamble to the proposed rule, it was not our intent to change the current regulatory requirement, but we agree that the language in the proposed § 488.5(e) does not accurately reflect our expressed intent. We are therefore revising these provisions in this final rule by deleting a separate paragraph (d) and renumbering and revising paragraph (e) to allow resubmission of an application for a program previously denied by us if the AO has revised the program to address the issues related to the denial, demonstrates reasonable assurance and resubmits the application in its entirety. We are also taking this opportunity to make a technical correction to change the terminology ''demonstrates reasonable assurance that its facilities meet the applicable Medicare program requirements'' to ''demonstrates reasonable assurance.'' The definition of ''reasonable assurance'' at § 488.1 in this final rule already requires meeting the applicable Medicare program requirements, so the deleted language was superfluous. Consistent with the current requirement, we are also indicating that an AO that has requested reconsideration of our denial may not resubmit an application for that type of provider or supplier accreditation until the reconsideration is administratively final.

• We proposed at § 488.5(f) a new proposed provision, entitled ''Public Notice and Comment,'' that would incorporate the timeframes for review of an AO request for CMS approval of an accreditation program that are set forth in section 1865(b) of the Act. Specifically, we proposed at § 488.5(f)(1) to replace the requirement currently set out at § 488.8(b)(1), concerning publication of a proposed notice announcing our receipt of an AO application in the **Federal Register**. To better capture the purpose of a proposed versus a final notice, we indicated that we proposed to revise the language or current provision by deleting reference to describing how the AO's accreditation program provides reasonable assurance that entities accredited by the organization meet the Medicare requirements, since this language is more appropriate for the provision concerning the final notice. In addition, we proposed to add language related to the timeframe for public comment, consistent with section 1865(a)(3)(A) of the Act. Further, we proposed at § 488.5(f)(2) to replace the requirement currently set out at § 488.8(b)(2), which requires us to publish a final notice announcing our decision to approve or disapprove an AO's accreditation program in the **Federal Register**. In accordance with section 1865(a)(3)(A) of the Act, the final notice must be published no later than 210 days after our receipt of a complete application. We stated that our proposed revision would streamline and simplify the language of the regulations, to more clearly communicate existing requirements. Finally, we proposed at § 488.5(f)(2)(i) to replace the requirements currently set out at § 488.8(b)(1), § 488.8(b)(2), and § 488.8(c), which address the contents of the final notice. We stated that once a national AO's accreditation program is approved by us and this decision is published in the **Federal Register**, we could approve any provider or supplier that is surveyed for Medicare participation on or after the effective date of the final notice (assuming that all other federal requirements have been met).

Comment: Two commenters responded to this provision by indicating the public cannot evaluate and comment on an applicant if it does not have the information in the application. One commenter requested that we publish in the final rule information on how to obtain a copy of an AO's application, while the other requested that the application be posted on the internet during the public comment period.

Response: The information about an AO's application which the Secretary is required to disclose to the public in accordance with section 1865(a)(3)(A) of the Act is the identity of the AO making the request, and the nature of the request. We appreciate the commenters' interest in having more information to enable them to make comments to us. However, AOs regard the detailed information about their programs to be proprietary information which is exempted from disclosure under the Freedom of Information Act (5 U.S.C. 552(b)(4)) and HHS regulations (see, for example, 45 CFR 5.65), and thus we do not provide copies of the applications when requested to do so, nor would we be able to post these applications on our Web site.

As discussed in our response to comments about the application of section 1865 of the Act to long term care facilities, we are making a technical correction to reflect the fact that the 210 day timeframe does not apply in the case of an application for a Medicare SNF accreditation program. We are also

making a technical correction to § 488.5(e)(2)(i) and (ii), which discuss final notice provisions when we approve, re-approve or disapprove an accreditation program. We are removing superfluous language that is already incorporated into the definition of ''reasonable assurance.'' We are also renumbering this paragraph as § 488.5(e), as a resulting of our consolidation of proposed paragraphs (d) and (e) discussed above.

7. Providers or Suppliers That Participate in the Medicaid Program Under a CMS-Approved Accreditation Program (§ 488.6)

• We proposed to broaden and revise the standard's title. We stated that the proposed regulations at § 488.6 would replace the requirement currently set out at § 488.5(b) (78 FR 20570). As with the previous version of this provision in both § 488.5(b) and § 488.6(b), eligibility for Medicaid participation may be established through Medicare deemed status for those providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements. Additional Medicaid eligibility requirements and state plan requirements, as applicable, would continue to apply. We received no comments on our proposal and are adopting it in this final rule. We have made one clarifying revision so that it more closely reflects the existing policy set out at § 488.5(b) and § 488.6(b).

8. Release and Use of Accreditation Surveys (§ 488.7)

• We proposed revising this standard's title to be more reflective of the standard's content. We proposed at § 488.7 to replace the requirement currently set out at § 488.6(c)(1), which states that an accredited provider or supplier must authorize its AO to release a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans) to us and the SA. We indicated that under the proposed revision the deemed status provider or supplier would be required to authorize release of a copy of its most recent accreditation survey only to us.

We proposed other changes as part of our effort to reorganize and clarify the regulations, as follows:

• We proposed at § 488.7(a) to replace the requirement currently set out at § 488.6(c)(2), which indicates that we may determine that a provider or supplier does not meet the Medicare conditions on the basis of our own analysis of the accreditation survey or any other information related to the survey. We indicated that the language of this requirement would remain unchanged, although we note that we made two technical revisions, that is, referring to ''conditions and requirements'' so that the provision would unambiguously apply to any type of provider or supplier accreditation program.

• We proposed at § 488.7(b) to replace the requirement currently set out at § 488.5(c)(3) regarding our authority and discretion to disclose an AO survey and information related to the survey when the accreditation survey is related to an enforcement action taken by CMS. All other disclosures of AO survey information are prohibited under section 1865(b) of the Act, with the exception of surveys of HHAs. We proposed to revise this provision to clarify its requirements.

We also stated that we were taking the opportunity to clarify in the preamble that we recognize that, in accordance with the Patient Safety Act and Quality Improvement Act (PSQIA) (Pub. L. 109–41) and implementing regulations at 42 CFR 3.206(b)(8)(i) and (ii), an AO may not further disclose patient safety work product it receives when such work product complies with the requirements for patient safety work product protected under the PSQIA.

Comment: A number of commenters indicated their opposition to the disclosure of accreditation surveys and related information. One commenter proposed that CMS provide any corrective action plan when releasing information about enforcement action.

Response: Section 1865(b) of the Act prohibits our disclosure of any accreditation surveys conducted by AOs, with the exception of surveys conducted of HHAs. In the case of HHAs, routine disclosure is expressly permitted under the Act. However, for accreditation surveys of any type of provider or supplier, section 1865(b) of the Act also provides that we may disclose an accreditation survey and related information to the extent that such survey and information relate to an enforcement action we have taken. In such cases our policy is to disclose the information upon receipt of a written request. If we have received related corrective action plans developed by the provider/supplier, we would include those in the disclosure.

Comment: One comment from a group of organizations indicated that, given the large amount of public funding nursing homes receive, consumers have a right to know about quality of care in a nursing home. They also questioned how Nursing Home Compare could be maintained without AO survey results, stating that deemed status would undermine Nursing Home Compare. This group also recommended that we change the language of the regulation to say we ''must,'' upon written request, disclose surveys and information related to an enforcement action.

Response: Section 1865(b) of the Act says that we ''may'' disclose an accreditation survey and other information related to an enforcement action we take, but does not require us to do so. The policy we proposed at § 488.7(b) reflects the statute and continues the policy that our regulations have reflected at least since 1993, when the provision at § 488.5(c)(3) was last amended. We do not believe it would be prudent for CMS to restrict the discretion permitted to us under the statute. Accordingly, we are not revising this final rule to state that we must make such a disclosure.

With regard to public disclosure requirements related to surveys of nursing homes and the potential impact on Nursing Home Compare of not disclosing accreditation surveys, we believe these are among the many issues we would need to consider should we ever receive an application from an AO seeking our approval of a Medicare long-term care accreditation program.

Comment: A number of commenters, mostly representing hospitals, expressed concern with the provision indicating that we may determine on the basis of our own investigation of the accreditation survey that a provider or supplier does not meet the applicable Medicare conditions or requirements. One commenter stated that, given the framework of the AO deeming structure and its checks and balances, CMS should not be second-guessing the decisions of the AOs. The commenter recommended instead that if CMS has concerns about a particular survey it should engage the AO in a conversation about those concerns. Several commenters found it unclear why CMS would keep this redundant requirement rather than trust the AOs to which CMS has delegated authority, and called for us to remove the provision. Another commenter indicated that it is not clear from the regulatory language what an ''investigation'' of the accreditation survey would entail and whether CMS could issue a compliance decision to the accredited facility, regardless of whether any federal requirements were found to have not been met in a validation survey. The commenter indicated this lack of clarity about the requirements of the CMS ''investigation'' of an AO's survey posed a significant risk to hospitals for action by CMS and urged

clarification of the parameters of the ''investigation'' and articulation of the potential adverse actions to be taken against healthcare providers as a result of the review. Along similar lines, another commenter objected to this provision, saying the regulation would not require CMS to conduct a site visit prior to rendering a decision, and was vague and ambiguous regarding what other information could be used in the investigation, raising the possibility of inconsistent decisions that could be adverse to the provider. The commenter also objected to there being no guidance on how far back CMS could look when taking into account ''other information'' and asked whether it could be 2 years or even 5 years. Another commenter also asked for clarification of the phrase ''investigation of the accreditation survey,'' inquiring if CMS would make a decision about compliance with the Medicare requirements based only on an accreditation survey, especially those that had no condition-level findings.

Response: This provision is a long-standing regulatory component of part 488. Section 1865(c) of the Act provides that if we find a provider entity has significant deficiencies, that entity shall not be deemed to meet the conditions or requirements. Neither approval of an AO's accreditation program nor a section 1864 agreement with an SA are delegations of authority to either AOs or SAs to make Medicare participation determinations. We state explicitly at § 488.12 that SA ''certifications'' of a provider's or supplier's compliance or noncompliance are recommendations to CMS, and that CMS makes the determination on the basis of these recommendations on whether a provider or supplier is eligible for Medicare participation. Likewise the current, longstanding provision at § 488.6(c)(2) states that we may determine that the provider or supplier does not meet the Medicare conditions based on our own investigation of the accreditation survey or related information. All AOs with current approved Medicare accreditation programs have been informed on more than one occasion that they must explicitly characterize their written notice to us concerning their positive accreditation decision for a specific facility as a ''recommendation'' for deemed status. Moreover, a recent decision of the Appellate Division of the Departmental Appeals Board (DAB) agreed with our reading of the statute that we are not compelled to accept an AO's recommendation of deemed status for a specific facility *(Wesley Medical Center, LLC, d/b/a/Galichia Heart Hospital, Dk. No. A–14–44, DAB Decision No. 2580 (June 30, 2014))*

As we stated in our response to comments concerning proposed § 488.5(a)(21), typically we rely upon AO recommendations concerning deemed status, and therefore review an AO's survey report, when the AO recommends deemed status for a prospective provider or supplier seeking initial participation in the Medicare program. Generally, we have no prior survey or other information on such applicants, so that the issue of how far back we may look at prior information is moot. Limited exceptions may occur, such as when the applicant was previously enrolled in Medicare and involuntarily terminated for failure to comply with Medicare requirements. In accordance with § 489.57(a), we are required in such cases to find that the reason for termination of the prior Medicare agreement has been removed and there is reasonable assurance it will not recur. Another exception would occur when an applicant for whom we recently denied participation based on either a state or AO survey is recommended for deemed status. In such cases we would review the AO's survey report in light of the survey findings on which we based our denial. Even if we were to begin relying directly upon AO surveys to take adverse enforcement action against current providers or suppliers, it is important to note that, in the case of non-long term care providers and suppliers, we take enforcement action based only on current noncompliance, so that the issue of a look-back timeframe would continue to be moot.

To illuminate what we mean by an ''investigation,'' we provide the following examples of situations when, after our review, we have rejected an AO's deemed status recommendation and have denied a prospective provider's or supplier's application for certification and Medicare participation. We emphasize that this is not an exhaustive list and that other circumstances could arise that require our investigation. We have had instances where our review of an AO's survey report indicates that it conducted a focused survey instead of a full accreditation survey in the case of a facility with a new owner who has rejected assignment of the prior owner's Medicare agreement. Our regulations and policy clearly indicate that, when a new owner rejects assignment, that prior Medicare agreement with the seller is voluntarily terminated and the new owner has the same status as any other new applicant for Medicare participation, and must undergo a survey to evaluate compliance with all Medicare or, in the case of an applicant seeking deemed status, accreditation requirements.

We have also had instances where an AO's survey report for a prospective provider or supplier indicated that deficiencies were identified that the AO did not find rose to substantial noncompliance with a Medicare condition. In these cases, the AO recommended deemed status after the facility agreed to an acceptable plan of correction. However, our review of the AO's survey report concluded that the AO's own description of one or more of the identified deficiencies clearly indicated substantial noncompliance, and that the AO should have advised us of this rather than awarding accreditation. In such circumstances, we would have denied the certification. In accordance with § 489.13(c) the effective date of a positive accreditation decision may not be earlier than the date on which the applicant is found to meet all applicable conditions. Further, section 2005A4 of the SOM states that an AO must notify us of substantial noncompliance, so that we can issue a denial of certification. The provision also allows the AO to continue to work with the applicant for up to 6 months after our initial denial of certification, before we issue a final notice of denial to the Medicare Administrative Contractor, which in turn would deny enrollment. When we believe an AO's own survey report does not support its recommendation of deemed status, we often reach out to the AO to discuss the situation, but still do not certify an applicant with substantial noncompliance.

Occasionally we obtain information that raises compliance issues not addressed by the AO's survey. For example, for hospitals or CAHs enrolling in Medicare, we collect extensive descriptive data via the Hospital/CAH Medicare Database Worksheet, Exhibit 286 in the SOM. This worksheet is not completed by the provider or AO, but is instead completed either by the SA, when it conducts a full survey, or by our regional office, usually by telephone call to the applicant, in the case of a deemed status hospital or CAH applicant for certification. There have been a few occasions when the applicant's responses raise significant questions about the manner in which it operates, and we have then followed up with the AO for more information. In rare instances where the AO's responses fail to clarify the situation, before issuing a denial of certification we have used an on-site survey by a state or federal

survey team to gather additional information to enable us to render an appropriate certification decision. After consideration of the public comments we are adopting proposed § 488.7 in this final rule without change.

9. On-Going Review of Accreditation Organizations (§ 488.8)

We proposed modifying the title of this standard with language that is more specific and clarifies that our oversight of accreditation programs is continuous. We also proposed further revisions at § 488.8 consistent with our effort to reorganize, streamline and clarify the regulations, as follows:

• We proposed at § 488.8(a) to replace the requirement currently set out at § 488.8(d), which addresses the continuing federal oversight of equivalency of an AO's approved accreditation program. We stated that the proposed revisions would ensure consistency with section 1875(b) of the Act, which requires our continuing oversight of the accreditation process of AOs approved in accordance with section 1865 of the Act and yearly reports to Congress concerning the operation of AO programs. The proposed revisions would replace the concept of a ''validation'' review with the broader concept of an ongoing AO ''performance'' review. We also proposed to remove reference at current § 488.8(d)(2)(i) to a ''20 percent'' validation survey rate of disparity as a threshold for triggering a review that could result in our termination of an AO's program approval. We stated that our experience over the past few years has demonstrated that, although the rate of disparity between AO and SA representative sample validation surveys of the same facility within a 60-day time period may be one reliable measure of some aspects of AO performance, a single measure used in isolation does not provide a complete and accurate picture of AO performance. We indicated that, as described in the CMS annual report to Congress, ''Review of Medicare's Program for Oversight of Accreditation Organizations,'' we employ a multi-faceted approach that utilizes not only the representative sample validation survey disparity rate, but also a number of other quantitative measures of AO performance, as well as the results of our periodic qualitative reviews of AO standards or of AO renewal applications to develop a comprehensive assessment of an AO's performance. We indicated that we believe it is not appropriate to include in the regulation a requirement, based on only one calculation, which would trigger an automatic, formal review of an AO's accreditation program's continuing approval. Likewise, we believe our ability to open a formal review of an AO program should not be limited by tying such review to one data point. As a result, we proposed deleting the specific reference in the regulation to a 20 percent disparity rate triggering a formal validation review. We proposed instead to provide at § 488.8(a) for an ongoing performance review of approved AO programs, and we identified at proposed § 488.8(a)(2) the representative sample validation survey disparity rate as only one of several components that may trigger a performance review. Further, we proposed in § 488.8(c) to provide for a formal accreditation program review when a performance review revealed evidence of substantial non-compliance. We stated that we believed that the proposed revision would enable us to continue to make use of the disparity rate in our ongoing assessment of AO performance, but also to make use of other performance indicators. Additional indicators would enable us to reach a more comprehensive assessment of the quality of an AO's program. We indicated that this revision would also make clearer that a formal accreditation program review could be opened as the result of a variety of serious compliance concerns. We also proposed at § 488.8(a)(1) through § 488.8(a)(3) to clarify that we would evaluate AOs' performance by looking at various aspects of their practices.

Comment: One commenter expressed opposition to our proposal to change the heading of this requirement from ''validation'' review to ''ongoing'' review, suggesting that the change would allow hospitals to be surveyed at any time for validation purposes, instead of as part of a random sample within 60 days of an AO's survey. The commenter stated that this would put deemed status and non-accredited hospitals on an unequal playing field, since hospitals choosing to be accredited by a private AO could be subject to a full validation survey beyond a 60-day period while hospitals surveyed by the state under contract to CMS are not governed by the same set of rules. The commenter further stated that the contracts between the states and CMS are confidentially negotiated and not transparent, and questioned why a hospital would have any incentive to work with an AO when it would be subject to a different set of standards. A number of other commenters also objected to our removing the ''fixed period'' during which a validation survey could be conducted.

Response: The commenters misunderstand both our current requirements and our proposal. Although proposed § 488.8 implements section 1875(b) of the Act, which requires us to conduct an ongoing ''validation'' of an AO's accreditation process, we believe the term ''validation'' in this context may be readily confused with the narrower concept of a validation survey analysis and disparity rate calculation, which is just one component of our overall process for validating, that is, evaluating, an accreditation program on an ongoing basis. The commenters assume incorrectly that we are making changes to when validation surveys may be conducted. That is not the case. It is important to note that section 1864(c) of the Act distinguishes between two types of validation surveys, as does the current provision at § 488.7: Representative sample validation surveys and validation surveys conducted in response to an allegation concerning a deemed status provider or supplier of substantial noncompliance with an applicable Medicare condition or requirement. The commenter appears to believe that only representative sample validation surveys are validation surveys, and we believe that the imprecise language at current § 488.8(d)(2) contributes to such confusion. In our annual report to Congress we calculate disparity rates only for representative sample validation surveys. As previously noted, section 3242 of the SOM requires SAs to conduct representative sample validation surveys no later than 60 calendar days after the scheduled end date of the AO's accreditation survey, and proposed § 488.8 would have no impact on this policy. Thus the commenters' fears are unfounded. We do wish to reiterate, however, that substantial allegation surveys are complaint-driven, and that a provider or supplier may undergo multiple state substantial allegation validation surveys within any given year depending on the number and nature of complaints. We also wish to clarify that state survey agencies are not our ''contractors'' in the sense that term is normally used for organizations from which federal agencies procure services. Instead, SAs are parties with whom we have entered into agreements under section 1864 of the Act, under which we pay the reasonable costs of the activities that states perform for us. The SOM, which is available to the public on our Web site at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/*

CMS1201984.html?DLPage=1&DLSort=0&DLSortDir=ascending, contains all of the regulations and subregulatory guidance which establish our expectations for the functions states perform under a section 1864 agreement. In addition, each year, based on the funding budgeted for state survey and certification activities in the federal budget, we communicate to the states how they should prioritize their federal workload, given the limitations on the resources available to cover their costs. Although we do not post these annual workload priorities on our Web site, they are certainly available in response to Freedom of Information Act requests. Thus we disagree that our relationships with the various SAs are not transparent. Finally, we do not understand the commenter's concern about hospitals that seek accreditation being subjected to different standards than those used by the states conducting validation surveys. It is true that hospitals, or any other type of deemed status provider or supplier, may be subject via accreditation to additional standards that exceed Medicare requirements. However, SAs do not evaluate providers' or suppliers' compliance with AO-only standards as part of their federal survey work. To the extent that a provider or supplier is cited as a result of a state validation survey for one or more deficiencies that an AO survey failed to identify, any seeming conflict is most likely the result of problems in an AO's accreditation survey process. We are always looking for ways in which we can better understand the source of these problems and help AOs understand what needs to be done so that their accredited facilities are always in compliance with the Medicare requirements, and do not find themselves surprised by different compliance expectations when the state conducts a survey. We believe that our proposal and our discussion of the comments we have received in this final rule also contribute to clarifying our expectations for AOs as well as providers and suppliers, and to removing providers' and suppliers' misconceptions about our requirements.

Comment: One commenter proposed modifying the language of this provision to state that ongoing review of AOs is applied to CMS-approved accreditation programs only. The commenter also stated that ''onsite observations should be as minimally disruptive as possible and be limited in scope''.

Response: We believe it is clear that the provisions of part 488 apply only to those accreditation programs for which AOs are seeking or have already received our approval. We make every attempt to minimize disruption to the AO's operations when we make onsite observations, and we limit the scope of our observations to matters pertaining to the program under review.

Comment: One commenter requested that CMS identify how it would conduct validation surveys of suppliers of the technical component of advanced diagnostic imaging.

Response: In this final rule we do not apply the provisions of part 488 to accreditation of the technical component of ADI suppliers, so the question is moot.

Comment: We received no comments about our proposal to remove the 20 percent representative sample survey disparity rate as an automatic trigger for our review of an AO's program. However, a number of commenters expressed concern that our reliance upon state validation surveys is seriously flawed. One commenter indicated that issues associated with the current validation survey framework include the following: (1) Assessment is one-way, in that CMS instructs its contractors, the SAs, to use the Medicare conditions as the standard to assess AO performance and that we assess only what the state found and the AO missed. The commenter pointed out that there is no analysis of what the AO found and the SA missed, creating an evaluation bias; (2) CMS must develop a new set of benchmarks, given that the way SAs and AOs make determinations of deficiencies differ too greatly. The commenter indicated the benchmarks need to be as outcome-based as possible, given that AOs should be given flexibility to innovate in their programs and processes; (3) there is variation among the states in how they conduct surveys and interpret findings. The commenter stated that patients and the public would be better served if all surveyors consistently focused on critically important issues that truly affect the delivery of safe, quality health care; (4) AOs consistently hear that states send in large survey teams, frequently including local fire marshals who are very familiar with a facility's physical plant, and that these teams stay at the facility longer than is feasible for AOs that must charge for their time onsite, and who therefore must balance their onsite time between clinical and infrastructure issues according to health and safety risk priorities; (5) there are differing interpretations of the severity of findings, with some AOs not scoring as deficiencies requiring improvement Life Safety Code (LSC) violations that are only low or medium categories of importance. The commenter stated that state surveys might generate a long list of such low-level deficiencies and then make a condition-level finding; (6) CMS frequently determines that a facility's condition constitutes an ''immediate jeopardy situation'' based on a situation that occurred well before the CMS survey, while the commenter (an AO) only makes a determination of an ''immediate jeopardy situation'' if there is a situation that presents itself during the survey that could cause harm to patients or the public.

Similarly, but in less detail, other commenters expressed objections to our reliance upon state representative sample validation surveys. One commenter called for us to establish a process for an AO to request reconsideration of a state's validation survey findings when the state's findings differ from the AO's findings. Another commenter said that state validation surveys are widely reported to be ''punitive'' in nature and often do not accurately reflect a provider's compliance. The commenter also noted variation among states in the size and scope of the survey teams and how deficiencies are identified. The commenter urged development of performance metrics for how the surveys will be used to evaluate AO performance. Another commenter indicated that CMS uses unannounced validation surveys to evaluate the AO's performance. It indicated a clear validation survey process based on unambiguous and understandable performance indicators is necessary to accurately evaluate an AO's performance.

Response: Section 1865(d) and section 1864(c) of the Act provide for validation surveys by SAs of providers and suppliers that have deemed status. Further, section 1875(b) of the Act specifically requires us to conduct a continuing ''validation'' of AO programs provided for in section 1865(a) of the Act and to report our findings annually. While we believe that the term ''validation'' in section 1875(b) of the Act is intended to cover a wider range of AO performance than the results of validation surveys, we do not believe the Act provides us discretion to omit state validation surveys from our analysis of an AO's performance.

With regard to the issue of the validation assessment being one-way and using the Medicare conditions as the standard, we note that section 1864(c) of the Act provides for a state to conduct a survey of a deemed status provider or supplier when we direct it to do so either as representative sample survey or in response to substantial allegation of noncompliance. The state must conduct the survey in accordance

with the requirements of section 1864(a) of the Act and does not have the authority to consider anything other than the applicable Medicare conditions when assessing compliance. Further, for the assertion that our analysis of the results of validation surveys does not consider deficiencies that the AOs found and the state missed, we note that while it is certainly possible that a state could overlook a deficiency that an AO found, given that the state survey occurs up to 60 days after the AO's survey, it is also possible that the surveyed provider or supplier has corrected deficiencies that the AO identified prior to the state's survey. In addition, most AO accreditation programs have standards that exceed those of Medicare. Therefore, an analysis of deficiencies that AOs cited and SAs missed would be of limited value since SAs are not evaluating compliance on these same standards. Implicit in the commenter's statements about benchmarking based on outcomes rather than what states focus on, and on LSC deficiencies it believes are not important, is a concern of the commenter with the substantive regulations that constitute the applicable conditions for a specific provider or supplier type. However, neither a provider/supplier nor an AO has the discretion to disregard Medicare requirements that it does not agree with, or considers ''less important.'' Section 1865(a) of the Act requires the AO's approved Medicare accreditation program to meet or exceed all applicable Medicare requirements. Likewise, we do not have the discretion to evaluate an AO's performance on any other basis than whether it meets or exceeds the applicable Medicare requirements. AOs or providers/suppliers are free to express their concerns with various substantive Medicare requirements and we evaluate such concerns in determining whether to revise requirements where we have the discretion to do so. Indeed, we have revised various conditions in recent years to reduce undue burdens on Medicare providers and suppliers. Once we change a regulation, then an AO may change its standards and survey process accordingly.

The allegation that states use larger survey teams and conduct longer surveys than do AOs has been raised in the past for hospital validation surveys. We reviewed our data concerning survey team size and hours and found that states tend to vary the size/length of survey according to the size of a hospital, as measured by the number of certified beds. We found no evidence that states fielded larger survey teams or conducted longer surveys when conducting validation surveys of deemed status hospitals as compared to their surveys of non-accredited hospitals. We note that section 1865(a)(2) of the Act requires us to consider in our review of an AO's Medicare accreditation program the AO's ability to provide adequate resources for conducting required surveys. Regardless of the size of accreditation survey teams, we require them to be able to accurately assess compliance with all Medicare requirements as a condition of our approval.

We note that our methodology for calculating the representative sample validation survey disparity rate gives AOs the benefit of the doubt in a number of ways. We do not compare state and AO surveys where they state found only lower-level deficiencies; instead, we compare only those surveys where they state identified substantial noncompliance, on the theory that substantial noncompliance is likely systemic, and therefore, was likely already present when the AO conducted its survey up to 60 days earlier. However, despite comparing only this more limited subset of surveys, for the denominator in the disparity rate calculation we use all representative sample validation surveys conducted in the given fiscal year. We have been criticized in the past for this methodology and urged to calculate instead a ''disagreement rate'' using for the denominator only those surveys where states found substantial noncompliance. We did in fact report a disagreement rate for several years in our report to Congress, but stopped doing so more recently because we believe it unfairly disregards those surveys in which neither the AO nor the state found substantial noncompliance. Our methodology in calculating the disparity rate gives AOs the benefit of the doubt in that we do not find a disparity between a state and an AO survey so long as the AO has identified a comparable deficiency, even if the AO does not indicate that the deficiency rises to the level of substantial noncompliance. We permit AOs considerable latitude, with the exception of initial Medicare surveys as required at § 489.13, in how they categorize deficiencies and what kinds of enforcement actions they take within their accreditation programs based on the deficiencies they identify. Therefore, we accept all evidence in a survey report of their identification of comparable deficiencies when comparing their findings to state findings for the disparity rate analysis. We see no reason to establish a process for reconsideration of a state's survey findings; we also believe that there is no feasible method for implementing such a reconsideration process.

In response to comments about the variability in state surveys, we acknowledge that there is variability and we employ a variety of mechanisms to assess and improve SA performance. As we noted previously, SAs are not contractors in the normal sense, but this does not mean that we do not provide ongoing oversight of their performance. We are also convinced that variability in SA performance is not relevant to the discussion of our use of validation survey results to evaluate AO performance. Consistently among the SAs and over time the largest source of disparate findings between states and AOs has been AO difficulties in assessing compliance with the LSC, compliance with which is designed to prevent fires in health care facilities and to reduce the adverse impact should a fire occur. Various AO practices may have contributed to their LSC compliance assessment difficulties, including purportedly issuing LSC waivers to providers, though they lack authority to do so, choosing not to issue citations requiring corrective action for what the AO considers to be minor LSC noncompliance, or focusing their survey activities on areas that they consider more important than fire protection requirements. Nevertheless, we expect all AOs with accreditation programs for providers or suppliers that are subject to LSC requirements to be able to assess compliance with the LSC.

We disagree with the comment objecting to our view that a long list of minor LSC deficiencies cited by a state could end up with a finding of substantial noncompliance. In accordance with § 488.26(b), the manner and degree to which a provider or supplier satisfies the standards within a requirement or condition is considered when determining compliance with that requirement or condition. For states or AOs assessing compliance for non-long term care providers and suppliers we have long interpreted this provision to mean that there could be substantial noncompliance as a result of various situations, including a situation where there is pervasive noncompliance on the part of a provider or supplier, even if every single instance of noncompliance on its own does not constitute substantial noncompliance. Such pervasive noncompliance is suggestive of systemic problems that need correction. If an AO systematically disregards what it views as ''minor''

types of noncompliance, it risks missing underlying systemic weaknesses in a provider's or supplier's systems.

We also disagree with the comment concerning state validation surveys being perceived as ''punitive'' in addition to being unannounced. We require both states and AOs to conduct unannounced surveys, and assuring compliance with our regulations is not ''punishment'' but part of our responsibility to protect patients and their families. Further, to the extent that a state survey finds substantial noncompliance, we are required to take appropriate enforcement action to bring the provider or supplier back into compliance or to take adverse action if it fails to do so. We expect that AOs finding the same noncompliance also take swift action within their accreditation programs to bring the provider or supplier back into compliance or to take adverse accreditation action when an accredited provider or supplier fails to correct its deficient practices.

Finally, for the comment about immediate jeopardy, the comment is not directly pertinent to the issue of validation surveys and our calculation of the disparity rate. As noted in this section of this final rule, in calculating the amount of the disparity, we do not consider the level of an AO's citation in its survey report so long as it identifies a deficiency comparable to the one that the state survey team found. Further, the comment incorrectly describes the criteria for immediate jeopardy situations, at least for non-long term care providers or suppliers. Since there are no approved long-term care accreditation programs, the comment incorrectly describes a supposed policy difference that currently exists between AO and state practices in citing an immediate jeopardy. For non-long term care providers and suppliers we assess only their current compliance, at the time of the survey, with the Medicare requirements. However, an event that occurred in the past and involved violations of our requirements may be evidence of current noncompliance with those requirements, unless there is also evidence to indicate that the provider or supplier identified and corrected the deficient practices associated with that event prior to the survey. In such cases there continues to be the potential for similar harm to patients or others in the future. In the case of a past event that clearly met the criteria for an immediate jeopardy determination, which we will discuss further in connection with our proposed revision to § 489.3, failure of the provider or supplier to address the underlying causes of that event may indicate that the immediate jeopardy is still present. We have had discussions with individual AOs that appear to have misunderstood this concept, to make clear to them that it is inappropriate for them to conclude that a past event can never be evidence of an immediate jeopardy situation at the time of the survey.

Comment: Several commenters requested clarification on the criteria that would trigger a program review other than the disparity rate, changes to CMS requirements, or changes to an AO's standards.

Response: In our proposal we indicated that we would consider the AO's survey activity (for example, whether it was conducting timely re-accreditation surveys), the results of validation surveys, and its continued fulfillment of the requirements in our proposal at § 488.5(a). We believe this provides considerable specificity as to the types of factors we consider. We proposed that our consideration would not be limited to these factors, however, because we are unable to anticipate all the situations that potentially could arise which might warrant our evaluation. After due consideration of the public comments we are in this final rule adopting § 488.8(a) without change.

- We proposed at § 488.8(b) to revise the requirement currently set out at § 488.8(d)(1), which addresses the conditions under which we would assess the equivalency of an AO's approved program to the comparable CMS requirements. We proposed at § 488.8(b)(1) to revise the requirement currently set out at § 488.8(d)(1)(i), which addresses the need for us to conduct a comparability review when we impose new requirements or change our survey process. We proposed adding language to the existing requirement which would provide us the flexibility to consider multiple factors when determining an appropriate timeframe for AOs to revise their accreditation program and submit revisions to us. We indicated that these factors may include: The effective date of any final rule which would affect the substantive standards which are applied to various providers and suppliers; the effective date of any revised interpretive guidance or survey process affecting accredited providers or suppliers; and the scope and magnitude of such changes. In addition, we proposed new language to set out the consequences if an AO failed to submit comparable changes in a timely manner, that is, we may open an accreditation program review in accordance with § 488.8(c). We indicated these proposed provisions would parallel revisions we proposed at § 488.5(a)(20).

We received comments on both this and the parallel provision at proposed § 488.5(a)(20) (adopted in this final rule as § 488.5(a)(19)) concerning how CMS would communicate its notice of regulation changes to AOs, calling for addition of a provision allowing AOs to request an extension of the timeframe for it to respond, and calling for a timeframe for CMS to respond to the AO's proposed revisions. We addressed these concerns in more detail in our discussion of proposed § 488.5(a)(20) (adopted in this final rule as § 488.5(a)(19)). Accordingly, we are making the same types of changes in this final rule at § 488.8(b): We indicate that we will provide written notice of the changes to the AO and that we will specify in this notice a timeframe of not less than 30 calendar days from the date of our notice to submit its proposed equivalent changes. We are stating that we may extend the deadline after giving due consideration to a timely request by an AO for an extension; that we will provide written notice after completion of the comparability review as to whether the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare standards; and that if we fail to provide written notice of the results of our comparability review no later than 60 days after receipt of the AO's proposed revisions, then the revised program would be deemed to meet or exceed all applicable Medicare requirements and to have our continued approval. Finally, we are making a technical correction to indicate that the equivalency of the accreditation program's requirements is assessed in light of changes to comparable ''Medicare'' requirements, rather than ''CMS'' requirements, since CMS operates a number of programs that are outside the scope of this regulation.

- We proposed at § 488.8(b)(2) to revise the requirement currently set out at § 488.8(d)(1)(ii) concerning circumstances in which an AO proposes to adopt new requirements or changes its survey process. Under the current regulations, an AO must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process. We proposed expanding the timeframe to allow adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. In addition, we proposed adding language to clarify that the AO may not implement any changes to its CMS-approved Medicare

accreditation program prior to receiving CMS approval. We stated that the purpose of the proposed new language was to ensure continuing comparability of the AO's accreditation program with the Medicare requirements. We indicated these changes would parallel comparable changes at proposed § 488.5(a)(12)(i), which was actually a technical error, since there was no proposed § 488.5(a)(12)(i), and the actual parallel provision was proposed at § 488.5(a)(19), renumbered as § 488.5(a)(18) in this final rule.

We received comments about this provision in conjunction with our proposal for § 488.5(a)(19). We responded to those comments in our discussion of proposed § 488.5(a)(19), indicating we were, based on the comments, revising § 488.5(a)(19), renumbered as § 488.5(a)(18), and making conforming changes to § 488.8(b)(2). We are revising this provision in conformity with the comments to remove all reference to the effective date of the AO's proposed revisions in determining the timeframe for submission of these proposals to us, and to provide for a default approval process to allow an AO to implement its proposed changes. As noted previously, if we fail to provide written notice of our findings within 60 calendar days after our receipt of the AO's proposed revisions, the program as revised will be deemed to have our continued approval. Further, we have made a correction to add a provision parallel to that at § 488.4(b)(1)(v), clarifying that if an AO implements changes without explicit or deemed approval, we may open a program review for that accreditation program.

• We proposed at § 488.8(c) and § 488.8(c)(1) to revise the requirement currently set out at § 488.8(e), which provides that if a comparability or validation review indicates that an accreditation program is not meeting all applicable Medicare requirements, we will provide written notice to the AO indicating that its accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. We proposed revising the standard's title to more accurately reflect the language of the standard that follows and deleting redundant language. We also proposed added language to broaden the regulation and allow us to consider other aspects of AO performance that may warrant the opening of a review of a CMS-approved accreditation program. We stated, for example, that if during a validation review, a question arose as to the ability of an AO to conduct re-accreditation surveys in a timely manner, or to provide us with timely and accurate data regarding deemed status facilities, we would add this matter to the review. We further proposed separating the existing standard into two separate parts to more clearly articulate the circumstances that may trigger our opening a review of a CMS-approved accreditation program and the written notice we must provide the AO upon opening such a review. We further proposed at § 488.8(c)(1)(i) to relocate the requirement currently set out at § 488.8(e)(1), which requires that our notice to the AO include a statement of the requirements, instances, rates or patterns of discrepancies that were found in the course of a comparability or validation review, as well as other related documentation associated with the review. We proposed replacing this language with broader language that more clearly describes current practices related to an accreditation program review. We stated that the proposed revisions would address the information that we would be required to include in the written notice that we send the AO indicating that an accreditation program review is being initiated. We proposed at § 488.8(c)(1)(ii) to revise the requirement currently set out at § 488.8(e)(3), which requires that the notice of our comparability or validation review include a description of the process available if the AO wishes an opportunity to explain or justify the findings made during such review. We indicated that the proposed language would clarify that the AO would not be limited to only one opportunity to offer factual information and documentation. Instead, we stated, such opportunities would be available throughout the accreditation program review process. We proposed at § 488.8(c)(1)(iii) to revise the requirement currently set out at § 488.8(e)(4), which describes the possible enforcement actions that we may take based on findings from a validation review. We proposed deleting the language, ''from the validation review,'' and replacing it with the conforming language, ''based on the findings of the accreditation program review.'' Finally, we proposed at § 488.8(c)(1)(iv) to revise the requirement currently set out at § 488.8(f)(2). The current provision states that if CMS determines after review that the AO failed to adopt requirements comparable to CMS's, or to submit new requirements in a timely manner, the AO may be given conditional CMS approval of its accreditation program with a probationary period of up to 180 days to adopt comparable requirements. To clarify the existing requirements, we proposed revising this provision to include in our required notice to the AO a description of the possible actions an AO would have to take to address the identified deficiencies, including a timeline for implementation not to exceed 180 calendar days from the date of issuance of the electronic version of our notice that an accreditation program review is being initiated.

Comment: One commenter proposed that we strengthen this provision by changing the language from ''CMS may initiate a program review . . .'' to ''CMS must initiate . . .'' making this an automatic requirement whenever substantial non-compliance is determined to be present in a CMS-approved program. The commenter also proposed reducing the maximum timeframe for an AO to implement corrective action from 180 days to 60 days, and also urged that we review any survey activity of the AO conducted during this 60-day period. The commenter indicated that allowing 180 days to correct identified deficiencies is much too long since that may subject patients to substandard care.

Response: We appreciate the concerns of the commenter, but believe that reducing the timeframe for an AO to implement corrective action from 180 days to 60 days may not provide adequate time for the AO to identify and implement the systemic changes typically needed to effect sustained improvement. Depending on the nature of the AO program's deficiencies, we have the discretion to employ greater use of validation surveys during this period to ensure patient safety. We also note that we have the authority to immediately withdraw our approval of an accreditation program if we determine that continued approval poses an immediate jeopardy situation for the patients of the AO's accredited entities. For the commenter's suggestion that a program review be mandatory, we do not see the need to limit our discretion in this manner. A program review is a formal process that entails a comprehensive review of an AO's program. We also address specific problems we have identified in an AO's program outside the formal program review process, and have found this to be an efficient and effective way to correct such problems. Therefore, we believe it is essential for CMS to retain discretion about when to use a more focused approach and when to initiate a formal program review. After due consideration of the public comment, we are implementing this provision in this final rule without change.

• We proposed at § 488.8(c)(2) to state explicitly that we review the AO's plan of correction for its acceptability. We received no comments on this provision and are in this final rule adopting it without change.

• We proposed at § 488.8(c)(3) to replace the requirement currently set out at § 488.8(f)(2). The current provision provides us authority to grant conditional ongoing approval of an AO's program with a probationary period of up to 180 days for the AO to adopt comparable requirements when the AO has failed to adopt requirements comparable to CMS's, or has failed to submit new requirements in a timely manner during a deeming review. We proposed expanding the current provision to clarify that a probationary period of up to 180 calendar days applies when an AO has failed to meet any of the applicable requirements of subpart A of part 488. We proposed further to clarify that an accreditation program review probationary period could not extend beyond the AO's term of approval. Finally, we proposed to clarify the differences between an accreditation program review and renewal application review related to a probationary period, versus a conditional approval with a probationary period.

• We proposed at § 488.8(c)(3)(i) to revise the requirement currently set out at § 488.8(f)(4), which provides that within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice to the AO and affected providers or suppliers. We proposed clarifying this provision by deleting the language, ''make a final determination'' and replacing it with, ''issue a written determination.'' We further proposed deleting the language, ''criteria described at paragraph (a)(1) of this section,'' and replacing it with, ''requirements of this subpart.''

• We proposed at § 488.8(c)(3)(ii) to revise the requirement currently set out at § 488.8(f)(5), which states that we may remove our recognition of an AO's program if the AO has not made improvements acceptable to us during the probationary period, with the removal of our approval effective 30 days from the date that we provide written notice to the AO. We proposed modifying this provision by expanding the timeframe to account for the process required to publish a notice in the **Federal Register**.

• We proposed at § 488.8(c)(3)(iii) to revise the requirement currently set out at § 488.8(f)(7), which requires us to publish a notice in the **Federal Register** when we withdraw our approval of an AO's accreditation program, including a justification for our decision. We proposed clarifying this provision by specifying that the effective date of our withdrawal of approval would be 60 calendar days from the date of the **Federal Register** notice. We note as a point of information that, if an AO has requested reconsideration in accordance with § 488.8(f) of our decision to withdraw our approval of its accreditation program, we would not publish a notice of our withdrawal of approval until and unless the final reconsideration decision issued in accordance with § 488.211 reaffirms the withdrawal of approval. We received no comments on proposed § 488.8(c)(3), including paragraphs (c)(3)(i) through (iii) and are adopting it in this final rule without change.

• We proposed at § 488.8(d) to revise the requirement currently set out at § 488.8(g), which states that if we determine that continued approval of an AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, we may immediately withdraw approval of that AO's accreditation program. We proposed clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

Comment: One commenter proposed that withdrawal of our approval be automatic if an immediate jeopardy situation is found, stating that this would provide a greater incentive to AOs to remain in compliance.

Response: We believe that an automatic withdrawal of our approval of an accreditation program is unnecessary and would be more vulnerable to challenge. We are confident that we will use our enforcement discretion appropriately to take prompt action should we ever make a determination that a CMS-approved accreditation program's continued approval puts patients in immediate jeopardy. After due consideration of the public comments we are adopting this provision in this final rule with one minor typographical correction.

• We proposed at § 488.8(e) a new provision that would address an AO's responsibility to notify its providers or suppliers in the event that CMS withdraws approval of its accreditation program or the AO voluntarily terminates its program. We stated that this provision was necessary to ensure that providers or suppliers affected by an AO's loss of CMS approval for an accreditation program would be informed that they were no longer deemed to meet the Medicare requirements. We believe notification would afford affected providers or suppliers an opportunity to seek accreditation through another CMS-approved AO accreditation program, or to continue participate in Medicare under the SA's jurisdiction.

Comment: One commenter proposed extending notification to all patients impacted by CMS withdrawing approval of an AO's CMS-approved accreditation program. This notification would be in addition to CMS publishing a notice of such action in the **Federal Register** under this provision as well as the AO's requirement to notify affected providers and suppliers in accordance with the requirements at § 488.5(a)(18).

Response: As we indicated in response to a similar comment on proposed § 488.5(a)(18) (renumbered as § 488.5(a)(17) in this final rule), we believe that it is not necessary to notify patients of a change in the organization responsible for overseeing their provider's or supplier's compliance with the Medicare requirements. Further, we believe that such a requirement would be unduly burdensome to both AOs and providers and suppliers.

Comment: Several commenters noted that there might be a contradiction between this proposed provision and the one at proposed § 488.5(a)(18), and that even if there is no contradiction, the two provisions create confusion that needs clarification.

Response: We revised proposed § 488.5(a)(18) (adopted as § 488.5(a)(17) in this final rule) to cross-reference § 488.8(e) for notice requirements for involuntary termination. Further, in reviewing this proposed revision in light of the commenters' observations, we noted that § 488.8(e) assumed that there would be a **Federal Register** notice of a voluntary termination by an AO of its CMS-approved Medicare accreditation program, even though there is currently no such requirement. To avoid confusion about the interaction between § 488.5(a)(17) and § 488.8(e) we are removing all reference in the latter to voluntary terminations. We are also making a technical correction to clarify that, in accordance with § 488.8(g)(1), there are consequences to a provider's or supplier's continued maintenance of its participation in Medicare on the basis of ''deemed status'' when we withdraw our approval of its AO's Medicare accreditation program.

• We proposed at § 488.8(f) to revise the requirement currently set out at § 488.8(h), which provides an AO that is not satisfied with CMS's determination to withdraw approval of its accreditation program the opportunity to request a reconsideration in accordance with subpart D of this part. We proposed clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

Comment: One commenter proposed retaining the existing language referring to ''deeming authority'' and for CMS to publish a definition that communicates the intent of this language. The commenter states that changing this term to ''CMS-approved accreditation program'' will impact recognition, reputation, and marketing for AOs.

Response: Consistent with our action in other areas of this rule, we have removed reference to ''deeming authority'' for AOs and instead refer to their Medicare accreditation programs as ''CMS-approved programs.'' We believe that the current language is misleading, since it implies that AOs have more authority than is permitted them under the Act and implementing regulations. Although an AO with a Medicare accreditation program we have approved may recommend its accredited providers and suppliers to us for deemed status, only CMS has the authority to actually grant deemed status to an accredited provider or supplier. After due consideration of the public comments, we are adopting this provision in this final rule without change.

• We proposed § 488.8(g) to revise the requirement currently set out at § 488.8(f)(8). The current requirement states that, after we remove approval of an AO's accreditation program, an affected provider's or supplier's deemed status continues in effect for 60 days after removal of approval. It further states that we may extend the period for an additional 60 days if we determine that the provider or supplier submitted an application within the 60 day timeframe to another approved AO or to us so that compliance with Medicare conditions can be determined. We proposed revising this provision by expanding the timeframe for continued deemed status of a provider or supplier to 180 calendar days from the date of our publication of the notice of removal of our approval, so long as the provider or supplier applies for accreditation under another AO's approved program within 60 calendar days of the **Federal Register** notice and also provides timely written notice to the SA of its accreditation application. We indicated that failure to adhere to these timeframes would result in placement of the provider or supplier under SA authority for its continued Medicare participation. We stated that our intent was to avoid duplication of AO and state survey resources.

Comment: One commenter expressed its opposition to this provision, saying that suppliers of the technical component of advanced diagnostic imaging services should not have to submit notice to the SA when applying for another accreditation, since SAs do not oversee such suppliers. It proposed instead that the accreditation period of such suppliers be transferred to another AO when the original AO is no longer approved by CMS, stating that the suppliers should not be penalized when an AO loses its status with CMS.

Response: We agree that it is not appropriate to require suppliers of the technical component of advanced diagnostic imaging services to notify SAs when they apply for accreditation with another AO, after we have removed our approval of the supplier's AO's ADI program. This is one of the many reasons we decided in this final rule to remove all reference to accreditation of suppliers of the technical component of ADI services from part 488. We will consider the commenter's alternative proposal for future rulemaking concerning ADI accreditation.

Comment: Several commenters expressed appreciation for our proposal to lengthen the period of continued deemed status, but questioned why we did not instead extend deemed status until the provider's or supplier's next scheduled accreditation survey. Since all Medicare accreditation programs employ unannounced surveys, we presume the commenters intend that the provider's or supplier's deemed status would be continued until the expiration date of its accreditation under the terminated AO's program. The commenters indicated that we should take this approach, unless we found serious deficiencies in the AO's ability to assess providers on the basis of quality and safety. One commenter also suggested that we require AOs to notify providers or suppliers of their obligation to notify the SA.

Response: If we remove our approval of an AO's Medicare accreditation program, generally it would mean that there is substantial evidence that the AO is unable to provide its accredited providers and suppliers adequate oversight. In this circumstance we believe it is necessary for us to move these providers and suppliers for oversight purposes as quickly as reasonably possible to another AO or to the SA's jurisdiction. Since another AO would need time to process an application, particularly if it were receiving multiple applications, and to conduct an accreditation survey, we believe it is appropriate to afford the provider or supplier sufficient time to accomplish the transition to another AO's program, and we believe that 180 calendar days should be enough time to accomplish this. Since accreditation typically is granted for a 3-year period, we do not believe it would be appropriate to allow up to 3 years for this transition to occur.

Comment: One commenter proposed that we require providers and suppliers to provide written notice to patients when it submits an application to another AO, that we place the provider or supplier under the oversight of the SA during the transition period between AOs, and that we provide patients with information on how to contact the SA with any complaints.

Response: As we indicated in response to similar comments about other provisions, we believe it would be unduly burdensome to require notice to patients when a provider or supplier applies to another accreditation program, and we do not believe this information would be useful to patients. In our view it is also unnecessary to provide patients with special notice about how to contact the SA with any complaints, since it is already routine for patients to submit their complaints about certified providers and suppliers to the SA, regardless of whether they have deemed status or not, and, when appropriate, we authorize substantial allegation validation surveys to investigate the complaint. Therefore SA surveys are conducted when needed during the transition period. For this reason we also believe it is not necessary to formally remove the accredited providers' or suppliers' deemed status immediately upon termination of an AO's Medicare accreditation program. We agree with the commenter who suggested that AOs should be required to notify their accredited providers and suppliers of the need for the latter to notify the SA when they have filed a timely application for accreditation with another AO. We believe that the revised provision at § 488.5(a)(17) adopted in this final rule accomplishes this.

Commenters on this provision, as well as on the provisions we originally proposed at § 488.5(a)(18), § 488.5(a)(19), and § 488.8(e), noted that we were inconsistent in sometimes applying requirements to the situations of both voluntary and involuntary

terminations of an AO's Medicare accreditation program. We have attempted to remove these inconsistencies wherever we have identified them. One such inconsistency is that, while we originally proposed at § 488.8(e) to require AOs to notify their accredited providers and suppliers of both voluntary and involuntary terminations of their programs, proposed § 488.8(g) addressed continued deemed status only in the case of involuntary terminations. We believe that it would not be fair to ''deemed status'' providers and suppliers to extend their deemed status only in the case of involuntary terminations, and that we should instead afford them similar flexibility in the case of an AO's voluntary termination of its Medicare accreditation program. Accordingly in this final rule we have reorganized the provision to contain two paragraphs, one addressing continued deemed status in the case of an involuntary termination, and one addressing it in the case of a voluntary termination. Since, as previously discussed, we do not publish **Federal Register** notices of an AO's decision to voluntarily terminate its approved Medicare accreditation program, in this revised provision, in accordance with public comments, we provide that the 180 calendar day extension of deemed status would begin as of the effective date of the AO's voluntary termination. We are also taking this opportunity to add headings to § 488.8(g)(1) to clarify the different circumstances addressed in each of these provisions.

- We proposed at § 488.8(h) to revise the requirement currently set out at § 488.9, concerning our onsite observation of an AO's operations. We proposed modifying the current provision, adding language that provides greater specificity and clarity. In addition, we proposed expanding the provision to give us greater flexibility in the timing of onsite visits to improve our oversight of approved AO accreditation programs.

Comment: One commenter requested we provide as much advance notice as possible prior to an onsite visit, noting that the FDA provides 3 to 4 months advance notice as well as optional dates. A number of commenters suggested we revise this provision to indicate that the on-site visit will relate only to programs we have approved, that the scope be reasonable and that the visit not disrupt normal business operations. One commenter asked that we clarify and provide detail on ''auditing meetings,'' and asked whether the process would be different than the one CMS has previously followed. Another commenter stated the provision is too broad, potentially intrusive and an over-reach of government authority. This commenter proposed that the provision be revised to indicate that CMS has the authority to conduct an onsite visit at an AO's corporate office at a mutually agreed time and that the onsite inspection could include, but would not be limited to, the review of relevant documents and interviewing staff. By contrast, another commenter said that our onsite inspections should not be optional and should be conducted during both the application review and the ongoing review process, on a regular basis.

Response: Our proposal was not intended to modify our existing policy and practices for on-site inspections of accrediting organizations. Generally we work with an AO in advance to find a mutually convenient time for both our observation of surveys and our visit to their corporate offices, and we intend to continue to do so. However, we reserve the right to make an unannounced visit or survey observation, should there be circumstances that warrant our doing so. We also do not believe it is necessary to state in this provision that we only assess the performance of an AO's CMS-approved accreditation programs when we are on-site, since we believe that is clear in § 488.4. We are surprised by the comment that this provision is overly broad and overreaches our authority, since it is almost identical to the provision currently at § 488.9, which was last adopted on November 23, 1993 and which has not been a source of controversy. In our proposal we changed the term ''validation review process'' to ''ongoing review process,'' to conform to changes we made in § 488.8(a) through (c). We also added language making it explicit that we may conduct the onsite inspection at any time. Finally, we added language to make it explicit that we may observe accreditation surveys. The existing regulatory at § 488.9 already contains the following language: ''. . . to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.'' We believe verification of all of these aspects of a Medicare accreditation program is necessary for us to determine whether the program meets or exceeds all applicable Medicare requirements, as required under section 1865 of the Act. For the commenter who called for these inspections to be mandatory, we believe that this is a matter best left to enforcement discretion. For example, if an AO has two CMS-approved Medicare accreditation programs with renewal dates in close proximity, to make efficient use of our limited resources, including travel resources, we have sometimes conducted only one corporate on-site visit to address both programs, although we continue to conduct separate survey observations. We also note that it is already our practice to conduct on-site inspections outside the application review process, when circumstances warrant our doing so, and we would continue to have the authority to do so under the revised regulation. After consideration of the public comments, we are in this final rule adopting this provision without change.

10. Validation Surveys (§ 488.9)

We proposed revising the title of this section, indicating that proposed § 488.9 sets out the language currently at § 488.7 addressing validation surveys. We stated that the regulatory language would remain unchanged, with the exception of deleting language related to a plan of correction that no longer reflects current SA practice; and deleting language regarding compliance with the LSC that would be duplicative of proposed language at § 488.12(a)(2). In addition, we proposed minor changes to conform this section to the rest of the final rule.

Comment: Several commenters stated this provision broadened the scope of the statutory provision governing substantial allegation validation surveys. They cited the statutory language, which authorizes the Secretary to enter into an agreement with states to survey ''. . . because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients . . .'' and suggested that this language is narrower than a ''substantial allegation of noncompliance.'' One commenter provided as an example that there may be a substantial allegation that a provider is noncompliant in dating and timing medical record entries, but this type of noncompliance does not rise to the level of a significant deficiency that affects health and safety. The commenter went on to state that CMS conducts between 3500 and 5000 complaint surveys in accredited

hospitals each year and yet only finds significant problems in 4 percent to 6 percent of those surveys, which is a tremendous waste of resources for the federal government and an unnecessary burden for hospitals.

Response: There has been no modification of our longstanding interpretation of the statutory language at section 1864(c) of the Act in our proposed rule and we are neither broadening nor narrowing the application of our statutory authority to conduct substantial allegation validation surveys. We note, however, that in response to similar comments we modified the definition of ''substantial allegation of noncompliance'' at § 488.1 in response. We did not, however, remove reference to substantial noncompliance by a provider or supplier with any applicable Medicare condition or requirement, because we believe such noncompliance adversely affects the health and safety of patients and thus an allegation of such noncompliance should be investigated by the SA. The commenter who gave the example of hospital medical record noncompliance related to dating and timing entries not rising to the level of endangering patient health and safety misunderstands the definition of a substantial allegation of noncompliance, since the allegation would have to represent substantial noncompliance with the hospital Medical Records CoP to be a substantial allegation warranting a validation survey. We would evaluate whether the manner or degree of noncompliance alleged appeared to suggest such substantial noncompliance with the Condition before authorizing a validation survey, since there could be cases where systemic failure of hospital staff to date and time medical record entries could, in fact, endanger the health and safety of the hospital's patients. We further note that in our response to comments on our proposed definition of ''substantial allegation of noncompliance'' at § 488.1 we indicated that we are revising revised the definition in this final rule to follow the Act's use of the term ''would'' instead of our proposed terminology suggesting that an allegation if present ''could or may'' affect the health and safety of patients and residents. This should reassure commenters who expressed concerns about the scope of substantial allegation validation surveys.

For wasting federal resources on substantial allegation validation surveys, we note for the record that the number of such surveys since FY 2012 has hovered around 3400, not 5,000, and that 7.4 percent have resulted in findings of substantial noncompliance. We also point out that the statutory and regulatory threshold for conducting a validation survey is not that an allegation must be accurate, but rather that if the alleged noncompliance was found to be present, it would represent substantial noncompliance. It is to be expected that a significant portion of substantial allegation surveys would not result in citations of substantial noncompliance, either because the allegation was never true, or because the provider or supplier corrected its deficient practices prior to our survey. We also note that we have been emphasizing in recent years to the states and our regional office staff that a complaint concerning a ''deemed status'' provider or supplier must meet the threshold of being a substantial allegation for a federal survey to be authorized. We also wish to point out that states often have broader authority to investigate complaints under their licensure authority, and that such state licensure complaint investigations are sometimes confused by providers or suppliers with federal substantial allegation validation surveys, since often the same personnel conduct both.

Comment: One commenter stated that hospitals report that it appears the numbers of citations have a direct impact on whether a validation survey is completed and that surveys not based on a representative sample cannot truly validate the AO's performance. Along these lines another commenter indicated that facilities selected by CMS for validation surveys have the least number of AO findings and that to be a truly representative sample, the validation survey site selection should not consider the number of findings on the accreditation survey, unless those findings meet the basis for a substantial allegation survey.

Response: We are puzzled as to what the commenters are referring, and their characterization of our selection process for validation surveys is inaccurate. At the time that we select providers or suppliers for inclusion in our representative sample for those validation surveys that are full surveys conducted within 60 days of the AO's accreditation survey the AO has not yet conducted its survey. Therefore, we do not and could not base our selection of the sample on an AO's findings.

Comment: A number of commenters reiterated their general criticisms of validation surveys conducted by states by stating that there is variation among the SAs in their survey findings and that state surveys should not be used as the benchmark for judging AO surveys.

Response: We addressed the substance of these criticisms in response to comments concerning § 488.8(a)(2) and believe our response is applicable here as well.

Comment: One commenter stated that validation surveys are essential to determine the adequacy of an AO's accreditation process and recommended that we require at least one validation survey annually for each year AO.

Response: Between the two different types of validation surveys under our current oversight program every AO has undergone more than one validation survey per year, with the exception of AOs that have only recently been approved for their first Medicare accreditation program. Further, section 1875 of the Act requires us to report annually on the performance of each CMS-approved Medicare accreditation program. Therefore, we do not believe it is necessary to include in the regulation a specific requirement as to the minimum number of validation surveys to be performed each year.

Comment: One commenter proposed CMS take immediate enforcement action related to deficiencies identified in a state substantial allegation validation survey instead of directing the SA to conduct another survey. The commenter indicated that a second survey is duplicative and wastes resources, and delays enforcement action that may negatively impact the health and safety of home health patients.

Response: We generally agree that it is preferable for us to take prompt enforcement action when a validation survey identifies substantial noncompliance with Medicare requirements, and we revised Chapter 5 of the SOM, concerning complaint investigations accordingly. Specifically, in sections 5110.2–2 and 5110.3 we clarify that we have the discretion to proceed immediately with enforcement action. However, when the validation survey was a substantial allegation validation survey that was narrowly focused assessing compliance with only a few of the applicable conditions, we believe that it is important for us to have the flexibility to exercise our enforcement discretion to determine whether the provider or supplier complies with a broader range, or even all, of the other Medicare conditions. After considering the public comments we are in this final rule adopting this provision with one technical correction at § 488.9(a)(2), to use the term ''substantial allegation of noncompliance'' rather than ''substantial allegation,'' to match the term used in the definition at § 488.1.

11. State Survey Agency Review: Statutory Provisions (§ 488.10)

We proposed to revise § 488.10 to implement section 125 of MIPPA (revising section 1865(a) of the Act) to clarify that our regulations apply to several types of providers and suppliers, not just hospitals. The regulation currently at § 488.10(c) addresses the authority of the Secretary to enter into agreements with SAs for the purpose of conducting validation surveys. It further states, ''Section 1865(d) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.'' We proposed revising this provision by separating it into two separate provisions, § 488.10(c) and § 488.10(d). We proposed modifying this provision by updating the regulatory citation to implement changes associated with section 125 of MIPPA. We further proposed modifying this provision to make it clear that the regulations would apply to all national AOs with CMS-approved accreditation programs, and all provider or supplier types.

Comment: We received one comment from a commenter who stated that the statute requires that validation surveys fall into two categories and then quoted the exact language at section 1864(c) of the Act regarding the two types of validation surveys. The commenter called for our regulatory text to adhere more closely to the statutory language and recommended we reword the provision as follows: ''Section 1864(c) of the Act authorizes the Secretary to enter into agreements with SAs for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary on a selective sample basis, or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect the health and safety of patients.''

Response: Both the existing and the proposed regulations refer to the two different types of validation surveys referred to in the Act, using the same language: ''conducted on a representative sample basis, or in response to substantial allegations of noncompliance.'' We assume the commenter is building on comments related to proposed § 488.9, which challenged the way in which substantial allegation validation surveys are characterized. Our responses to those comments apply here as well. After considering the public comments we are adopting this provision in this final rule without change.

12. State Survey Agency Functions (§ 488.11)

We proposed to revise § 488.11(b) by deleting the word, ''accredited,'' and replacing it with ''deemed'' as a conforming change for increased clarity. We also proposed deleting the citation, ''§ 488.7,'' and replacing it with ''§ 488.9.'' This change would be consistent with the proposed reorganization of the requirements.

Comment: One commenter requested that we replace the term ''deemed facilities'' with ''deemed organizations,'' saying that not all health care providers operate out of a facility. This commenter also stated that the parameters for conducting validation surveys be the same as that which the commenter recommended for proposed § 488.9, namely that surveys be conducted on a representative sample basis without regard to the number of findings on an AO's survey or in response to substantial allegations which would, if found to be present, adversely affect health and safety of patients.

Response: We indicated our disagreement with the commenter's remarks concerning validation surveys in our response to the comments concerning proposed § 488.9, and our responses there apply equally to what is substantially the same comment here. For the provider's suggestion to substitute ''organizations'' for ''facilities,'' we believe that term is too broad and vague. We also believe the commenter's assumption that the term health care facility refers only to an organization that provides health care services within a ''bricks and mortar'' building is incorrect. However, in reviewing this comment we realized that our proposed language also was not technically precise or consistent with the definitions in part 488. In this final rule, therefore, we are replacing the term ''deemed facilities'' with ''deemed status providers and suppliers.''

13. Effect of Survey Agency Certification (§ 488.12)

Currently § 488.12 addresses provider or supplier certification recommendations made by the SA to CMS and § 488.12(a)(2) addresses whether an accredited hospital is deemed to meet the Medicare CoPs or is subject to a full review by the SA. We proposed modifying this provision by inserting broader language to make it clear that the revised regulations pertain not to hospitals exclusively, but rather to all deemed status providers and suppliers. We further proposed modifying this provision for clarity and conforming changes. We received no comments on this proposal and are adopting it in this final rule without change.

14. Loss of Accredited Status (§ 488.13)

We proposed a new provision at § 488.13 entitled, ''Loss of Accreditation.'' We believe that this proposed section is necessary to address the consequences of a provider's or supplier's loss of accreditation, whether voluntary or involuntary, by an AO's CMS-approved accreditation program. Voluntary loss of accreditation occurs when a provider or supplier chooses to withdraw from a CMS-approved accreditation program. Involuntary loss of accreditation occurs when an AO terminates a provider's or supplier's accreditation due to non-compliance with the AO's CMS-approved accreditation program requirements, or to the provider's or supplier's non-payment of AO fees. We stated that the proposed new provision would address the timing of a SA survey in such circumstances. We received no comments in response to our proposal and are adopting it in this final rule without change.

15. Providers or Suppliers, Other Than SNFs and NFs, With Deficiencies (§ 488.28)

We proposed to revise § 488.28(a) to replace outdated language, such as referring to ''Medicare'' instead of the ''Health Insurance for the Aged and Disabled Program'' and to make explicit in the regulation our longstanding enforcement policy that in immediate jeopardy situations we may require a shorter timeframe for a provider or supplier to come into compliance. We stated that we believed it would be beneficial to make this practice explicit in this proposed rule.

Comment: Several commenters expressed concerns related to how immediate jeopardy is cited.

Response: These issues are addressed in section II.B.17. of this final rule in our discussion of the definition of ''immediate jeopardy'' at § 489.3 in this final rule.

We are also taking this opportunity to make a technical correction in this final rule, replacing the term ''the Secretary'' with ''CMS,'' to be consistent with our usage throughout this rule.

16. Statutory Basis (§ 489.1)

We proposed to revise § 489.1(b), which addresses the scope of part 489. We stated that this proposed revision

would expand which provisions of part 489 apply to suppliers that are subject to certification requirements as well as to providers. We indicated that currently § 489.1(b) indicates that only the regulations at § 489.13, governing the effective date of the provider agreement or supplier approval, are applicable to suppliers that require certification in accordance with § 488.3 and § 488.12 to participate in Medicare, as well as to all providers. We also reported that various supplier-specific rules in this chapter that require certification also establish requirements related to termination of the certified supplier's participation agreement with the Medicare program. However, only some of these supplier-specific certification rules provide for termination of the agreement where the certified supplier places restrictions on the persons it will accept for treatment and fails to either exempt Medicare beneficiaries or apply the restrictions in the same way for Medicare beneficiaries as all other persons seeking care in the supplier facility. We stated that we believe that this non-discrimination provision should also apply as a basis for termination of all Medicare-certified suppliers.

Likewise, we pointed out that neither the certified supplier-specific rules governing termination of their agreements, nor the current termination of provider agreement rules at § 489.53 provide for termination of the supplier agreement where the certified supplier denies immediate access to state surveyors or other authorized entities or refuses to allow photocopying of its records. We indicated that currently, the only enforcement remedy in the face of such denial or refusal by a certified supplier would be exclusion of the certified supplier from Medicare by the OIG under 42 CFR 1001.1301(a). We stated it would be quicker and more efficient for us to handle such a denial or refusal of access to the certified supplier facility or copying of its records in the same manner as is currently used for providers, that is, CMS termination of the Medicare agreement.

Accordingly, we proposed amending § 489.1(b) to expand the enumeration of provisions of part 489 that apply to suppliers subject to certification, as well as to providers. Because these provisions would apply only to those types of suppliers that require certification and not to all suppliers, we proposed to include language in revised § 489.1(b) describing which types of suppliers would be affected, using the same language currently found at § 489.13. We stated that this language would indicate that the affected types of suppliers participate in Medicare based on surveys conducted by the SA or CMS surveyors, or on the basis of accreditation under a CMS-approved AO's Medicare accreditation program.

We also proposed redesignating the current language in § 489.1(b), which makes the effective date rules at § 489.13 applicable to certified suppliers as well as to providers, as new paragraph § 489.1(b)(1). Further, we proposed adding a new paragraph at § 489.1(b)(2) indicating that the termination provisions at § 489.53(a), § 489.53(a)(2), and § 489.53(a)(13) and proposed new § 489.53(a)(18) (discussed in section II.B.18. of this final rule) would apply to certified suppliers as well as to providers.

We received no comments on the proposed revisions. However, we are making a technical correction in this final rule to add the definition of ''immediate jeopardy'' at § 489.3 as a provision that also applies to suppliers. Although this is clear in the wording of the definition itself, we believe to be consistent this should also be addressed in § 489.1 and are revising this latter provision in this final rule accordingly.

17. Definitions (§ 489.3)

We stated that the current regulations at § 489.3 define the term ''immediate jeopardy'' as a situation in which the provider's non-compliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a ''resident.'' We indicated that this definition is identical to the one at § 488.301, which, in that context, applies only to long term care facilities, that is, NFs and SNFs. We also noted, however, that the current regulation at § 489.53(d) addresses exceptions permitted for the required notice of termination which we must provide to the provider or supplier. We indicated that this regulation permits exceptions in the case of immediate jeopardy situations in hospitals that have violated the Emergency Medical Treatment and Labor Act (EMTALA) requirements at § 489.24(a) through (e), as well as to immediate jeopardy situations in SNFs. Thus, it has been our longstanding policy that the definition of immediate jeopardy at § 489.3 applies to all types of certified health care facilities and not just long term care facilities. Nevertheless, we proposed to revise the definition of immediate jeopardy at § 489.3 to make more explicit that it applies to all types of providers and as well as all types of suppliers subject to certification.

Comment: One commenter proposed to expand the definition to include harm to staff and visitors as well as residents and patients, saying that there are hazardous environments in imaging centers with Magnetic Resonance Imaging (MRI) suites or Computed Tomography (CT) scanners.

Response: We appreciate the commenter's concerns, but believe that it would inappropriately expand the scope of federal surveys to require assessment of potential harm to staff and visitors. An immediate jeopardy must involve non-compliance with a Medicare requirement, and these requirements are focused on the care services provided by a provider or supplier to patients or residents. We also suspect that it would ordinarily be the case that an environment that poses an immediate threat of serious harm to staff or visitors would also pose the same threat to patients or residents, and thus the protections afforded under our requirements to patients and residents would also benefit staff and visitors.

Comment: A number of commenters took issue with including in the definition the phrase ''likely to cause'' serious injury, harm, impairment of death. Most commenters indicated that they believe there is a great deal of subjectivity in the application of this definition, and that as a result there is considerable variability among states and CMS regional offices in immediate jeopardy citation practices. Some of these commenters called for removing the phrase ''likely to cause'' and limiting immediate jeopardy citations to those that have actually caused serious harm. Another commenter suggested substituting the phrase ''more likely than not.'' Some commenters did not request a modification of the definition, but did ask for more specific guidance in the SOM about examples of immediate jeopardy situations.

Response: Our proposal did not introduce the phrase ''likely to cause'' into the definition of immediate jeopardy; rather, this is a longstanding component of the existing definition. Moreover, we believe it is entirely appropriate and necessary for patient safety to treat as immediate jeopardy situations we identify that have the potential to cause serious harm if they are not addressed immediately, regardless of whether we are able to identify any harm already caused by the situation.

The commenters who called for more guidance may not be aware of the SOM, Appendix Q, ''Guidelines for Determining Immediate Jeopardy''. Among the guidance contained in this document is a discussion of the three

components that must all be present to cite immediate jeopardy: Potential or actual harm that is serious; immediacy; and culpability on the part of the provider or supplier. The Appendix provides a detailed, albeit not exhaustive, list of triggers that should lead surveyors to consider whether there is immediate jeopardy, as well as examples of hypothetical and real cases. We acknowledge that there is some variability in the tendency to cite immediate jeopardy, but continue to work with SAs and our Regional Office staff to achieve greater consistency. After consideration of the public comments we are in this final rule adopting this provision without change.

18. Termination by CMS (§ 489.53)

We proposed to revise § 489.53(a), which addresses the basis for us to terminate a Medicare provider agreement. We proposed deleting the language ''with any provider'' from the heading for this provision since we are proposing that several of the termination provisions apply to certified suppliers, as well as providers. We proposed retaining language stating that we may terminate the agreement with any provider if we find that any of the failings enumerated in § 489.53(a) is attributable to that provider. We further proposed adding language indicating that we may, in addition to applying the various provisions in this chapter governing the termination of agreements with suppliers, terminate agreements with those suppliers that fail to comply with the requirements set out in § 489.53(a)(13) and proposed new § 489.53(a)(18).

We proposed adding language in § 489.53(a)(2) to indicate that when a provider or supplier places restrictions on the persons accepted for treatment services without either exempting Medicare beneficiaries from such restrictions, or applying the restrictions to Medicare beneficiaries in the same manner as to all other persons seeking care, this may be grounds for termination of the Medicare agreement. We stated that the current language at § 489.53(a)(2) applies only to providers.

We proposed adding language at § 489.53(a)(13) to indicate that failure by a provider or supplier to permit photocopying of any records or other information by, or on behalf of us, as necessary, to determine or verify compliance with participation requirements, may be grounds for terminating the Medicare agreement. We stated that the current language at § 489.53(a)(13) applies only to providers.

Further, we proposed adding a new § 489.53(a)(18) to state explicitly that denial of immediate access to an SA or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, CoPs, CfCs, or conditions for certification, may be grounds for termination of the provider agreement or supplier approval. We indicated that, consistent with the definition at 42 CFR 1001.1301(a)(2), we interpret ''failure to grant immediate access'' to mean the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Finally, we proposed a technical correction to § 489.53(d)(2)(i). We stated that § 489.53(d) governs the timeframe for provision of a minimum 15-day advance notice of termination of a provider agreement by us to the affected provider, while § 489.53(d)(2) governs exceptions to the general timeframe in situations involving immediate jeopardy. We indicated that the first exception, at § 489.53(d)(2)(i), applies to hospitals that have been determined by us to have an EMTALA violation which poses an immediate jeopardy. We explained that in these cases we are required to give the hospital a preliminary notice of termination in 23 days if the hospital does not correct its identified deficiencies or refute the finding, and a final notice of termination at least 2, but not more than 4, days before the effective date of termination. We proposed clarifying that this exception to the timing notice provision applies to a hospital that has been found to be in violation of any of the EMTALA requirements found at § 489.24, paragraphs (a) through (f). We stated that the current regulation refers to hospitals with emergency departments found in violation of § 489.24, paragraphs (a) through (e) rather than (a) through (f). We indicated that this proposed clarification would not change current EMTALA citation or enforcement practices.

Comment: One commenter expressed concern that inclusion of the term ''supplier'' would require physicians to accept all Medicare patients and that this is not authorized by statute. The commenter requested the provision be modified to indicate that it does not apply to physicians.

Response: We believe that revised § 489.1(b) makes it clear that the definition of ''immediate jeopardy'' at § 489.3 and the provisions at § 489.13, § 489.53(a)(2), § 489.53(a)(13), and § 489.53(a)(18) apply only to supplier entities which, for participation in Medicare, are subject to a determination by us on the basis of a state or AO survey, that is, suppliers that must be certified by us as meeting CoP, CfC, conditions for certification, or long term care requirements to participate in the Medicare program. Thus, we believe it is clear that the provisions of part 489 do not apply to those types of suppliers that are not subject to our survey and certification requirements. We note in particular that physician suppliers are not subject to surveys or other certification requirements as a condition for their participation in the Medicare program, and that none of the provisions of § 489.53 apply to physician suppliers.

We are making a technical revision in this final rule at § 489.53(a)(13) to replace the word ''photocopying'' with ''copying.'' As more providers and suppliers move from paper medical records to electronic health records, we envision that it could in some cases be more efficient for surveyors as well as providers and suppliers if surveyors obtain digital electronic copies of pertinent medical records, or portions thereof, as well as of any other documents that they require as evidence to support their findings of noncompliance. We believe that the term ''photocopying'' is becoming outdated and that it is preferable to use the more generic term ''copying.'' We are adopting in this final rule the other provisions of § 489.53 as proposed.

III. Collection of Information Requirements

While this rule does contain information collection requirements, we believe they are exempt under 5 CFR 1320.3(c)(4). The requirements would affect less than 10 entities in a 12-month period. To date, there have only been a total of nine entities that meet the criteria necessary to become accrediting organizations with CMS-approved Medicare accreditation programs, with the ninth having just been added as recently as July, 2014. Should the number of eligible entities exceed 10, we will prepare an information collection request for OMB approval. As required by the Paperwork Reduction Act of 1995, we will announce the information collection request via the required **Federal Register** notices and allow the public ample time to review the request and submit comments.

IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation

and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. 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 small entities, either by nonprofit status or by having revenues of $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will 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 2014, that threshold level is currently approximately $141 million. This rule has no consequential effect on state, local, or tribal governments or on the private sector.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Rulemaking

We generally publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

This final rule includes several technical corrections that were not included in the proposed rule and for which a notice-and-comment period is unnecessary, because they are purely technical and conforming, or because they clarify possible ambiguities in the proposed rule. Specifically, we are revising:

- § 488.2 to correct our characterization of the statutory reference at section 1832(a)(2)(J) of the Act to refer to ''Requirements for partial hospitalization services provided by CMHCs'' and at section 1881 of the Act to refer to ''Requirements for ESRD facilities'';
- § 488.3(a)(2) to correct a reference to ''parts 482 through 485'' to make the reference to ''parts ''482 through 486'', to cover other types of provider entities for which accreditation is permitted;
- § 488.4(a) not only in response to comments, but also to make a technical correction by referring to a national accreditation program as having ''applied for CMS approval of a provider or supplier accreditation program,'' rather than for ''approval to accredit providers and suppliers'';
- § 488.4(a)(11)(ii) to make stylistic changes and to change the order of two sentences in that provision;
- § 488.5(a)(4)(i) to add the word ''an'' prior to the word ''agreement'';
- § 488.5(a)(12) to clarify that referral to ombudsman or licensing bodies is expected when applicable;
- § 488.5(d)(1)(ii), which was located at § 488.5(e)(2) in our proposal, to remove language that was superfluous because it is already contained in the definition of ''reasonable assurance'';
- § 488.5(e)(2)(i) and (ii), which were located at § 488.5(f) in our proposal, to remove language that was superfluous because it is already contained in the definition of ''reasonable assurance'';
- § 488.6 to restore language that was located at § 488.5(b) and § 488.6(b) indicating that Medicare approval does not substitute for any additional requirements under Medicaid.
- § 488.8(b)(1)(iv) to appropriately cite its reference to a prior paragraph in the same section;
- § 488.8(b)(2)(iii) to enhance clarity and consistency by adding a provision parallel to that at § 488.8(b)(1)(v) indicating we may open an accreditation program review in the event of failure to comply with the requirements of § 488.8(b)(2)(i) and (ii).
- § 488.9(d) to correct a typographical error, changing ''publishes'' to ''publish''; and
- § 488.9(a)(2) to refer to a ''substantial allegation of noncompliance'' rather than to a ''substantial allegation,'' to correspond to the term for which we provide a definition at § 488.1.

The changes outlined in this section are purely technical, and a period of comment is unnecessary because the changes are either purely technical and conforming, or clarify possible ambiguities in the proposed rule. We do not believe any of these changes to be substantive. We believe it would be contrary to the public interest to delay codifying the technical corrections outlined in this section, and therefore find good cause to waive the notice of proposed rulemaking for the technical revisions and corrections.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services is amending 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

§ 401.126 [Amended]

■ 2. In § 401.126, amend paragraph (b)(2)(i) by removing the reference ''§ 488.6'' and by adding in its place the reference ''§ 488.5''.

§ 401.133 [Amended]

■ 3. In § 401.133, amend paragraph (d) by removing the references ''§ 488.5, § 488.6 or § 493.506'' and by adding in its place the references ''§ 488.5 or § 493.506''.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 4. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

■ 5. Section 488.1 is amended by—
■ a. Removing the definitions of ''Accredited provider or supplier'' and ''AOA''.
■ b. Revising the definition of ''Certification''.
■ c. Adding the definitions of ''Conditions for certification'' and ''Deemed status'' in alphabetical order.
■ d. Revising the definition of ''Full review''.
■ e. Adding the definition of ''Immediate jeopardy'' in alphabetical order.
■ f. Removing the definition of ''JCAHO''.
■ g. Adding the definition of National accrediting organization'' in alphabetical order.
■ h. Revising the definitions of ''Provider of services or provider'', ''Reasonable assurance'', ''State survey agency'', and ''Substantial allegation of noncompliance''.
■ i. Removing the definition of ''Validation review period''.

The revisions and additions read as follows:

§ 488.1 Definitions.

* * * * *

Certification means a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements.

Conditions for certification means the health and safety standards RHCs must meet to participate in the Medicare program.

* * * * *

Deemed status means that CMS has certified a provider or supplier for Medicare participation, based on all of the following criteria having been met: The provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization under the applicable Medicare accreditation program; the accrediting organization has recommended the provider or supplier to CMS for Medicare participation; CMS has accepted the accrediting organization's recommendation; and CMS finds that all other participation requirements have been met.

Full review means a survey of a provider or supplier for compliance with all of the Medicare conditions or requirements applicable to that provider or supplier type.

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare requirements, conditions of participation, conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

National accrediting organization means an organization that accredits provider entities, as that term is defined in section 1865(a)(4) of the Act, under a specific program and whose accredited provider entities under each program are widely located geographically across the United States.

Provider of services or provider refers to a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

* * * * *

Reasonable assurance means that an accrediting organization has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

* * * * *

State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions provided for in sections 1864, 1819(g), and 1919(g) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that would, if found to be present, adversely affect the health and safety of patients or residents and raises doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements.

* * * * *

■ 6. Section 488.2 is amended by—
■ a. Adding the following statutory provisions in numerical order.
■ b. Revising the description of section 1883 of the Social Security Act.

The additions and revisions read as follows:

§ 488.2 Statutory basis.

* * * * *

1138(b)—Requirements for organ procurement organizations and organ procurement agencies.

* * * * *

1820—Requirements for CAHs.

1832(a)(2)(C)—Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.

1832(a)(2)(F)—Requirements for ASCs.

1832(a)(2)(J)—Requirements for partial hospitalization services provided by CMHCs.

1861(e)—Requirements for hospitals.

* * * * *

1861(p)(4)—Requirements for rehabilitation agencies.

* * * * *

1861(aa)—Requirements for RHCs and FQHCs.

1861(cc)(2)—Requirements for CORFs.

1861(dd)—Requirements for hospices.

* * * * *

1861(ff)(3)(A)—Requirements for CMHCs.

* * * * *

1863—Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.

* * * * *

1875(b)—Requirements for performance review of CMS-approved accreditation programs.

* * * * *

1881—Requirements for ESRD facilities.

1883—Requirements for hospitals that furnish extended care services.

* * * * *

■ 7. Section 488.3 is revised to read as follows:

§ 488.3 Conditions of participation, conditions for coverage, conditions for certification and long term care requirements.

(a) *Basic rules.* To be approved for participation in, or coverage under, the Medicare program, a prospective provider or supplier must meet the following:

(1) Meet the applicable statutory definitions in section 1138(b), 1819, 1820, 1832(a)(2)(C), 1832(a)(2)(F), 1832(a)(2)(J), 1834(e), 1861, 1881, 1883, 1891, 1913 or 1919 of the Act.

(2) Be in compliance with the applicable conditions, certification requirements, or long term care requirements prescribed in part 405 subparts U or X, part 410 subpart E, part 416, part 418 subpart C, parts 482 through 486, part 491 subpart A, or part 494 of this chapter.

(b) *Special conditions.* The Secretary shall consult with state agencies and national AOs, as applicable, to develop CoP, CfC, conditions for certification and long term care requirements.

(1) The Secretary may, at a state's request, approve health and safety requirements for providers or suppliers in the state that exceed Medicare program requirements.

(2) If a state or political subdivision imposes requirements on institutions (that exceed the Medicare program requirements) as a condition for the purchase of health services under a state Medicaid plan approved under title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a state plan for Old Age Assistance under title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original title XVI of the Act), the Secretary imposes similar requirements as a condition for payment under Medicare in that state or political subdivision.

■ 8. Section 488.4 is revised to read as follows:

§ 488.4 General rules for a CMS-approved accreditation program for providers and suppliers.

(a) The following requirements apply when a national accrediting organization has applied for CMS approval of a provider or supplier accreditation program and CMS has found that the program provides reasonable assurance for providers or suppliers accredited under the program:

(1) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the accrediting organization's CMS-approved accreditation program, the accrediting organization may recommend that CMS grant deemed status to the provider or supplier.

(2) CMS may deem the provider or supplier, excluding kidney transplant centers within a hospital and ESRD facilities, to be in compliance with the applicable Medicare conditions or requirements. The deemed status provider or supplier is subject to validation surveys as provided at § 488.9.

(b) [Reserved]

■ 9. Section 488.5 is revised to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) *Information submitted with application.* A national accrediting organization applying to CMS for approval or re-approval of an accreditation program under § 488.4 must furnish CMS with all of the following information and materials to demonstrate that the program provides reasonable assurance that the entities accredited under the program meet or exceed the applicable Medicare conditions or requirements. This information must include the following:

(1) Documentation that demonstrates the organization meets the definition of a ''national accrediting organization'' under § 488.1 as it relates to the accreditation program.

(2) The type of provider or supplier accreditation program for which the organization is requesting approval or re-approval.

(3) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable accreditation requirements and standards.

(4) A detailed description of the organization's survey process to confirm that a provider or supplier meets or exceeds the Medicare program requirements. This description must include all of the following information:

(i) Frequency of surveys performed and an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily-mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, CfC, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with information extracted from each accreditation survey for a specified provider or supplier as part of its data submissions required under paragraph (a)(11)(ii) of this section, a copy of all survey reports and related information for applicants seeking initial participation in Medicare, and, upon request from CMS, a copy of the most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at § 489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within two business days from the date the accrediting organization identifies the immediate jeopardy.

(5) The criteria for determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited,

including variations in team size and composition for individual provider or supplier surveys.

(6) The overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

(7) A description of the education and experience requirements surveyors must meet.

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel.

(9) A description of the organization's evaluation systems used to monitor the performance of individual surveyors and survey teams.

(10) The organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

(11) A description of the organization's data management and analysis system for its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the organization uses its data to assure the compliance of its accreditation program with the Medicare program requirements.

(ii) A statement acknowledging that the organization agrees to submit timely, accurate, and complete data to support CMS's evaluation of the accrediting organization's performance. Data to be submitted includes, but is not limited to, accredited provider or supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions. The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within three business days from the date the organization takes an action.

(14) A list of all facilities currently accredited by the organization under the program for which CMS approval is sought, including the type and category of accreditation currently held by each provider or supplier, and the expiration date of each provider's or supplier's current accreditation.

(15) A schedule of all surveys expected to be conducted by the organization for the accreditation program under review during the 6-month period following submission of the application.

(16) The three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities.

(17) A statement that it will:

(i) Provide written notification to CMS and to all providers or suppliers accredited under a CMS-approved accreditation program at least 90 calendar days in advance of the effective date of a decision by the organization to voluntarily terminate its CMS-approved accreditation program, including the implications for their deemed status in accordance with § 488.8(g)(2); and

(ii) Adhere to the requirements for written notice to its accredited providers or suppliers at § 488.8(e) in the case of an involuntary termination.

(18) A statement that it will provide written notification to CMS of any proposed changes in the organization's CMS-approved accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS except as provided for at § 488.8(b)(2).

(19) A statement that, in response to a written notice from CMS to the organization of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS-approved accreditation program to ensure continued comparability with the CMS conditions or requirements or survey process. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization or by a date specified in the notice, whichever is later. CMS will give due consideration to an organization's request for an extension of the deadline.

(ii) The proposed changes will not be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.8(b)(1)(iv).

(20) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to permit its surveyors to serve as witnesses in a legal proceeding if CMS takes an adverse action against a provider or supplier on the basis of the organization's accreditation survey findings, and will cooperate with CMS to make surveyors and other staff available when needed.

(b) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application or re-application for CMS's approval of an accreditation program, CMS will notify the organization and afford it an opportunity to provide the additional information.

(c)(1) *Withdrawing an application.* An accrediting organization may withdraw its initial application for CMS's-approval of its accreditation program at any time before CMS publishes the final notice described in paragraph (e)(2) of this section.

(2) *Voluntary termination of a CMS-approved accreditation program.* An accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. The accrediting organization must notify CMS of its decision to voluntarily terminate its approved accreditation program at least 90 calendar days in advance of the effective date of the termination. In accordance with the requirement at § 488.4(a)(17)(i), the accrediting organization must also provide written notice at least 90 days in advance of the effective date of the termination to each of its deemed status providers or suppliers.

(d) *Re-submitting a request.* (1) Except as provided in paragraph (d)(2) of this section, an organization whose request for CMS's approval or re-approval of an accreditation program has been denied may resubmit its application if the

organization satisfies all of the following requirements:

(i) Revises its accreditation program to address the issues related to the denial of its previous request.

(ii) Demonstrates that it can provide reasonable assurance.

(iii) Resubmits the application in its entirety.

(2) If an accrediting organization has requested, in accordance with subpart D of this part, a reconsideration of CMS's determination that its request for approval of an accreditation program is denied, it may not submit a new application for approval of an accreditation program for the type of provider or supplier at issue in the reconsideration until the reconsideration is administratively final.

(e) *Public notice and comment.* CMS publishes a notice in the **Federal Register** when the following conditions are met:

(1) *Proposed notice.* When CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program, it publishes a proposed notice. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS.

(2) *Final notice.* When CMS decides to approve or disapprove a national accrediting organization's application, it publishes a final notice within 210 calendar days from the date CMS determines the AO's applications was complete, unless the application was for a skilled nursing facility accreditation program. There is no timeframe for publication of a final notice for a national accrediting organization's application for approval of a skilled nursing facility accreditation program. The final notice specifies the basis for the CMS decision.

(i) *Approval or re-approval.* If CMS approves or re-approves the accrediting organization's accreditation program, the final notices describes how the accreditation program provides reasonable assurance. The final notice specifies the effective date and term of the approval (which may not be later than the publication date of the notice and which will not exceed 6 years.

(ii) *Disapproval.* If CMS does not approve the accrediting organization's accreditation program, the final notice describes, except in the case of a skilled nursing facility accreditation program, how the organization fails to provide reasonable assurance. In the case of an application for a skilled nursing facility accreditation program, disapproval may be based on the program's failure to provide reasonable assurance, or on CMS's decision to exercise its discretion in accordance with section 1865(a)(1)(B) of the Act. The final notice specifies the effective date of the decision.

■ 10. Section 488.6 is revised to read as follows:

§ 488.6 Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program.

A provider or supplier that has been granted ''deemed status'' by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program if they are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

§ 488.9 [Removed]

■ 11. Section 488.9 is removed.

§ 488.7 [Redesignated as § 488.9]

■ 12. Section 488.7 is redesignated as new § 488.9.

■ 13. New § 488.7 is added to read as follows:

§ 488.7 Release and use of accreditation surveys.

A Medicare participating provider or supplier deemed to meet program requirements in accordance with § 488.4 must authorize its accrediting organization to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require (including, but not limited to, corrective action plans).

(a) CMS may determine that a provider or supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

■ 14. Section 488.8 is revised to read as follows:

§ 488.8 Ongoing review of accrediting organizations.

(a) *Performance review.* In accordance with section 1875(b) of the Act, CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis. This review includes, but is not limited to the following:

(1) Review of the organization's survey activity.

(2) Analysis of the results of the validation surveys under § 488.9(a)(1), including the rate of disparity between certifications of the accrediting organization and certifications of the SA.

(3) Review of the organization's continued fulfillment of the requirements in § 488.5(a).

(b) *Comparability review.* CMS assesses the equivalency of an accrediting organization's CMS-approved program requirements to the comparable Medicare requirements if the following conditions exist:

(1) CMS imposes new Medicare certification requirements or changes its survey process.

(i) CMS provides written notice of the changes to the affected accrediting organization.

(ii) CMS specifies in its written notice a timeframe, not less than 30 calendar days from the date of the notice, for the accrediting organization to submit its proposed equivalent changes, including its implementation timeframe, for CMS review. CMS may extend the deadline after due consideration of a written request for extension by the accrediting organization, submitted prior to the original deadline.

(iii) After completing the comparability review CMS provides written notification to the organization whether or not the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare requirements.

(iv) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide the written notice to the organization required in paragraph (b)(1)(iii) of this section, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(v) If an organization fails to submit its proposed changes within the required timeframe, or fails to implement the proposed changes that have been determined by CMS or deemed to be comparable, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(2) An accrediting organization proposes to adopt new requirements or to change its survey process.

(i) An accrediting organization must provide written notice to CMS of any proposed changes in its accreditation requirements or survey process and must not implement any changes before receiving CMS's approval, except as provided below.

(ii) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide written notice to the organization that the accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare requirements, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(iii) If an organization implements changes that have neither been determined by CMS nor deemed to be comparable to the applicable Medicare requirements, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(c) *CMS-approved accreditation program review.* If a comparability or performance review reveals evidence of substantial non-compliance of an accrediting organization's CMS-approved accreditation program with the requirements of this subpart, CMS may initiate an accreditation program review.

(1) If an accreditation program review is initiated, CMS provides written notice to the organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. The notice provides all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the accrediting organization to offer factual information related to CMS's findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review.

(iv) The actions the accrediting organization must take to address the identified deficiencies including a timeline for implementation not to exceed 180 calendar days after receipt of the notice that CMS is initiating an accreditation program review.

(2) CMS reviews the accrediting organization's plan of correction for acceptability.

(3) If CMS determines as a result of the accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program that the accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the accrediting organization's CMS-approved accreditation program on probation for a period up to 180 calendar days to implement corrective actions, not to exceed the accrediting organization's current term of approval. In the case of a renewal application where CMS has placed the accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the accrediting organization as to whether or not a CMS-approved accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS has determined that the accrediting organization does not meet the requirements, CMS withdraws approval of the CMS-approved accreditation program. The notice of determination provided to the accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (c)(3)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days from the date of publication of the notice.

(d) *Immediate jeopardy.* If at any time CMS determines that the continued approval of a CMS-approved accreditation program of any accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved accreditation program of that accrediting organization and publish a notice of the removal, including the reasons for it, in the **Federal Register**.

(e) *Notification of providers or suppliers.* An accrediting organization whose CMS approval of its accreditation program has been withdrawn must notify, in writing, each of its accredited providers or suppliers of the withdrawal of CMS approval and the implications in accordance with paragraph (g)(1) of this section for the providers' or suppliers' deemed status no later than 30 calendar days after the notice is published in the **Federal Register**.

(f) *Request for reconsideration.* Any accrediting organization dissatisfied with a determination to withdraw CMS approval of its accreditation program may request a reconsideration of that determination in accordance with subpart D of this part.

(g) *Continuation of deemed status.* (1) *Involuntary termination.* After CMS removes approval of an accrediting organization's accreditation program, an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the removal of the approval if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(2) *Voluntary termination by accrediting organization.* When an accrediting organization has voluntarily terminated its CMS-approved accreditation program and provides its accredited providers and suppliers the notice required at § 488.5(a)(17), an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the termination effective date if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of the notice from the accrediting organization. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(h) *Onsite observations of accrediting organization operations.* As part of the application review process, the ongoing review process, or the continuing oversight of an accrediting organization's performance, CMS may conduct at any time an onsite inspection of the accrediting organization's

operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, observation of surveys, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

■ 15. Newly designated § 488.9 is revised to read as follows:

§ 488.9 Validation surveys.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation of noncompliance, the SA surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) *Selection for survey.* (1) A provider or supplier selected for a validation survey must cooperate with the SA that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the SA in accordance with § 488.10(a), and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(c) *Consequences of a finding of non-compliance.* (1) If a CMS validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions or requirements, the provider or supplier will no longer be deemed to meet the Medicare conditions or requirements and will be subject to ongoing review by the SA in accordance with § 488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions for the deficiencies identified in the state validation survey in accordance with § 488.24, or may first direct the SA to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at § 488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under § 489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) *Re-instating deemed status.* An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare CoP, CfC, conditions of certification, or requirements.

(e) *Impact of adverse actions.* The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

■ 16. Section 488.10 is amended by revising paragraphs (b) through (d) to read as follows:

§ 488.10 State survey agency review: Statutory provisions.

* * * * *

(b) Section 1865(a) of the Act provides that if an institution is accredited by a national accrediting organization recognized by the Secretary, it may be deemed to have met the applicable conditions or requirements.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary.

(d) Section 1865(c) provides that an accredited institution that is found after a validation survey to have significant deficiencies related to health and safety of patients will no longer meet the applicable conditions or requirements.

■ 17. Section 488.11 is amended by revising paragraph (b) to read as follows:

§ 488.11 State survey agency functions.

* * * * *

(b) Conduct validation surveys of deemed status providers and suppliers as provided in § 488.9.

* * * * *

■ 18. Section 488.12 is amended by revising paragraph (a)(2) to read as follows:

§ 488.12 Effect of survey agency certification.

* * * * *

(a) * * *

(2) A provider or supplier accredited under a CMS-approved accreditation program remains deemed to meet the Medicare conditions or requirements, or will be placed under the jurisdiction of the SA and subject to further enforcement actions in accordance with the provisions at § 488.9.

* * * * *

■ 19. Section 488.13 is added to read as follows:

§ 488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the SA will conduct a full review in a timely manner.

■ 20. Section 488.28 is amended by revising paragraph (a) to read as follows:

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements, it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to CMS. In the case of an immediate jeopardy situation, CMS may require a shorter time period for achieving compliance.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 21. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 22. Section 489.1 is amended by revising paragraph (b) to read as follows:

§ 489.1 Statutory basis.

* * * * *

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the following rules in this part also apply to the approval of supplier entities that, for participation in Medicare, are subject to a determination by CMS on the basis of a

survey conducted by the SA or CMS surveyors; or, in lieu of an SA or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with the requirements of part 488 of this chapter at the time of the accreditation survey and accreditation decision, in accordance with the following:

(1) The definition of immediate jeopardy at § 489.3.

(2) The effective date rules specified in § 489.13.

(3) The requirements specified in § 489.53(a)(2), (13), and (18), related to termination by CMS of participation in Medicare.

* * * * *

■ 23. Section 489.3 is amended by revising the definition of ''Immediate jeopardy'' to read as follows:

§ 489.3 Definitions.

* * * * *

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

■ 24. Section 489.53 is amended by revising paragraphs (a) introductory text, (a)(2), (a)(13), and (d)(2)(i) introductory text and adding a new paragraph (a)(18) to read as follows:

§ 489.53 Termination by CMS.

(a) *Basis for termination of agreement.* CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider, and may, in addition to the applicable requirements in this chapter governing the termination of agreements with suppliers, terminate the agreement with any supplier to which the failings in paragraphs (a)(2), (13) and (18) of this section are attributable:

* * * * *

(2) The provider or supplier places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

* * * * *

(13) The provider or supplier refuses to permit copying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements.

* * * * *

(18) The provider or supplier fails to grant immediate access upon a reasonable request to a state survey agency or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage, or conditions for certification.

* * * * *

(d) * * *

(2) * * *

(i) *Hospitals.* If CMS finds that a hospital is in violation of § 489.24(a) through (f), and CMS determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

* * * * *

Dated: March 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 12, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–12087 Filed 5–21–15; 8:45 am]

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 606, 610, 630, et al.

Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, 630, 640, 660, and 820

[Docket No. FDA–2006–N–0040 (formerly Docket No. 2006N–0221)]

RIN 0910–AG87

Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations applicable to blood and blood components, including Source Plasma, to make the donor eligibility and testing requirements more consistent with current practices in the blood industry, to more closely align the regulations with current FDA recommendations, and to provide flexibility to accommodate advancing technology. In order to better assure the safety of the nation's blood supply and to help protect donor health, FDA is revising the requirements for blood establishments to test donors for infectious disease, and to determine that donors are eligible to donate and that donations are suitable for transfusion or further manufacture. FDA is also requiring establishments to evaluate donors for factors that may adversely affect the safety, purity, and potency of blood and blood components or the health of a donor during the donation process. Accordingly, these regulations establish requirements for donor education, donor history, and donor testing. These regulations also implement a flexible framework to help both FDA and industry to more effectively respond to new or emerging infectious agents that may affect blood product safety.

DATES: This rule is effective May 23, 2016.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Jonathan R. McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Final Rule

The final rule helps to protect donors of blood and blood components by requiring establishments to evaluate donors for factors that may cause donation to adversely affect their health. In addition, the final rule is being issued to assure the safety, purity, and potency of the blood and blood component products used for transfusion and for further manufacture.

The final rule applies to establishments that collect and/or process blood and blood components, including transfusion services. This rule requires establishments to assess a donor's medical history to determine that the donor is in good health and to screen the donor for factors that can adversely affect the safety, purity, or potency of blood and blood components. In addition, the rule provides requirements for testing donations for relevant transfusion-transmitted infections. This rule revises and updates existing regulations.

FDA is issuing this rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264), and certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that apply to drugs and devices (21 U.S.C. 201 *et seq.*).

Summary of the Major Provisions of the Final Rule

Consistent with the proposed rule, in § 630.3(*l*)), we define transfusion-transmitted infection as a disease or disease agent that: (1) Could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure and (2) for which there may be a risk of transmission by blood or blood components, or by a blood derivative product manufactured from blood or blood components, because the disease or disease agent is potentially transmissible by that blood, blood component or blood derivative product.

Sometimes, a transfusion-transmitted infection will also meet the definition of a relevant transfusion-transmitted infection. We define relevant transfusion-transmitted infection in § 630.3(h) to include two groups of transfusion-transmitted infections. The first group, in § 630.3(h)(1) is a list of 10 named transfusion-transmitted infections: Human immunodeficiency virus, types 1 and 2 (referred to, collectively as HIV); Hepatitis B virus (referred to as HBV); Hepatitis C virus (referred to as HCV); Human T-lymphotropic virus, types I and II (referred to, collectively, as HTLV); *Treponema pallidum* (referred to as syphilis); West Nile virus; *Trypanosoma cruzi* (referred to as Chagas disease); Creutzfeldt-Jakob disease (referred to as CJD); Variant Creutzfeldt-Jakob disease (referred to as vCJD); and *Plasmodium* species (referred to as malaria). In recognition of current industry practices and in response to comments to the proposed rule, we included West Nile virus and Chagas disease in the definition of relevant transfusion-transmitted infection at § 630.3(h)(1)(vi) and (vii), respectively. Establishments currently perform donor screening for these relevant transfusion-transmitted infections. Blood establishments other than Source Plasma establishments already perform testing for the first seven listed transfusion-transmitted infections, and Source Plasma establishments already perform testing for HIV, HBV, HCV, and more limited testing for syphilis. Testing requirements for Source Plasma establishments are more limited because Source Plasma undergoes further processing into blood derivative products, and those additional manufacturing steps have been shown to inactivate or remove certain infectious agents. We consider these donor testing and screening practices to meet current standards, and would address any changes in our recommendations for complying with the final rule in guidances issued in accordance with good guidance practice (21 CFR 10.115). The second part of the definition of relevant transfusion-transmitted infections, § 630.3(h)(2), establishes the criteria which will be used to identify other transfusion-transmitted infections that may present risks to the safety, purity, and potency of blood and blood components in the future. A transfusion-transmitted infection will meet the additional criteria for a relevant transfusion-transmitted infection when the following conditions are met: (1) Appropriate screening measures for the transfusion-transmitted infection have been developed and/or an appropriate screening test has been licensed, approved, or cleared for such use by FDA and is available and (2) the disease or disease agent may have sufficient incidence and/or prevalence to affect the potential donor population, or may have been released accidentally or intentionally in a manner that could place potential donors at risk of

infection. Under the first prong of these criteria, a transfusion-transmitted infection would become relevant only when an appropriate intervention is available to prevent contamination of the blood supply. Under the second prong, the disease or disease agent must also meet one of the following two criteria: (1) It may have sufficient incidence and/or prevalence to affect the potential donor population or (2) it may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection.

In the event that circumstances have changed, and that a transfusion-transmitted infection meets the definition of a relevant transfusion-transmitted infection, FDA intends to issue guidance in accordance with good guidance practices to advise stakeholders of FDA's assessment of how the transfusion-transmitted infection now meets the definition of relevant transfusion-transmitted infection. In the same guidance, we would also address appropriate donor screening measures, including medical history assessments, in accordance with § 630.10(e), and any appropriate donor testing in accordance with § 610.40(a)(3) (21 CFR 610.40(a)(3)). We may also address educational materials in accordance with § 630.10(b).

We are finalizing minor changes to the requirements in § 606.100(b) (21 CFR 606.100(b)) to maintain standard operating procedures largely as proposed. In addition, final § 606.100(b)(22) more explicitly requires establishments to have procedures to control the risks of bacterial contamination of platelets, including all steps required under § 606.145.

We address requirements for establishments to take steps to control bacterial contamination of platelets in § 606.145, which is located in the part entitled ''Current Good Manufacturing Practice for Blood and Blood Components'' instead of in § 630.30(a)(5), as proposed. This placement more clearly reflects the importance of these steps to current good manufacturing practice. Section 606.145 requires establishments to assure that the risks of bacterial contamination of platelets are adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA, and explicitly addresses the responsibility of transfusion services to comply with this current good manufacturing practice. Establishments must take appropriate steps to identify the contaminating organism, and in the event that the organism is identified, the responsible physician for the collection establishment must determine whether that organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor. Such a determination would lead to donor deferral and notification.

In response to comments, we have significantly narrowed the recordkeeping requirement that we proposed in § 606.160(e) (21 CFR 606.160(e)). Instead of requiring collection establishments to share a record of all ineligible donors with appropriate personnel at all locations operating under the same license or under common management, final § 606.160(e) requires establishments to maintain two records: (1) A record of all donors found to be ineligible or deferred at the collection location and (2) a cumulative record of donors deferred from donation at all locations operating under the same license or under common management because their tests were reactive for evidence of infection due to HIV, HBV, or HCV. Establishments other than Source Plasma establishments must include donors deferred for evidence of infection due to HTLV and Chagas disease. A related provision, § 630.10(d), sets out requirements for establishments to consult these records before collection. If a pre-collection review of the cumulative record is not feasible, establishments must review it before releasing blood or blood components.

We maintain current testing requirements in § 610.40, and include additional provisions. In § 610.40(a), we address testing for Chagas disease, West Nile virus, and syphilis. This section would also require testing for additional relevant transfusion-transmitted-infections in the event that donor screening tests are licensed, approved, or cleared, and are available, and that such testing is necessary to reduce adequately and appropriately the risk of transmission of the relevant transfusion-transmitted infection by blood or blood components. In addition, this section provides that, under appropriate conditions and for certain relevant transfusion-transmitted infections, it may become appropriate to test at a frequency other than at each donation, or, when the conditions in the regulations are met, even to stop testing for that relevant transfusion-transmitted infection. Section 610.40(a)(4) describes types of evidence that may support such a determination.

In § 610.40(e), we are maintaining the existing requirement for further testing when a donation tests reactive for a relevant transfusion-transmitted infection. When a licensed, approved, or cleared supplemental test is not available, the rule provides greater flexibility for the use of licensed, approved, or cleared tests to provide additional information concerning the reactive donor's infection. This section also requires establishments to perform additional testing of a donation found reactive by a non-treponemal donor screening test for syphilis.

Final § 630.5 provides requirements for medical supervision of collection activities, such as determining the eligibility of a donor of blood or blood components, including Source Plasma, collecting blood or blood components, and for performing other donor procedures such as returning red blood cells during apheresis, or immunizing Source Plasma donors as part of an approved immunization program. This section requires establishments to establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when medically necessary, and must assure that a person who is currently certified in cardiopulmonary resuscitation is located on the premises whenever collections are performed.

Section 630.10 establishes general donor eligibility requirements and consolidates most donor eligibility requirements for Whole Blood and Source Plasma into a single section. A donor is not eligible and must be deferred if the donor is not in good health or if the establishment identifies any factor that may cause the donation to adversely affect the health of the donor or the safety, purity, or potency of the blood or blood component. This section requires the establishment to provide the donor with educational material related to a relevant transfusion-transmitted infection when donor education about that infection is necessary to assure the safety, purity, and potency of blood and blood components, to consult records of deferred donors, to assess the donor for risk factors for relevant transfusion-transmitted infections and other factors that might adversely affect the donation or the donor's health, and to obtain proof of the donor's identity and a postal address where the donor may be contacted for 8 weeks after donation.

Section 630.10(f) requires establishments to perform a limited physical assessment of the donor. This assessment must include donor temperature, blood pressure, pulse, minimum weight, condition of the skin at phlebotomy site and on arms, and hemoglobin or hematocrit levels. The rule maintains current requirements for hemoglobin and hematocrit levels for

female donors, but since lower levels are also within the normal range for women, the rule would authorize collection from female donors with levels no lower than 12.0 grams of hemoglobin per deciliter of blood, or a hematocrit value no lower than 36 percent, provided that the establishment has taken additional steps to assure that the alternative standard is adequate to assure donor safety, in accordance with a procedure that has been found acceptable for this purpose by FDA. The rule raises the minimum standard for male donors from 12.5 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent, to 13 grams and 39 percent, respectively.

Under § 630.10(g)(2) establishments must obtain the donor's acknowledgement that the donor has reviewed educational material required to be provided under this section as well as information about the risks and hazards of the specific donation procedure. In the proposed rule, this was called the ''Donor's written statement of understanding.''

Section 630.15 establishes additional donor eligibility requirements for the collection of Whole Blood and Red Blood Cells collected by apheresis and Source Plasma and Plasma collected by plasmapheresis. For donors of Whole Blood and Red Blood Cells collected by apheresis, § 630.15(a) requires that donation frequency be consistent with protecting the donor's health, describes minimum intervals between donations (typically 8 weeks, and 16 weeks for a double Red Blood Cell donation), and addresses donations by donors undergoing therapeutic phlebotomy.

The requirements in § 630.15(b) applicable to donors of Source Plasma and Plasma collected by plasmapheresis are largely consistent with current regulations and practices. The responsible physician, subject to delegation in accordance with § 630.5(c), must conduct an appropriate medical history and physical examination of the donor at least annually, and must defer a donor found to have a medical condition that would place the donor at risk from plasmapheresis, and for red blood cell loss, as described in the rule. This section also addresses informed consent requirements for donors of Source Plasma and Plasma collected by plasmapheresis. These requirements complement other requirements for the collection of plasma by plasmapheresis in parts 630 and 640 (21 CFR parts 630 and 640), including restrictions on frequency of collection specified in §§ 640.32 and 640.65).

Section 630.20 permits, under certain circumstances, the collection of blood and blood components from individuals who are ineligible under one or more of the eligibility requirements under §§ 630.10 and 630.15. This section provides exceptions for autologous donors and donors who are participants in an approved plasmapheresis program for products for which there are no alternative sources, and for dedicated donations where there is documented exceptional medical need. For all collections authorized under this section, we have clarified the responsible physician's role and responsibilities in these collections.

We are finalizing § 630.25 largely as proposed. This section modifies certain requirements in §§ 630.15(b) and 640.65(b) as they are applicable to the collection of plasma from infrequent plasma donors. For greater clarity, we have included a definition of ''infrequent plasma donor'' in new § 630.3(e) and we use that defined term in this section.

We have finalized requirements in § 630.30(a) to define when a donation is suitable. Section 630.30(b) expressly prohibits an establishment from releasing an unsuitable donation for transfusion or further manufacturing use unless it is an autologous donation, or an exception is provided. It further requires a blood establishment to defer the donor of an unsuitable donation, although final § 630.30(b)(2) requires deferral of donors of platelets found to be bacterially contaminated only when the establishment determines in accordance with § 606.145 that the bacterial contamination shows evidence of bacteria endogenous to the bloodstream of the donor. This is because we recognize that a frequent cause of bacterial contamination in platelets is due to the passage of the collection needle through the donor's skin, which is not sterile. For this reason, the presence of bacteria that are common skin flora does not warrant deferral of the donor.

We have finalized the donor notification provisions in § 630.40. Consistent with the proposed rule, § 630.40(a) requires establishments to notify donors whose platelet component has tested positive for a bacterial contamination that is likely due to an infection endogenous to the bloodstream of the donor, such as *Streptococcus bovis.* Identification of this bacterium indicates that the donor may have a serious health condition such as colon cancer.

Section 640.21 addresses eligibility of donors of platelets. Consistent with the proposed rule, § 640.21(b) provides that a plateletpheresis donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function. We have modified this requirement for donors of Whole Blood that is the source of Platelets for transfusion. Section 640.21(c) requires that a Whole Blood donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function unless the unit is labeled to identify the ingested drug that adversely affects platelet function. Section 640.21(g) incorporates existing informed consent requirements.

Based on comments to the proposed rule, we have finalized the requirements for collection of Platelets by plateletpheresis to be consistent with ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods,'' dated December 2007. These provisions address donor platelet counts, frequency and size of plateletpheresis collection, and deferral for red blood cell loss.

We are finalizing the limits on distribution of Source Plasma in § 640.69(e) with minor changes. The final rule now provides that establishments must establish a paid Source Plasma donor's qualification by determining on at least two occasions in the past 6 months that the donor is eligible under § 630.10(e) and that the donor's results are negative on all tests required under § 610.40(a). Consistent with current industry standards, we have also finalized the inventory hold provision proposed in § 640.69(f) to require establishments to hold Source Plasma donated by paid donors in quarantine for a minimum of 60 days. In addition, we clarify the conditions that would prevent an establishment from distributing Source Plasma from quarantine.

We are not finalizing proposed § 640.73, ''Reporting of donor reactions'', in this rule. Instead, FDA intends to finalize this section when FDA finalizes the proposed Safety Reporting Requirements for Human Drug and Biologicals (68 FR 12406, March 14, 2003). We will address in that final rule the comments on proposed § 640.73.

We are finalizing § 640.120 largely as proposed. Final § 640.120(b) authorizes the Director of the Center for Biologics Evaluation and Research (CBER) ''to respond to a public health need'' by issuing an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the CFR if necessary to provide for appropriate donor screening and testing or to assure

that blood, blood components, or blood products will be available in a specified location or locations to address an urgent and immediate need for blood, blood components, or blood products. Under these provisions, this authority will be available to FDA to assure the availability of blood and blood components that are safe, pure, and potent.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This final rule is not a significant regulatory action under the Executive orders, and it will not have an economic impact, or require expenditures, at magnitudes warranting review under those statutory provisions.

Costs and Benefits

This rule sets forth requirements for donor eligibility and donation suitability to ensure the safety, purity, and potency of the blood and blood components used for transfusion or for further manufacture. Costs estimated in this analysis include costs related to the standard operating procedures and bacterial testing requirements for blood collection establishments and transfusion services. The total upfront costs are $16,042,628, and include costs related to the review, modification, and creation of standard operation procedures. The mean annual costs of $892,233 include costs related to the bacterial testing of single units of Whole Blood-derived platelets and speciation of bacterially contaminated platelets. We anticipate that this final rule will preserve the safety, purity, and potency of blood and blood components by preventing unsafe units of blood or blood components from entering the blood supply, and by providing recipients with increased protection against communicable disease transmission. The requirements set forth in this rule will also help to decrease the number of blood transfusion related fatalities that are associated with the bacterial contamination of platelets. The annual value of additional fatalities averted related by testing of Whole Blood-derived platelets is estimated to be approximately $27 million to $90 million and the annual value of averted nonfatal sepsis infections is estimated to be $3.19 million to $4.91 million.

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I. Introduction

In the **Federal Register** of November 8, 2007 (72 FR 63416), FDA published the proposed rule ''Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use'' to amend the regulations for blood and blood components, including Source Plasma and Source Leukocytes, by adding donor eligibility and donation suitability requirements that are consistent with current practices in the blood industry, and to more closely align the regulations with current FDA recommendations. We proposed this rule to help ensure the safety of the nation's blood supply and to help protect the health of donors by requiring establishments to evaluate donors for factors that may adversely affect the safety, purity, and potency of blood and blood components or the health of a donor.

This effort was undertaken as part of the Department of Health and Human Services Blood Action Plan (Ref. 1). The Blood Action Plan was developed in response to recommendations from Congress and other groups including the Government Accountability Office (previously the General Accounting Office) and the Institute of Medicine (Refs. 2, 3). This rulemaking is one of the final remaining action items under the Blood Action Plan.

In response to numerous requests, we extended the comment period for the proposed rule, initially scheduled to close on February 8, 2008, for an additional 180 days to August 4, 2008 (73 FR 1983, January 11, 2008). FDA received 29 letters of comment on the proposed rule, most of which raised multiple issues. Some comments responded to questions that we solicited in the preamble to the proposed rule in order to obtain additional information and data for this rulemaking. For example, we solicited comments on testing for bacterial contamination in platelets (72 FR 63416 at 63421) and requested data addressing the continued need for syphilis testing to address the risks of transfusion-related syphilis infection, and its value as a surrogate marker for other communicable diseases (72 FR 63416 at 63422).

II. Comments on the Proposed Rule and FDA's Responses

We received 29 letters containing multiple comments from blood establishments, biologics manufacturers, industry trade associations, and other interested persons. In this section, we respond first to general comments and then, in the corresponding section of this preamble, to those on specific provisions of the proposed rule. To make it easier to identify the comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment in the order in which we discuss it. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received. Certain comments were grouped together because the subject matter of the comments was similar.

A. General

(Comment 1) One comment commended FDA's efforts to update the regulations for blood and blood components to accommodate scientific and industry advances. These advances are vital to assuring the safety, purity

and potency of the blood supply. Another comment stated that they fully support the intent of the proposed rule to help assure the safety of the blood supply and to help protect donor health.

(Response) We acknowledge and appreciate these supportive comments.

(Comment 2) One comment applauded and supported FDA efforts to streamline the regulations and bring them up-to-date with current recommendations and current FDA guidance documents. The comment stated that appropriate standards will afford the medical community the ability to alleviate blood shortages, contribute to the success of public health initiatives, and contribute to quality medical care.

(Response) We appreciate the comment. We revised and updated the regulations applicable to blood and blood components, including Source Plasma and Source Leukocytes, with the goal of ensuring optimal donor safety measures as well as assuring that the public will continue to have access to safe, pure and potent blood and blood components.

B. Definitions (§§ 606.3, 610.39, 630.3, 640.125)

We have combined our discussion of the definitions contained in §§ 606.3, 610.39, 630.3, and 640.125 in this section of the preamble. An understanding of the terms we define is important to an understanding of other sections of this rule that use those terms. We hope to help the reader by discussing these foundational definitions early in this preamble, before we discuss the substantive provisions using those terms.

We are finalizing the definition of *blood* in §§ 606.3(a) and 630.3(a) as a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human. We received no comments on the proposed definition. The definition in the final rule differs from the proposal only in the reference to ''a fluid'' instead of ''the fluid,'' and the substitution of the phrase ''was collected from'' for ''circulates in.'' We made these minor changes for accuracy, and to reflect the practical fact that when blood becomes a ''product'' it is no longer circulating in a human vascular system, but has been collected from the human vascular system. We are finalizing without change the proposed definition of *blood component* in §§ 606.3(b) and 630.3(b) as ''a product containing a part of human blood separated by physical or mechanical means.'' We had proposed to modify the definition of blood component in proposed § 1270.3(b) (21 CFR 1270.3(b)). We are not finalizing that provision because, due to the Agency's issuance of new regulations applicable to human cellular and tissue based products (21 CFR part 1271), the regulations in part 1270 (21 CFR part 1270), including the definition we proposed to amend, now apply only to human tissue recovered before May 25, 2005. (See § 1270.3(j)). For this reason, it is unnecessary to finalize proposed § 1270.3(b).

We are also finalizing as proposed the definitions of *donor* (§ 630.3(c)), *eligibility of a donor* (§ 630.3(d)), and *suitability of the donation* (§ 630.3(j)).

In § 630.3(e), we have added a definition of *infrequent plasma donor,* which means a donor who has not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks, and has not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year. We provided a similar definition in the preamble to the proposed rule, and are adding it to the codified section in order to make the definition more accessible and clear. The preamble described an infrequent plasma donor as a donor: (1) Who has not donated Whole Blood in the preceding 8 weeks or plasma by apheresis in the preceding 4 weeks, or participated in a double Red Blood Cells unit collection program within the preceding 16 weeks; (2) who has not donated more than 12.0 liters of plasma in the past year (14.4 liters of plasma for donors weighing more than 175 pounds); (3) who is determined by the responsible physician to be in good health; and (4) who is not participating in an immunization program for the production of high-titer plasma. Under proposed § 630.25(a), exceptions from certain donor eligibility requirements could apply to such donors who have not donated within the preceding 4 weeks. The definition of infrequent plasma donor in the final rule focuses on the donor's prior donations of plasma and co-collections of plasma because deferral for Whole Blood and Red Blood Cell donation and requirements for donor health are addressed in other sections of this rule (§§ 630.10 and 630.15), and final § 630.25 states that the exceptions in § 630.25 are applicable only for infrequent plasma donors who are not participating in an immunization program. The final rule defines an infrequent plasma donor as a donor who has not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks, and has not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year. This definition makes clear that for purpose of this exception, co-collection of plasma with another blood component is considered in the same way as collection of plasma. We decided to make this reference to co-collection by apheresis of plasma more explicit in response to comments discussed in comment 115, which asked FDA to harmonize deferral periods after red blood cell loss for apheresis donors of plasma and of apheresis donors of plasma co-collected with platelets.

Due to the addition of this new definition in § 630.3(e), we have redesignated the remaining definitions alphabetically, beginning with *intimate contact with risk for a relevant transfusion-transmitted infection* (now final § 630.3(f)), through *transfusion-transmitted infection* (now final § 630.3(*l*)). Several of these definitions use the term *transfusion-transmitted infection,* which is alphabetically last. To help the reader understand the definitions that incorporate the term *transfusion-transmitted infection,* we will first explain the term *transfusion-transmitted infection.*

Consistent with the proposed rule, we define *transfusion-transmitted infection,* final § 630.3(*l*), as a disease or disease agent: (1) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure and (2) for which there may be a risk of transmission by blood or blood components or by a blood derivative product manufactured from blood or blood components, because the disease or disease agent is potentially transmissible by that blood, blood component or blood derivative product.

Sometimes, a *transfusion-transmitted infection* will meet the additional criteria established in the definition of a *relevant transfusion-transmitted infection.* We define *relevant transfusion-transmitted infection* in § 630.3(h) to include two groups of transfusion-transmitted infections. The first group, in § 630.3(h)(1) is a list of 10 named transfusion-transmitted infections: HIV; HBV; HCV; HTLV; syphilis; West Nile virus; Chagas disease; Creutzfeldt-Jakob disease (CJD); variant Creutzfeldt-Jakob disease (vCJD); and *Plasmodium species* (malaria). In recognition of current industry practices and in response to comments received on the proposed rule, West Nile virus

and Chagas disease are included in the definition of relevant transfusion-transmitted infection at § 630.3(h)(1)(vi) and (vii), respectively. Establishments currently perform donor screening for these relevant transfusion-transmitted infections. Blood establishments other than Source Plasma establishments already perform testing for the first seven listed transfusion-transmitted infections, and Source Plasma establishments already perform testing for HIV, HBV, HCV, and more limited testing for syphilis. Testing requirements for Source Plasma establishments are more limited because Source Plasma undergoes further processing into blood derivative products, and those additional manufacturing steps have been shown to inactivate or remove certain infectious agents. We consider these donor testing and screening practices to meet current standards, and would address any changes in our recommendations for complying with the final rule in guidances issued in accordance with good guidance practice.

The second part of the definition of *relevant transfusion-transmitted infections,* § 630.3(h)(2), establishes the criteria which will be used to identify other *transfusion-transmitted infections* that present risks to the safety, purity, and potency of blood and blood components at some time in the future. Under these criteria, a *transfusion-transmitted infection* will be identified as a *relevant transfusion-transmitted infection* when the following conditions are met: (1) Appropriate screening measures for the transfusion-transmitted infection have been developed and/or an appropriate screening test has been licensed, approved, or cleared for such use by FDA and is available and (2) the disease or disease agent may have sufficient incidence and/or prevalence to affect the potential donor population, or may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection. Under the first prong of these criteria, a *transfusion-transmitted infection* could be identified as a relevant transfusion-transmitted infection only when an intervention is available to prevent infection of the blood supply. This intervention could be a donor screening measure such as questions during the medical history interview about medical history, travel, or other behaviors, or a donor screening test to detect the disease or disease agent or evidence of the infection. Under the second prong, the *transfusion-transmitted infection* must be relevant to the donor population, either because it may have sufficient incidence and/or prevalence to affect the donor population, or because it may have been released in a manner that could place potential donors at risk of infection.

In the event that FDA determines that, under current conditions, a *transfusion-transmitted infection* now meets the definition of a *relevant transfusion-transmitted infection,* FDA intends to issue guidance in accordance with good guidance practices to advise stakeholders of FDA's assessment of how the *transfusion-transmitted infection* now meets the definition of *relevant transfusion-transmitted infection.* In the same guidance, we would also address appropriate screening measures, including medical history assessments, in accordance with § 630.10(e), and any appropriate donor testing for *relevant transfusion-transmitted infections* in accordance with § 610.40(a)(3). We anticipate issuing such guidance initially as a draft for comment, unless, due to urgent circumstances, it is not feasible or appropriate to issue the document first in draft. Under those circumstances we would invite comment on the final guidance, and revise it as appropriate.

We note that members of the Transfusion Transmitted Diseases Committee of AABB, formerly the American Association of Blood Banks, published an article in 2009 identifying 68 emerging infectious disease agents that are potentially transmitted by blood (Ref. 4) and recently updated this list of potential threats (Ref. 5). We recognize the value of such scientific assessments to the recognition and management of emerging infections among blood donors and blood recipients, and note that blood establishments already exercise medical judgment in implementing measures to respond to emerging infectious diseases. However, FDA intends to enforce requirements for screening and/or testing in this final rule with respect to an emerging infectious disease agent that is newly identified as meeting the definition of *relevant transfusion-transmitted infection* only after FDA issues a final guidance identifying the disease or disease agent as a relevant transfusion-transmitted infection under the criteria in this final rule, and recommends appropriate screening and/or testing measures.

Transfusion-transmitted infections that may, due to changed circumstances, meet the definition of *relevant transfusion-transmitted infections* in the future include dengue viruses or babesia. These infections meet the definition of *transfusion-transmitted infection* because they are life-threatening and are known to be transmitted by blood or blood components. We are continuing to monitor the incidence and prevalence of these infections in the donor population, as well as the development and availability of screening measures and screening tests. As discussed in the previous paragraph, if we determine at a future time that one of these *transfusion-transmitted infections* meets the criteria for a *relevant transfusion-transmitted infection,* we would issue guidance to explain our assessment. We would also address in that guidance appropriate screening and/or testing measures under §§ 630.10(e) and 610.40(a)(3).

We revised the defined term *intimate contact* in the proposed rule to *intimate contact with risk for a relevant transfusion-transmitted infection* (§ 630.3(f)). This term means having engaged in an activity that could result in the transfer of potentially infectious body fluids from one person to another. By including the phrase ''with risk for a relevant transfusion-transmitted infection'' in the term, we have clarified that the term applies to only those body fluids potentially infectious for infections that are or have been determined to be *relevant transfusion-transmitted infections.* Also, in response to several comments, discussed in more detail in comment 7, we deleted the reference to the exchange of ''blood or saliva'' from the definition.

We define *physician substitute* in § 630.3(g), *responsible physician* in § 630.3(i) and *trained person* in § 630.3(k). These definitions describe the qualifications an individual must possess to perform certain donor eligibility assessments and blood and blood component collection procedures as described in § 630.5. The *physician substitute* definition is unchanged from the proposed, except that instead of requiring, among other criteria, that the individual be ''trained and authorized to perform specified functions under the direction of the responsible physician,'' the final rule specifies that the individual be ''trained and authorized under State law, and/or local law when applicable, to perform the specified functions under the direction of the responsible physician.'' We make this change to clarify that authorization under existing and applicable state and local law, such as compliance with state practice limitations, is required. The definition of *responsible physician* is unchanged from the proposed rule. For clarity we substituted the non-plural term *trained person,* for the term *trained*

personnel, which was used in the proposed rule. We have also specified that a *trained person* must be ''authorized under State law, and/or local law when applicable.''

We did not receive any comments to the proposed definition of *you* as ''an establishment that collects blood and blood components'' (proposed § 630.3(*l*)). However, we are not finalizing that proposed definition. We did not intend to limit the term *you* to establishments that *collect* blood and blood components. In fact, we intended the term also to apply to establishments that perform other manufacturing steps, such as testing laboratories and transfusion services. Accordingly, we concluded that including *you* as a defined term was confusing, and we are not finalizing the proposed definition.

Finally, in new § 610.39, we have added a cross-reference to the definitions in § 630.3 to make clear that when these terms are used in part 610, subpart E (§§ 610.40 through 610.48), the definitions in § 630.3 apply. Although our practice in subpart E has been to cross-reference specific sections, express incorporation of these definitions into the subpart will support the clarity of these provisions. Similarly, we have added new § 640.125 to new subpart M in part 640, entitled ''Definitions and Medical Supervision.'' Section 640.125 provides a cross-reference to the definitions in § 630.3, making those definitions applicable when those terms are used in part 640. This provision is consistent with the proposed rule, which stated in the introductory paragraph to proposed § 630.3 that the definitions were applicable in part 630 and in part 640.

(Comment 3) One comment recommended that the definition of *blood component* in proposed §§ 606.3(c) and 630.3(b) should include a cross-reference to the regulations in which specific blood components (such as Red Blood Cells and Platelets) are defined. The comment stated that the proposed definition fails to impart the complexity of different blood components and their intended uses, that there is little similarity between blood components intended for transfusion and Source Plasma, and that the requirements for donor eligibility and testing are unique for Source Plasma. Another comment proposed that a comprehensive definition be provided for Source Plasma.

(Response) All blood components contain risks for transmission of infectious agents, and collection of donations presents risks for donor safety regardless of the intended use of the donation. There is significant consistency among donor eligibility requirements for all types of blood components; these are addressed in § 630.10. In addition, different types of blood components may present different issues, both for the safety, purity, and potency of the collection, and for the safety of the donor. The regulations have long included requirements specific to Source Plasma, Platelets, Red Blood Cells, and other blood components, and we maintain many of those requirements in the final rule. However, we disagree that the definition of *blood component,* which includes all products derived from human blood separated by physical or mechanical means, will be improved by cross-references to the sections that address requirements for specific types of blood components. Instead, we address requirements applicable to a specific type of blood component in the sections applicable to those blood components. For example, in part 640, subpart B (§§ 640.10 through 640.17) addresses Red Blood Cells and contains standards for those blood components, as subparts C (§§ 640.20 through 640.27), D (§§ 640.30 through 640.34), and G (§§ 640.60 through 640.76) do for Platelets, Plasma, and Source Plasma, respectively. Finally, we reviewed the current definition of Source Plasma in § 640.60, which states that ''the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. The definition excludes single donor plasma products intended for intravenous use.'' We conclude that it is sufficiently comprehensive.

(Comment 4) One comment questioned FDA's inclusion of a person who ''presents as a potential candidate for such donation'' in the definition of *donor.* The comment requested clarification on when a person ''presents'' to donate, and asked whether a donor ''presents'' simply by walking through the door, or whether a donor ''presents'' when the blood establishment starts the donor interview to assess the donor's eligibility under the regulations. The comment stated that certain blood establishments collect blood from donors who have specific characteristics unrelated to donor eligibility, such as a history of a specific disease. The comment stated that preliminary interviews to determine whether an individual has such a characteristic should not be considered to be interviews with a ''donor.'' The comment asserted that requirements to maintain donor records in § 606.160(b)(1) (21 CFR 606.160(b)(1)) should not apply to records of these preliminary interviews because the specialty centers determine specialty information before assessing the general eligibility of the potential candidate. The comment proposed the following definition, ''Donor means a person who: (1) Donates blood or blood components for transfusion or for further manufacturing or (2) a potential candidate who has begun the interactive assessment of eligibility by center personnel.''

(Response) Under the definition of *donor* in final § 630.3(c), an individual would be a ''donor'' once the establishment begins any of the interactions that are required under this rule. Accordingly, an individual who has not yet donated, but has received educational material in accordance with § 630.10(b), or started to provide donor information related to medical history under § 630.10(e), would be a donor. For example, questioning of the ''donor'' regarding travel history or risk behaviors that could lead to deferral under §§ 630.10(e)(2)(iii) and 630.10(e)(1)(i), respectively, would be considered part of determining donor eligibility. However, other interactions not required under this rule, such as taking a blood sample at a health fair to identify rare blood types or unique antigens or antibodies could be considered preliminary interactions, provided that an interaction required under this rule (such as testing for a relevant transfusion-transmitted infection) was not also initiated during the same encounter. If an establishment's interactions with an individual are only preliminary and are not otherwise required under these regulations, the individual would not yet be considered a ''donor.''

(Comment 5) One comment recommended that FDA adopt terminology that excludes paid donors from the definition of a *donor.* The comment stated that people being paid to have their plasma collected are not giving a donation.

(Response) We decline to accept the recommendation. Consistent with the general use of the term in blood collection establishments, FDA uses the term *donor* to apply to all donors, whether or not they are paid. FDA regulations do not preclude paid donations for blood for transfusion or for further manufacture. We acknowledge that the existing regulations have specific provisions applicable to paid donors. For example, FDA requires the container label of blood and blood components intended for transfusion to include the statement ''paid donor'' or ''volunteer donor.'' Section 606.121(c)(8)(v)(A) defines a

paid donor as a person who receives monetary payment for a blood donation. We do not require that Source Plasma be labeled in this way because it is widely understood that Source Plasma is collected predominantly from paid donors.

(Comment 6) Several comments agreed with the definitions of eligibility of a donor and suitability of the donation in proposed § 630.3(d) and (i), respectively. The comments stated the terms are helpful in clarifying many requirements.

(Response) We agree, and have finalized the definitions as proposed in § 630.3(d) and (j), respectively.

(Comment 7) Several comments stated that the definition of *intimate contact,* designated in the final rule at § 630.3(f), should be reworded to describe an activity (sexual contact or living with) that could result in an exchange of blood with another individual.

(Response) As stated earlier, we revised the term from *intimate contact to intimate contact with risk for a relevant transfusion-transmitted infection.* The term means having engaged in an activity that could result in the transfer of potentially infectious body fluids from one person to another. The new definition does not reference blood or saliva specifically; it also does not define the specific activity that could result in the transfer of potentially infectious body fluids. The definition applies only when intimate contact presents risks for transmission of a *relevant transfusion-transmitted infection.* This definition of *intimate contact with risk for a relevant transfusion-transmitted infection* and the associated requirement in § 630.10(e)(1)(v) to assess donors for this risk replaces current § 640.3(c)(2), which requires deferral of donors who have a history of close contact within 12 months of donation with an individual having viral hepatitis. The new provisions refine the current requirement, and we note that the donor history questionnaires prepared by AABB and the Plasma Protein Therapeutic Association, which have been recognized as acceptable by FDA for screening donors of blood, blood components and Source Plasma, already address the risk of transmission of HBV and HCV by including questions about the donor's ''sexual contact'' and ''living with'' individuals with hepatitis (Refs. 6, 7, 8).

We also note that FDA has recommended that a donor be deferred on the basis of sexual contact with an individual infected with HIV. Questions related to sexual contact with an individual infected with HIV are also included in the donor history questionnaires found acceptable by FDA (Refs. 6, 7, 8). FDA intends to issue guidance as needed to identify other relevant transfusion-transmitted infections where we consider intimate contact to present significant risks for transmission of such infection.

(Comment 8) Several comments stated that the proposed definition of *intimate contact* was not consistent with public health messages that the risk of transmission of HIV transmission through kissing is remote.

(Response) We agree with this comment in part and have revised the proposed definition. Public health messages have not identified casual kissing as a risk for HIV. However, CDC has identified open-mouth kissing with an HIV infected person as a risk if there are breaks in the skin or tongue (Ref. 9). FDA's guidance for donor deferral is limited to ''having sexual contact with an HIV infected individual'' (Ref. 10). It does not recommend deferral for kissing.

(Comment 9) One comment agreed with the proposed definition of *physician substitute;* however, the comment stated that the term could be misleading for the general public and could imply that physician substitutes can perform all duties of a licensed physician at the Source Plasma establishments.

(Response) We disagree that the term *physician substitute* implies that physician substitutes can perform all the duties of a licensed physician. We believe the definition in § 630.3(g) describes sufficiently the training and qualifications of a *physician substitute,* who must be a graduate of an education program for healthcare workers that includes clinical training, currently licensed or certified as a health care worker in the jurisdiction where the collection establishment is located, and currently certified in cardiopulmonary resuscitation. Moreover, the definition now makes explicit that a *physician substitute* must be trained and authorized under State law, and/or local law when applicable, to perform specified functions under the direction of the responsible physician. Finally, § 630.5 describes the activities the responsible physician may delegate to the physician substitute, and those the responsible physician is not authorized to delegate.

(Comment 10) Several comments stated that syphilis and CJD should not be included in the definition of *relevant transfusion-transmitted infection.*

(Response) We disagree with the comments. Syphilis is a *relevant transfusion-transmitted infection* which screening tests have long been used to detect. As discussed in our response to comment 31, we continue to review data to determine whether it is still necessary to perform screening tests for this infection. However, data submitted to date do not justify a determination that testing to identify syphilis infection is no longer needed to protect the blood supply. Accordingly, we have included syphilis in the definition of a *relevant transfusion-transmitted infection* at final § 630.3(h)(1)(v).

We have also determined that CJD and vCJD are *relevant transfusion-transmitted infections* because of the risks they present. Screening tests are not yet available for CJD and vCJD. It is current practice for establishments to perform screening by means of a medical history interview, and FDA has issued guidance recommending donor screening for these diseases (Ref. 11). Consistent with these current practices, we have included CJD and vCJD in the definition of a *relevant transfusion-transmitted infection* at § 630.3(h)(1)(viii) and (ix), respectively.

However, our inclusion of certain transfusion-transmitted infections within the definition of *relevant transfusion-transmitted infection* does not necessarily mean an establishment will always be required to perform donor history screening, or donor testing for that *relevant transfusion-transmitted infection.* Specifically, in line with the more flexible testing paradigm and criteria we have adopted in final § 610.40(a), it is possible that testing for syphilis will no longer be necessary to reduce adequately and appropriately the risk of transmission of syphilis by blood or blood components. The same applies to CJD and vCJD, and to relevant transfusion-transmitted infections other than HIV, HBV, and HCV. New § 610.40(a)(4) describes the evidence that may be used to support such a determination.

(Comment 11) One comment recommended the inclusion of West Nile virus, Chagas disease, and bacteria in the definition of *relevant transfusion-transmitted infection,* noting that blood components are routinely tested for West Nile virus and Chagas disease.

(Response) We agree that West Nile virus and Chagas disease present significant risks to the safety, purity, and potency of the blood supply, and that the performance of screening tests for these *transfusion-transmitted infections* has become routine. Accordingly, we have added these two infections to the definition of *relevant transfusion-transmitted infections* in this final rule. However, testing or screening of blood donors to identify

specific bacterial infections is not routinely performed for donors of all blood components, although under final § 630.10(e)(2)(i) establishments must assess all donors for symptoms of a recent or current illness. We decline to add bacteria to the definition of *relevant transfusion-transmitted infection* at this time, but we have addressed bacterial testing of platelets in § 606.145 of this rule.

(Comment 12) One comment recommended that *responsible physician* be defined to differentiate between the duties of a physician overseeing blood collection at an individual facility and a corporate physician with broader oversight responsibilities. Another comment stated that regional responsible physicians should be responsible for endorsing standard operating procedures (SOPs), and for supervising employees' compliance with those SOPs. Locally based physicians should not control or approve SOPs as this would lead to inconsistency in operations.

(Response) We decline to provide distinct definitions for ''corporate responsible physician'' and ''locally based physician''. As discussed in section II.C of this preamble, § 606.100(b) requires blood establishments to establish, maintain, and follow written SOPs for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components. These regulations do not prescribe the roles of corporate and locally based physicians in developing and approving SOPs. In fact, one process for establishing SOPs may be appropriate for one type of blood establishment, such as a licensed blood establishment that collects blood and blood components in multiple states, but inappropriate for a smaller blood establishment that collects and distributes blood and blood components within a limited geographic area.

C. Standard Operating Procedures (§ 606.100)

We are finalizing § 606.100(b), on which we received no comments, largely as proposed. In this section we revised the requirements for SOPs to require more specifically that blood establishments follow those procedures, to distinguish transfusions as either ''allogeneic'' or ''autologous,'' and to require more explicitly that establishments establish, maintain, and follow written standard operating procedures for investigating product deviations and for recordkeeping related to current good manufacturing practice requirements and other applicable requirements and standards. We are also finalizing as proposed § 606.100(b)(20) and (b)(21), which require procedures for donor deferral as prescribed in § 610.41, and procedures, including appropriate follow up, for notification of donors under § 630.40, and, for autologous donors, their referring physicians. We have also added § 606.100(b)(22), which requires establishments to have procedures to control the risks of bacterial contamination of platelets, including all steps required under § 606.145. We are including this provision to clarify that taking steps to control bacterial contamination of platelets is a step in the collection, processing, storage, and distribution of platelets, for which SOPs are required. Our discussion of comments received regarding bacterial testing of platelets can be found at comments 13 through 24 in section II.D.

D. Control of Bacterial Contamination of Platelets (§ 606.145)

We have finalized in new § 606.145 the requirement we proposed as § 630.30(a)(5), which, for platelet components, would have required establishments who collect blood and blood components to ''take adequate steps to assure that the donation is tested for bacterial contamination and found negative.'' We are finalizing this in part 606 in order to underscore the importance of including methods to control the risk of the proliferation of bacteria in platelets as current good manufacturing practice for blood and blood components.

Unlike other blood components, platelets do not function optimally following refrigeration. They are stored at room temperature, an environment conducive to the growth of bacteria. If the platelet unit is contaminated, bacteria can flourish and grow quickly in the warm, nutrient-rich platelet storage bag. Bacterial contamination is estimated to occur in as many as 1/1,000 to 1/3,000 platelet collections (Refs. 12, 13). The transfusion of bacterially contaminated platelets puts recipients at risk, with reactions varying due to a number of factors, including the pathogenicity of the bacteria, the quantity of the bacteria transfused, and the immune status of the recipient. Reactions range from no obvious clinical effects to severe and life-threatening infections (Ref. 14). Under current regulations (§ 606.170(b)), blood collection establishments and transfusion services are only required to report to FDA when adverse reactions related to blood collection or transfusion are confirmed to be fatal. Deaths due to bacterial contamination of platelets have been reported to FDA in recent years as follows: in 2008, there were two fatalities reported as complications of platelet transfusions, with subsequent reports of five in 2009, one in 2010, three in 2011, and two in 2012 (Ref. 15).

The final rule requires blood collection establishments and transfusion services to assure that the risks of bacterial contamination of platelets are adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA. This final rule requires these manufacturers to meet this standard, and, unlike the language in the proposed rule, does not necessarily require that components be ''tested . . . and found negative.'' Even though testing of platelet components using an FDA approved or cleared test would currently meet this requirement, the standard setting language used in the final rule would provide for appropriate use of new technologies in the future. For example, if pathogen reduction technology is approved or cleared and available in the future, then use of pathogen reduction technology may also meet the requirements of this provision. We intend to issue guidance addressing how establishments would use FDA approved or cleared devices or methods that FDA has determined to be adequate to assure that the risks of bacterial contamination of platelets are adequately controlled.

Transfusion services are manufacturers that release platelet components for transfusion to an identified recipient but do not routinely collect blood and blood components. Under this rule, transfusion services may rely on the steps taken by the blood collection establishment to assure that the risks of bacterial contamination of a platelet component are controlled, as long as those methods adequately control risks from the growth of bacteria until the transfusion service releases the product for transfusion. If the collection establishment did not take steps to control the risk of bacterial contamination, then the transfusion service must do so. We note that collection establishments currently take steps to control the risk of bacterial contamination in most platelet components, and expect that transfusion services will have to take steps to control the risk of bacterial contamination only for limited numbers and types of platelet components. For example, a transfusion service may intend to release for transfusion a platelet component derived from a single unit of whole blood. Collection

establishments do not typically subject such components to testing by culture-based methods, in part because the volume of the sample required for currently available culture tests would significantly deplete the volume of the component. For such platelet components, § 606.145 would require the transfusion service to take steps, such as the performance of an FDA-cleared rapid test, to assure that the risk of bacterial contamination is adequately controlled.

In the proposed rule (72 FR 63416 at 63421), FDA asked for comments on the following additional points related to testing for bacterial contamination: (1) Whether to require the identification of the species of the bacterial contaminant; (2) whether to require donor deferral and notification when identification of the contaminant indicates possible endogenous bacteremia, and not contamination during collection and processing; and (3) whether to extend bacterial testing requirements to other transfusable blood components. We discuss the first issue at comments 18 through 21, and the second issue at comments 103 through 106, related to §§ 630.30 and 630.40. With respect to the third issue, as discussed at comment 24, we have decided not to codify a requirement for bacterial testing of other blood components in this rule.

(Comment 13) One comment supported requirements for bacterial testing of platelets prior to transfusion in order to reduce the risk of post-transfusion infection, sepsis, or mortality.

(Response) We appreciate this support for bacterial testing of platelets.

(Comment 14) Several comments opposed a requirement to obtain a negative test result prior to determining a platelet donation to be suitable. Two comments noted that this standard is difficult to apply when a culture-based method is used. The comments stated that in current practice, cultured platelets are released as negative-to-date while incubation is continued. The comments asked FDA not to finalize the proposed requirement.

(Response) We agree that the proposed requirement that platelets be ''tested for bacterial contamination and found negative'' may have been too prescriptive. Accordingly, § 606.145(a) requires manufacturers to assure that the risks of bacterial contamination of platelets are adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA. This could permit release on the basis of an adequate culture test method that is ''negative-to-date'' on the date of release, even if the establishment continues to incubate the culture. In some circumstances, the culture may later indicate the presence of bacteria in a platelet component that was appropriately released as ''negative-to-date''. In that event, the establishment would initiate appropriate action under 21 CFR 606.100(c) and part 7, which may include notifying consignees and retrieving transfusable blood components prepared from that collection.

(Comment 15) Some comments expressed concern that the testing requirement in this provision would be difficult for blood centers to implement because there are currently no cleared or approved release tests for bacterial testing of platelet products. One of the two cleared quality control tests does not report a single negative result, only a negative-to-date reading. The comment recommended that FDA not finalize these requirements and, instead, provide separate guidance after FDA approves a release test to identify bacteria in platelets.

(Response) We decline to delay establishing a requirement that establishments assure that the risk of bacterial contamination of platelets is adequately controlled. Some manufacturers have been conducting bacterial testing on platelet components for over a decade. We note that the College of American Pathologists has established bacterial testing of platelets as an accreditation standard (Ref. 16). In March 2004, AABB established an accreditation standard requiring accredited blood banks and transfusion services to have methods to limit and detect bacterial contamination in all platelet components (Ref. 17). We have modified the language in the proposed rule so that we require manufacturers to assure that the risks of bacterial contamination of platelets are controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA. We intend to issue guidance addressing the use of methods that FDA has determined to be acceptable for this purpose.

(Comment 16) One comment asserted that a requirement for negative test results could become outdated. Methods for bacterial testing continue to evolve and the possibility exists that a pathogen reduction procedure will obviate the need for bacterial screening.

(Response) We recognize that, as technology develops, new methods, including pathogen reduction, may become adequate to satisfy the requirements in § 606.145(a), and may replace testing. We anticipate that, in the future, we will recognize such developments by updating our guidance on the methods that would meet the requirements of § 606.145(a).

(Comment 17) One comment requests that the Agency add a requirement that bacterial contamination testing be performed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) (CLIA) to perform the testing. The comment asserts that the CLIA requirements complement FDA requirements and lead to higher quality laboratory testing.

(Response) We appreciate the comment. However, we note that final § 606.145(a) requires manufacturers to ''assure that the risks of bacterial contamination of platelets are adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA.'' In the future, technology may develop adequate methods that do not include testing, instead incorporating, for example, pathogen reduction technology. Under these circumstances, laboratory testing may no longer be necessary to assure platelet safety from bacterial contamination. For this reason, we are not specifying a specific requirement to ''test'' in the final rule, and do not require that ''tests'' be performed in a laboratory certified under CLIA.

(Comment 18) One comment observed that bacterial speciation may be viewed as an important part of an investigation of a failed product quality control test. Species identification assists in isolating the source of the contamination, such as when the species is associated with environmental contamination, skin flora, or is an enteric organism. Furthermore, species identification permits appropriate investigation and donor counseling to take place. The comment noted that the identification of certain skin bacteria may raise questions about adequate performance of skin preparation procedures, and may support further examination of the donor's antecubital areas for scarring and pitting at the donor's next donation. The identification of enteric organisms such as *Streptococcus bovis* may be an indication of an underlying illness in the donor.

(Response) We agree with these observations. Bacteria may be introduced into a platelet component by means that do not indicate any illness in the donor, such as passage of the collection needle through the donor's non-sterile skin, or other environmental factors. However, in rare cases, the presence of bacteria is due to its

endogenous presence in the donor's bloodstream. This can reveal a serious illness in the donor (Ref. 18). For example, the presence of *Streptococcus bovis* in the blood is associated with colonic pathology, including malignancy (Refs. 18, 19). Speciation of bacteria can provide information valuable to the processing establishment about deficiencies in platelet collection and processing methods, and may provide information that may be important to the donor's health. To assure blood safety, final § 606.145(b) requires that, in the event that a blood collection establishment identifies platelets as bacterially contaminated, that establishment may not release for transfusion the platelets or any other component prepared from the same collection, and must take appropriate steps to identify the organism. Final § 606.145(c) requires that, in the event that a transfusion service identifies platelets as bacterially contaminated, the transfusion service must not release the platelets, and must notify the blood collection establishment that provided the platelets. The transfusion service must take appropriate steps to identify the organism; these steps may include contracting with the collection establishment or a laboratory to identify the organism. The transfusion service must further notify the blood collection establishment either by providing information about the species of the contaminating organism when the transfusion service has been able to identify it, or by advising the blood collection establishment when the transfusion service has determined that the species cannot be identified. Final § 606.145(d) provides that in the event that a contaminating organism is identified under § 606.145(b) or (c), the responsible physician for the collection establishment must determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, in accordance with a standard operating procedure developed under § 606.100(b)(22). This determination may not be further delegated.

Finally, we note that requirements to take appropriate steps to identify contaminating organisms apply only when bacterial contamination is found. In the event that approved or cleared devices or other methods that employ pathogen reduction technology, rather than relying on identifying contamination, are determined to be adequate and appropriate, the use of such technologies may eventually limit the situations where establishments would need to identify the presence of contaminating bacteria. If fewer instances of contamination are identified due to widespread use of pathogen reduction technologies, the instances where establishments are required to identify the contaminating organisms would also be reduced in number.

(Comment 19) Several comments stated that they consider the decision whether to identify the species of the bacterial contaminant to fall within the purview of the collection facility's medical director. Some stated that the standard of care already includes speciation of isolated bacteria and donor notification when felt to be medically appropriate, and regulation is not required in this area. One comment stated that, consistent with the College of American Pathologists and AABB accreditation standards, blood establishments should have a defined policy for how to investigate and handle bacterial contamination. However, this policy represents medical decision making that should not be addressed in regulation.

(Response) Current good manufacturing practices applicable to the manufacture of drugs, including transfusable platelet components, already require a manufacturer to thoroughly investigate the failure of a batch or any of its components to meet any of its specifications (21 CFR 211.192). Identifying the species of contaminating bacteria can provide information concerning the likely pathway that permitted the bacteria to enter the contaminated component. That information may then permit a manufacturer to determine whether, and how, a deficient manufacturing practice (for example, poor arm preparation, non-sterile docking, or contamination of the collection container) allowed the contamination to occur. Such a determination could enable the manufacturer to take appropriate corrective actions, which may include, for example, additional training of personnel. Because speciation of bacteria provides information that is important to a manufacturer's investigation of the failure of a platelet component to be free of bacteria, a decision concerning whether or not to identify the species of contaminating bacteria is not solely for the medical director to make. Instead, it falls within the province of production and process controls. For this reason, we have included in § 606.145 an explicit current good manufacturing practice requirement for manufacturers to take appropriate steps to identify the organism. In addition, in the event that the contaminating organism is identified, § 606.145(d) requires the responsible physician for the collection establishment to determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, in accordance with a standard operating procedure developed under § 606.100(b)(22).

(Comment 20) Some comments noted that FDA did not provide a definition of an endogenous bacterial infection, and stated that they are not aware of any bright line dividing an endogenous bacteremia from contamination, since the organisms involved overlap significantly.

(Response) The proposed rule referenced ''endogenous'' bacteria in proposed § 630.40(a), which would have required notification of a donor ''whose platelet component has tested positive for an endogenous bacterial contamination.'' In § 606.145(d), we now require the responsible physician for the collection establishment to determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, in accordance with a standard operating procedure. Examples of contaminating organisms that the responsible physician, based on his or her medical judgment, may determine to be likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor include *Streptococcus bovis, Streptococcus veridins,* and *Salmonella.* We require the responsible physician to make this determination in accordance with a standard operating procedure.

(Comment 21) Another comment stated that FDA should not require testing for a contaminating organism until the Agency approves a test specifically for that purpose. The comment supported the introduction of bacterial screening when assays become available that are accurate, rapid, and economically feasible.

(Response) We believe that, consistent with current standards of the College of American Pathologists and AABB, a majority of collection establishments are currently using bacterial detection methods such as culture to identify the contaminating organism. Section 606.145(b) and (c) require that blood collection establishments and transfusion centers take appropriate steps to identify the organism. To satisfy this requirement, an establishment would use adequate and currently available technologies, which may include appropriate culture methods. As we noted in our response to comment 15, we intend to issue guidance

addressing how establishments would use FDA approved or cleared devices or methods that FDA has determined to be adequate to assure that the risks of bacterial contamination of platelets are adequately controlled.

(Comment 22) Some comments noted that, when a transfusion service pools platelets separated from Whole Blood with other units of Whole Blood-derived platelets immediately before releasing the pooled platelet component for transfusion, there is not enough time to use culture methods to assess the pooled unit for bacterial contamination. The comments stated that the proposed rulemaking would, as a practical matter, prohibit the use of components prepared from platelets separated from Whole Blood and then pooled immediately prior to transfusion. The comments further stated that while systems exist that allow Whole Blood-derived platelets to be pooled by a collection facility before storage and tested for bacteria using culture-based methods, these systems are not used by most collection facility component laboratories.

(Response) We disagree that the requirements in final § 606.145 will prohibit the use of platelet components prepared at the transfusion service by pooling units of Whole Blood-derived platelets, and note that practices have evolved since the comment raised these objections. Since the proposed rule published, FDA has cleared rapid bacterial detection devices that detect bacteria in platelets. These devices do not use culture-based methods, and provide a result in less than 1 hour. The transfusion service may use such devices to control the risks of bacterial contamination before releasing a pooled platelet unit for transfusion. We also note that pre-storage pooling has become the prevailing practice for platelet units derived from Whole Blood. Based on data presented at the July 2012 AABB Workshop (Ref. 20), currently about 65 percent of Whole Blood-derived platelets are cultured by collection establishments as pre-stored pools. About 35 percent of those platelet components are tested as pools constituted within 4 hours prior to transfusion using an FDA-cleared rapid test (Ref. 20).

(Comment 23) Some comments stated that the standards requiring testing for platelet contamination, such as those of AABB, do not currently apply to Whole Blood-derived platelets. Transfusion services may not subject the platelet components they pool to bacterial testing, and instead use, at the time of release for transfusion, surrogate methods such as pH meters, to assess whether bacterial contamination is likely.

(Response) Testing using surrogate methods such as pH meters is inadequate to determine whether platelets are bacterially contaminated. Studies have shown that pH does not constitute an adequate surrogate marker for bacterial contamination in platelets, and has poor sensitivity and poor positive predictive value (Ref. 13). Other FDA cleared devices, including rapid tests, are available for use by a transfusion service to identify the presence of bacterial contamination. The use of such devices can help assure the safety of the platelet component, and protect the recipient from bacterial infections. Accordingly, final § 606.145(a) requires blood collection establishments and transfusion services to assure that the risks of bacterial contamination of platelets are adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA.

(Comment 24) Some comments stated that it is not appropriate to extend requirements addressing bacterial contamination of platelets to the manufacture of other transfusable blood components. They note that the rate of reported septic reactions to Red Blood Cells and plasma products is very low, and methods to identify bacterial contamination in these products are not well developed. Furthermore, there appears to be little rationale for requiring bacterial testing of blood products that, unlike platelets, are stored at cold temperatures that do not promote bacterial growth.

(Response) We agree that transfusable blood components other than platelets are stored at cold temperatures that do not promote bacterial growth, and that the rate of septic reactions to these products is very low. The final rule includes requirements specific to bacterial contamination of platelet components, and also provides that, in the event that a blood collection establishment or transfusion service identifies platelets as bacterially contaminated, that establishment must not release the product or any other component prepared from the same collection. In the event of technological changes, or significant evidence that transfusion recipients are at greater risk from bacterial contamination of Red Blood Cell and Plasma products than is presently considered to exist, we will consider again whether additional requirements specific to blood components other than platelets are necessary.

E. Records (§ 606.160)

The final rule makes the conforming changes described in proposed § 606.160(b)(1)(ix) and (xi), now identified as § 606.160(b)(1)(x) and (xi). These changes relate to the move of the donor notification provisions from § 630.6 to § 630.40. Current § 606.160(b)(1)(x) is redesignated as § 606.160(b)(1)(ix). We also inserted the word ''postal'' before the word ''address'' in the current requirement, so that the recordkeeping requirement would closely track the requirement in final § 630.10(g)(1) to obtain a ''postal address.''

In response to comments, we have significantly narrowed the requirements we proposed in § 606.160(e). We have not finalized a requirement to share a record of all ineligible donors with appropriate personnel at all locations operating under the same license or under common management. Instead, final § 606.160(e)(1) requires establishments to maintain at each location a record of all donors found to be ineligible or deferred at that location, so that blood and blood components from such individuals are not collected or distributed while they are ineligible or deferred. This provision is related to current § 606.160(e), which requires that ''A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.'' Final § 606.160(e)(2) through (4) requires establishments to maintain a cumulative record of donors deferred from donation under § 610.41 based on their reactive tests for evidence of infection due to HIV, HBV, or HCV. In addition, establishments other than Source Plasma establishments must include in this cumulative record donors deferred from donation for evidence of infection due to HTLV or Chagas disease. Establishments must maintain the cumulative record of deferred donors at all locations operating under the same license or under common management, must update the cumulative record at least monthly, and revise the cumulative record for donors who are requalified under § 610.41(b). Final § 630.10(d) sets out requirements for establishments to consult the cumulative record of deferred donors before collection, or if pre-collection review is not feasible, before release of any blood or blood component prepared from the collection.

(Comment 25) We received several comments objecting to the scope of donor deferrals that would be included in the list of ineligible donors described in the proposed rule.

(Response) We agree that the types of donor deferrals that were proposed to trigger inclusion in the list of ineligible donors were broad, and that requiring extensive deferral records to be updated and consulted at the donation site before collection could be unduly burdensome. The final rule requires establishments to enter into the cumulative list only those donors who were deferred under § 610.41 due to reactive test results for HIV, HBV, or HCV, as well as HTLV or Chagas disease for donors other than Source Plasma donors.

(Comment 26) We received several comments objecting to a requirement for a common donor deferral registry to be used by all donor screening locations operating under a single operating license or common management. Some expressed concern that it would be technologically difficult to make this information available to all locations under a single operating license or under common management.

(Response) Under the final rule establishments must enter into the cumulative list only those donors who were deferred under § 610.41 due to reactive screening test results for HIV, HBV, or HCV, as well as HTLV or Chagas disease for donors other than Source Plasma donors. We believe that it is a current industry practice to maintain such lists (Refs. 21, 22). In the final rule, we have significantly narrowed the scope of information subject to this requirement in a manner that is consistent with this industry practice, and to reduce the technological challenges of making reliable information available.

We disagree with the suggestion that it is technologically difficult for facilities operating under a single license, or under common management, to make this more limited cumulative record of deferred donors available at collection sites for consultation by all facilities operating under a single operating license or under common management. The cumulative record is now required to list only a subset of deferred donors, who are identified by very specific and objective criteria. This information may be made available by providing a copy of the cumulative record of deferred donors at each collection site. Establishments may also comply with this requirement by providing for a pre-collection query of a centrally maintained cumulative record of deferred donors. In the event that pre-collection review is not feasible, § 630.10(d)(1) requires establishments to consult the cumulative record prior to release of any blood or blood component prepared from the collection.

(Comment 27) In the preamble to the proposed rule we also solicited comments on the feasibility of sharing donor deferral lists among licensed and registered establishments. Such shared lists are known as national donor deferral registries, and are already in use among establishments collecting Source Plasma. We received several comments opposing a requirement for a national donor deferral registry. Some described national donor deferral registries as unnecessary or burdensome. One comment emphasized differences between Source Plasma and collections of Whole Blood and other blood components, and stated that the Source Plasma donor deferral registry would be a poor model for other collection establishments. The comment cited technical limitations such as computer down times and connectivity from remote locations, and stated that the creation of a national donor deferral system for whole blood donors would be burdensome and time-consuming.

(Response) As noted, it is currently the practice of most Source Plasma collection establishments to determine whether a donor is permanently deferred because the donor tested reactive for HIV, HBV, or HCV by accessing a shared list of deferred donors called the National Donor Deferral Registry (NDDR). We recognize that the NDDR is a voluntary, self-regulating initiative by the Source Plasma collection industry that is operated by a third party administrator. We agree it is an important industry practice to ensure the safety of plasma-derived therapies. Moreover, we are aware that, to increase efficiency and to protect donor confidentiality and proprietary information across non-affiliated Source Plasma establishments, information entered into the NDDR is coded as to infectious disease test result. This rule is not intended to interfere with that practice. We believe that the current NDDR goes beyond the requirements in the final rule, since it is a national list of donors deferred by multiple licensed establishments (Ref. 23). For Source Plasma establishments, we believe that participation in the NDDR would meet the requirements under this section. If a Source Plasma establishment does not participate in the NDDR, the establishment must establish its own cumulative record of deferred donors with all other establishments operating under common management or a single license, as required under this section.

We are not requiring blood collection establishments to share donor deferral information in a national donor deferral registry.

(Comment 28) In the preamble of the proposed rule (72 FR 63416 at 63420), we stated that we were considering whether to include, in the final rule, a provision requiring that the donor deferral records be used and disclosed only for purposes consistent with subchapter F of 21 CFR Chapter I. One comment expressed concern about the importance of protecting donor information. Another comment explained why additional protections are not needed. For example, the NDDR used by Source Plasma collectors is never available in its entirety to its users. When an NDDR check is performed, the database is queried to determine whether a record for the potential donor is present. If a record is present, the establishment performing the check is informed that a record exists. No other information is shared. One comment stated confidentiality of information is of extraordinary importance to the industry. The comment stated that each company uses its own best methods for handling confidential information consistent with its operational policies and procedures in submitting relevant information to the NDDR. One comment stated that in their current system, unique donor identifiers such as social security numbers are not available.

(Response) As we discussed earlier in this section, we are not requiring establishments to participate in a national donor deferral registry system, and we are not requiring the sharing of information outside a single license or outside common management.

F. Test Requirements (§§ 610.40, 640.5, 640.71(a))

We have modified proposed § 610.40(a), (b), and (e) in order to address concerns that the proposed rule did not permit an adequately flexible approach to donor testing. Although the testing for HIV, HBV, HCV, and HTLV that is required under current § 610.40(a) would continue under the new rule, we have also provided additional flexibility for FDA to permit testing less frequently than at every donation, or as appropriate, to stop testing, for relevant transfusion-transmitted infections other than HIV, HBV, and HCV, provided that the practices are supported by evidence related to the risk of transmission of such infection, such as epidemiological data and developments in risk reduction technology. In § 610.40(a), we have clarified requirements for Chagas disease and West Nile virus testing and have continued the existing requirement

to test donations for evidence of syphilis. We have also provided requirements for testing for infectious agents that may be identified in the future as relevant transfusion-transmitted infections, in the event that testing becomes necessary to ensure blood safety.

Final § 610.40(b) clarifies that the tests performed to comply with § 610.40(a) must be ''licensed, approved, or cleared screening tests''; current § 610.40(b) refers only to ''approved screening tests''. We made this change because § 610.40(b) is now applicable to syphilis testing, and syphilis screening tests are generally ''cleared,'' and not licensed or approved.

The final rule contains a different heading for § 610.40(c). Instead of ''Exceptions to testing for allogeneic transfusion or further manufacturing use,'' which is used in current § 610.40(c), the heading is now ''Exceptions to testing for dedicated donations, medical devices, and samples.'' We made this change because the exception from testing for HTLV is now addressed in § 610.40(a)(2)(ii) and (iii), and we are removing the exception for HTLV now found in current § 610.40(c)(2). Since § 610.40(c) no longer addresses Source Plasma (the most commonly identifiable blood component collected for further manufacturing use) the new heading is more accurate.

In § 610.40(e), we are maintaining the existing requirement for further testing when a donation tests reactive for a relevant transfusion-transmitted infection. When a licensed, approved, or cleared supplemental test is not available, the rule provides greater flexibility to allow the use of licensed, approved, or cleared tests, as adequate and appropriate to determine the reactive donor's infection status. We address further testing for donations reactive for syphilis in § 610.40(e)(2).

Under the proposed rule, existing testing practices for HIV, HBV, HCV, and HTLV would continue. In addition, we proposed that, when a test for the disease or disease agent is approved or cleared for donor screening and FDA determines that testing is necessary to reduce the risk of transmission of the relevant transfusion-transmitted infection by the blood or blood component, blood collection establishments would be required to test for CJD, vCJD, and malaria, which were identified as relevant transfusion-transmitted infections in proposed § 630.3(g)(1)(vi) through (viii). We further proposed that, when the conditions concerning the availability and necessity of testing were met, establishments would be required to test for other relevant transfusion-transmitted infections meeting the standard in proposed § 630.3(g)(2).

We also solicited comments with supporting data on whether to discontinue the requirement for testing for syphilis, and we indicated that we might drop the requirement for syphilis testing if sufficient data were submitted (72 FR 63416 at 63422). We stated that testing for a relevant transfusion-transmitted infection may not be required if viral inactivation or removal procedures have been validated to ensure inactivation or removal of the infectious agent and screening for risk factors is available, unless the risk of harm from transmission is too great to rely solely on viral inactivation procedures and screening for risk factors. We are finalizing this provision using the concepts proposed, but have provided greater flexibility to permit establishments to stop testing, or vary testing frequency, when the evidence shows testing each donation intended for transfusion is no longer necessary to reduce the risk of transmission of the relevant transfusion-transmitted infection by the blood or blood component. Such changes must be made in accordance with procedures found acceptable for this purpose by FDA. We have retained requirements for syphilis testing of blood and blood components for transfusion, since we did not receive data sufficient to support their elimination. However, if such evidence is developed in the future, the rule would allow establishments to change their testing practices in accordance with procedures found acceptable for this purpose by FDA. We have removed existing § 610.40(i), which required testing for syphilis, and address testing transfusable blood and blood components for syphilis in § 610.40(a). To reflect this new citation for the syphilis testing requirement, we made conforming changes to §§ 610.40(d), (g), (h)(1), (h)(2)(vi), and (h)(2)(vii), 610.41 and 610.42.

Current § 640.5 provides additional standards for testing Whole Blood. We did not propose changes to § 640.5 in the proposed rule. However, based on comments received and discussed at comment 29, we recognize that greater flexibility in testing schedules may be appropriate, and that it may be adequate and appropriate to test donors for certain relevant transfusion-transmitted infections less frequently than at every donation, or while observing geographic or seasonal limitations. Accordingly, we are making a related change to the introductory paragraph of § 640.5, which currently provides ''All laboratory tests shall be made on a specimen of blood taken from the donor at the time of collecting the unit of blood, and these tests shall include the following.'' Because it may be appropriate to perform testing other than on each collection, we are modifying this to state ''All laboratory tests shall be made on a specimen of blood taken from the donor, and these tests shall include the following.''

We are also making one other minor conforming change, removing current § 640.5(a) which requires ''Whole Blood shall be negative to a serological test for syphilis.'' This provision is duplicative of the requirement to test for syphilis in new § 610.40(a)(2), and to avoid confusion we are deleting § 640.5(a).

For similar reasons, we are amending the provisions of current § 640.71(a) which specify certain donor screening tests related to Source Plasma. We are removing the phrase ''the following tests'' and adding in its place ''testing performed in accordance with § 610.40 of this chapter and § 640.65(b)'' and we are removing the list of tests set out in current § 640.71(a)(1) through(4). We are making these changes so that § 640.71(a) will conform to final § 610.40.

1. Section 610.40(a)

Final § 610.40(a) addresses testing for the infectious agents already required under current § 610.40(a), and now identified in § 630.3(h)(1) as relevant transfusion-transmitted infections. We continue to require testing of each donation for evidence of infection due to HIV; HBV; and HCV. We also continue to require testing of each donation, except Source Plasma, for evidence of infection due to HTLV and syphilis. We are adding a requirement to test donations, except Source Plasma, for West Nile virus and Chagas disease.

As in the existing regulations, testing requirements for certain relevant transfusion-transmitted infections vary for Source Plasma. For example, we have concluded that, in the absence of testing, the risk of HTLV, a highly cell-associated pathogen, is sufficiently mitigated by plasma derivative manufacturing steps, including validated viral inactivation and removal procedures. These manufacturing procedures therefore obviate the need to test individual donations of Source Plasma for HTLV. We have further determined that these manufacturing procedures obviate the need to test individual donations of Source Plasma for West Nile virus and Chagas disease. Testing of Source Plasma donors for syphilis must be performed every 4 months in accordance with § 640.65(b).

The final rule allows for the possibility that, in the future, evidence related to the risk of transmission of HTLV, syphilis, West Nile virus, and Chagas disease could support the conclusion that testing of each donation is no longer necessary to reduce adequately and appropriately the risk of transmission of that relevant transfusion-transmitted infection by the blood or blood component. Under final § 610.40(a)(2)(iii)(A), if testing each donation is not necessary to reduce adequately and appropriately the risk of transmission of a relevant transfusion-transmitted infection, an establishment may adopt an adequate and appropriate alternative testing procedure that has been found acceptable for this purpose by FDA. Section 610.40(a)(4) makes clear that an assessment that testing each donation is not necessary could be based on, for example, changing science, or epidemiological or other scientific data. It may also include evidence related to seasonal or regional variations in the activity of the relevant transfusion-transmitted infection. Under final § 610.40(a)(2)(iii)(A), following an assessment that testing each donation is not necessary, establishments may adopt alternative procedures that have been found acceptable for this purpose by FDA such as initial or periodic testing of donations from the same donor due to the epidemiology of the relevant transfusion-transmitted infection.

An example of such an alternative testing paradigm is FDA's current recommendation contained in guidance for one-time testing of a donor for Chagas disease, instead of testing the donor at each donation (Ref. 24). FDA made this recommendation after reviewing comments to the draft guidance and consulting with the Blood Products Advisory Committee (April 2009) (Ref. 25). Consistent with § 610.40(a)(2)(iii)(A), we continue to recognize this testing practice as an acceptable alternative testing paradigm for Chagas disease. In the future, new epidemiologic or other scientific data could demonstrate that a different testing paradigm, including testing of the donor at each donation, is needed to adequately and appropriately reduce the risk of transmission of Chagas disease.

This rule also provides that establishments may stop testing blood and blood components for HTLV, syphilis, West Nile virus, or Chagas disease in the event that such testing is no longer necessary. Section 610.40(a)(2)(iii)(B) authorizes such an action taken in accordance with procedures found acceptable for this purpose by FDA, when testing is no longer necessary to reduce adequately and appropriately the risk of transmission of such infection by blood or a blood component, based on evidence related to the risk of transmission of that relevant transfusion-transmitted infection. Section 610.40(a)(4) describes the evidence that would support such a finding, such as a change in the epidemiology of the relevant transfusion-transmitted infection, or the implementation of pathogen reduction technology. We note that the rule does not require establishments to test donors of Source Plasma for these relevant transfusion-transmitted infections because of reduced risk of transmission by fractionated products manufactured from Source Plasma.

We recognize that there are no donor screening tests currently licensed, approved, or cleared for the following relevant transfusion-transmitted infections identified in § 610.40(a)(3): CJD, vCJD, or malaria. In the event that a donor screening test is licensed, approved or cleared for one of these infections, the rule would require the use of the test, if testing is necessary to reduce adequately and appropriately the risk of transmission of that relevant transfusion-transmitted infection.

Similarly, FDA has not yet identified any relevant transfusion-transmitted infections under the criteria in § 630.3(h)(2). In the future, if a transfusion-transmitted infection is identified by FDA to meet the criteria for a relevant transfusion-transmitted infection under § 630.3(h)(2), and FDA has licensed, approved or cleared a donor screening test, FDA may seek advice from the Blood Products Advisory Committee on the use of the donor screening test, and seek public comment by issuing guidance in accordance with good guidance practices. When a transfusion-transmitted infection has met both the standards under final § 630.3(h)(2) and § 610.40(a)(3), such that it now meets the criteria for a relevant transfusion-transmitted infection and testing is necessary to reduce adequately and appropriately the risk of transmission of that relevant transfusion-transmitted infection, use of the test would be required. When testing for a particular relevant transfusion-transmitted infection become necessary under final § 610.40(a)(2) or (a)(3), FDA intends to enforce the testing requirements under this regulation only after issuing a final guidance advising establishments and the public of the Agency's assessment of the applicable criteria.

Should testing become necessary to reduce adequately and appropriately the risk of transmission of a relevant transfusion-transmitted infection under § 610.40(a)(3), FDA will also consider the application of § 610.40(a)(3)(ii)(A), which we drafted to parallel § 610.40(a)(2)(iii)(A). Under this provision, if testing each donation is no longer necessary to reduce adequately and appropriately the risk of transmission of a relevant transfusion-transmitted infection, an establishment may adopt an adequate and appropriate alternative testing procedure that has been found acceptable for this purpose by FDA. Under § 610.40(a)(4), such methods may address seasonal or regional variations in the activity of the relevant transfusion-transmitted infection, or where, due to the epidemiology of the relevant transfusion-transmitted infection, initial or periodic testing of donations from the same donor (instead of testing each donation) would be sufficient. In the event that the standard set forth in § 610.40(a)(3)(ii)(A) and (a)(4) is met, FDA intends to reassess the applicability of alternative testing procedures, and if needed, seek advice from the Blood Products Advisory Committee and issue new guidance in accordance with good guidance practices. Similarly, § 610.40(a)(3)(ii)(B), which we drafted to parallel § 610.40(a)(2)(iii)(B), recognizes that, at some later point in time, if evidence related to the risk of transmission of such infection supports a determination that testing is no longer necessary to adequately and appropriately reduce the risk of transmission of that relevant transfusion-transmitted infection. When testing is not necessary, establishments may stop such testing in accordance with procedures found acceptable for this purpose by FDA. Sections 610.40(a)(3)(ii)(A) and (a)(3)(ii)(B) provide mechanisms for tailoring testing requirements to more accurately address the risks presented by a relevant transfusion-transmitted infection, while assuring that blood establishments perform adequate and appropriate testing of blood donations.

We recognize that greater flexibility in testing schedules may be appropriate, and have incorporated these changes into this final rule. Accordingly, we are making a related change to the introductory paragraph of § 640.5, which currently provides ''All laboratory tests shall be made on a specimen of blood taken from the donor at the time of collecting the unit of blood, and these tests shall include the following.'' Because it may be appropriate to perform testing other than on each collection, we are

modifying this to state ''All laboratory tests shall be made on a specimen of blood taken from the donor, and these tests shall include the following.''

(Comment 29) One comment supported a requirement to test for relevant transfusion-transmitted infections that meet the definition under proposed § 630.3(g)(2), when such testing is available and is necessary to reduce the risk of transmission of the relevant transfusion-transmitted infection by the blood or blood component, because of the need to identify and respond to current and future agents.

(Response) We agree with this comment. We have drafted final § 610.40(a)(3) to provide a framework for applying the rule's testing provisions to infectious agents that may, in the future, meet the standard for relevant transfusion-transmitted infection, as defined in final § 630.3(h)(2). For example, under § 630.3(h)(2), a transfusion-transmitted infection such as babesia or dengue virus may meet the definition of a relevant transfusion-transmitted infection if the disease or disease agent meets criteria for incidence and/or prevalence or may have been accidentally or intentionally released, and if appropriate screening measures have been developed and/or an appropriate screening test has been licensed, approved, or cleared for such use and is available. In the event that such a test has been licensed, cleared, or approved, its use would be required under this section when necessary to reduce the risk of transmission of the relevant transfusion-transmitted infection. Whether testing is necessary would depend on all the relevant circumstances, including, for example, whether screening for travel history or another risk factor would, by itself, adequately reduce the risk of transmission. FDA intends to seek advice on relevant scientific issues from the Blood Products Advisory Committee as appropriate.

(Comment 30) One comment suggested that testing be required for West Nile virus, Chagas disease, and bacteria because testing for those agents is currently conducted.

(Response) We agree that establishments should be required to conduct testing for West Nile virus and Chagas disease for blood and blood components for transfusion. Under the proposed rule, these infectious agents would have been evaluated under the standards for relevant transfusion-transmitted infection in proposed § 630.3(g)(2). To provide greater clarity on this regulation, we have specified these diseases by name in the definition of relevant transfusion-transmitted infection at § 630.3(h)(1)(vi) and (vii), and testing for these agents is addressed in § 610.40(a)(2). We recognize that bacterial contamination of platelets presents significant issues related to the safety, purity, and potency of platelets. We have addressed the risk presented by bacterial contamination of platelets in §§ 606.145 (see comments 13 through 24), 630.30 (see comments 103 through 106), and 630.40 (see comment 107). We address bacterial contamination of blood components other than platelets in response to comment 24.

(Comment 31) Several comments stated that FDA should not require that blood donors be tested for syphilis. One comment recommended that testing for syphilis continue to be required, but for public health reasons, rather than for its value in protecting blood safety.

(Response) We are continuing to require testing for syphilis at this time. We note that in the proposed rule, FDA requested information on the value of testing for syphilis as a marker of increased risk behavior, as a surrogate test for other infectious diseases, and in preventing the transmission of syphilis through blood transfusion. We stated that if we received adequate data, FDA would eliminate or modify this testing requirement in the final rule. This was the second time we invited the submission of such data; we also invited it in an earlier proposed rule, ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (64 FR 45340, August 19, 1999). Syphilis testing was discussed at the September 2000 Blood Products Advisory Committee meeting and studies that might help determine that such testing would no longer be needed were identified (Ref. 26). We have not received adequate scientific data in response to our solicitations.

However, the final rule recognizes the possibility of discontinuing the requirement for syphilis testing of blood and blood components intended for transfusion. We have moved this requirement from § 610.40(i) to § 610.40(a). The more flexible framework found in § 610.40(a)(2)(iii) provides a mechanism under which an establishment could stop testing for syphilis or adopt different testing frequency, provided that evidence related to the risk of transmission demonstrates that testing of each donation is no longer necessary to reduce adequately and appropriately the risk of transmission of syphilis, and provided that the change is made in accordance with procedures found acceptable for this purpose by FDA. In the event that the evidence supports such a determination under § 610.40(a)(2)(iii)(B), FDA intends to issue guidance recognizing procedures for ending syphilis testing of blood and blood components for transfusion.

(Comment 32) Another comment asserted that current syphilis testing practices are deficient, since many confirmed positives are in fact false positives.

(Response) We recognize that syphilis screening tests, like other screening tests, may yield false positive results on some donations. However, § 610.40(h)(2)(vi) permits the use of blood and blood components that test reactive for syphilis if the donation is further tested by an adequate and appropriate test which demonstrates that the reactive screening test is a biologic false-positive. In addition, consistent with the current regulation, the final rule permits the reentry of positive donors who have been successfully requalified under § 610.41(b).

(Comment 33) Several comments stated that testing for CJD and vCJD should not be required.

(Response) There are no currently licensed, approved, or cleared donor screening tests for these agents. If and when donor screening tests for CJD or vCJD become available, testing would be required under this provision only if testing was necessary to adequately and appropriately reduce the risk of transmission of CJD or vCJD, taking into account the risks presented by donated blood and blood components.

(Comment 34) One comment stated that the use of the defined term relevant transfusion-transmitted infection in the proposed rule (§ 630.3(g)) in § 610.40(a) would require testing for agents such as cytomegalovirus (CMV), even though screening of all donors for CMV is not currently thought to be necessary.

(Response) We agree that, currently, it is not necessary to test all donors for CMV. For this reason, donor screening testing for CMV is not now required under § 610.40 of the final rule, which in § 610.40(b) requires testing only ''as *necessary* to reduce adequately and appropriately the risk of transmission'' (emphasis added).

2. Section 610.40(e)

In this section, FDA is maintaining the requirement for further testing when a donation tests reactive for a relevant transfusion-transmitted infection. Consistent with the existing regulation and the proposed rule, establishments must perform further testing using an approved supplemental test when one is available. However, the final rule now

recognizes that supplemental tests may be licensed, approved, or cleared. We eliminated the term ''additional'' as unnecessary. When a supplemental test is not available, the final rule requires the use of other tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status. This language provides greater clarity concerning the purpose of further testing. Under this paradigm, if an approved supplemental test was not available, or became unavailable, an establishment would conduct further testing using, for example, an alternative algorithm to provide additional information to the establishment concerning the donor's infection status. For example, a testing algorithm that was adequate and appropriate to determine the reactive donor's infection status might include the use of multiple approved donor screening tests. We intend to issue guidance on these issues as needed.

Section 610.40(e)(2) requires establishments to perform further testing when a donation is reactive by a non-treponemal donor screening test for syphilis. Previously, we did not require establishments to perform any supplemental testing after a reactive test for syphilis. However, further testing may help to rule out syphilis infection. Additionally, a reactive test result on a non-treponemal syphilis test may be a biologic false-positive result, which may potentially be indicative of a serious illness in the donor, such as lupus erythematosus (Ref. 27). In this setting, further testing will provide important information for donor notification, including information that is appropriate for medical follow up and counseling under § 630.40(b)(4). Blood establishments must perform further testing using a licensed, cleared, or approved supplemental test for syphilis, when available. When no such supplemental test is available, FDA would consider the use of a licensed, approved, or cleared treponemal test to be adequate and appropriate to provide additional information concerning the donor's infection status. Establishments are not required to perform further testing of a donation found to be reactive by a treponemal donor screening test for syphilis, since those tests do not present similar risks of a biological false positive result.

(Comment 35) FDA received several comments raising concern about the lack of availability of supplemental tests for certain infectious agents for which FDA currently requires donor screening.

(Response) FDA recognizes the importance of confirming the infection status of a deferred donor. This information is important to donor notification, and in some instances determines whether a donor should be entered into the cumulative record of deferred donors under § 606.160(e). Accordingly, we have revised this section to require, when a supplemental test is not available, the use of one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status.

G. Donor Deferral (§ 610.41)

We have made conforming changes in final § 610.41(a) to incorporate the ''relevant transfusion-transmitted infection'' terminology, the inclusion of syphilis testing in § 610.40(a) instead of § 610.40(i), and updated the term from ''supplemental'' testing to ''further'' testing, to reflect the change in § 610.40(e). At the same time we clarified the meaning of the second sentence of § 610.41(a)(1), which now states, ''However, you must defer the donor if further testing for HBV or HTLV has been performed under § 610.40(e) and the donor is found to be positive, or if a second, licensed, cleared, or approved, screening test for HBV or HTLV has been performed on the same donation under § 610.40(a) and is reactive, or if the donor tests reactive for anti-HBc or anti-HTLV, types I and II on more than one occasion.'' Previously this provision stated, ''When a supplemental (additional, more specific) test for anti-HBc or anti-HTLV, types I and II has been approved for use under § 610.40(e) by FDA, such a donor must be deferred.'' Consistent with current guidance, establishments now defer a donor who tests reactive for anti-HBc or anti-HTLV, types I and II, on more than one occasion, or when further testing on the same donation is positive, or when a second licensed, cleared, or approved screening test for HBV or HTLV has been performed on the same donation and is reactive (Refs. 28, 29).

H. Purpose and Scope (§ 630.1)

Final § 630.1 describes the purpose and scope of the combined subparts of part 630 that require blood establishments to perform the following activities: determine that on the day of donation the donor is in good health and is eligible to donate blood or blood components; determine the suitability of the donation for use in transfusion or further manufacturing; and notify a donor who is deferred from donating because the donor did not satisfy the eligibility criteria described in part 630 or because the donor's test results revealed a relevant transfusion-transmitted infection as described under § 610.40. This section is consistent with the proposed rule, with one change. Since we are not defining the term ''you'' in § 630.3, we have finalized § 630.1(b) to describe the scope as ''Blood establishments that manufacture blood and blood components, as defined in § 630.3(a) and (b) of this chapter, must comply with subparts A, B, and C of this part.'' Accordingly, the requirements in part 630 apply to any establishment or facility that collects, or performs other manufacturing steps for, blood or blood components for transfusion, including components for autologous use, for further manufacturing use, or for use as a component of a medical device.

I. Medical Supervision (§§ 630.5, 640.130)

Final § 630.5(a) requires a responsible physician, as defined in § 630.3(i), to determine the eligibility of a donor of blood or blood components, including Source Plasma, in accordance with the regulations in 21 CFR Chapter I, subchapter F. This section describes the activities related to the collection of blood and blood components that the responsible physician may delegate to a physician substitute or other trained person, taking into account the training and medical expertise needed to assess whether the donor's health permits the collection, and to mitigate the risks related to donation. Recognizing that conditions may change, final § 630.5(a)(1)(i)(C) provides that the Director, CBER, may authorize the delegation of additional activities, after determining that delegating the activity would present no undue medical risk to the donor or to the transfusion recipient. The requirements in this section are not intended to preempt State or local laws when those laws require a higher level of medical oversight for certain blood collection activities This section combines the existing requirements related to eligibility for donors of Whole Blood (§ 640.3) and Source Plasma (§ 640.63) into a single section.

For the collection of blood and blood components other than Source Plasma and plasma collected by plasmapheresis, § 630.5(b) authorizes the responsible physician to delegate the following activities to a physician substitute or other trained person: Determining the eligibility of a donor and documenting assessments related to that determination; collecting blood and blood components; returning red blood cells to a donor during apheresis procedures; and obtaining the informed consent of a plateletpheresis donor as described in § 640.21(g). Under

§ 630.5(b)(2), the responsible physician is not required to be present at the collection site when any of these activities are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is not only adequately trained and experienced in the performance of these activities but also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures.

However, under § 630.5(b)(1)(i)(A), the responsible physician must not delegate the examination and determination that the health of a donor would not be adversely affected by donating, when the donor's systolic blood pressure falls outside the range of 90 to 180 millimeters (mm) of mercury, or when the diastolic blood pressure falls outside the range of 50 to 100 mm of mercury. Additionally, the responsible physician must not delegate the examination and determination that the health of a donor would not be adversely affected by donating Whole Blood or Red Blood Cells more frequently than specified under § 630.15(a)(1).

Under § 630.5(b)(1)(i)(B), the responsible physician must not delegate the following determinations: That the health of a donor whose pulse measurement falls outside the range of 50 to 100 beats per minute, or is irregular, would not be adversely affected by donating; that the health of an ineligible autologous donor permits the collection procedure; and that a dedicated plateletpheresis donor is in good health. The responsible physician may make the determinations addressed in § 630.5(b)(1)(i)(B) by telephonic or other offsite consultation.

Under § 630.5(b)(1)(i)(C), the responsible physician must not delegate the determination of the health of the donor or the determination that the blood or blood component collected would present no undue medical risk to the transfusion recipient, as required for dedicated donations by an ineligible donor for a specific transfusion recipient based on documented exceptional medical need. The responsible physician may make this determination by telephonic or other offsite consultation. In recognition that conditions may evolve in the future, we have added § 630.5(b)(1)(v) to permit the responsible physician to delegate other activities when authorized by the Director, CBER, based on a determination that delegating the activities would present no undue medical risk to the donor or to the transfusion recipient. We anticipate that the Director, CBER, would authorize such delegations under 21 CFR 640.120, or in response to submissions from individual establishments, as appropriate. In addition, such authorizations may be discussed in guidance issued under good guidance practices.

For the collection of Source Plasma and plasma collected by plasmapheresis, § 630.5(c)(1)(i) authorizes the responsible physician to delegate to a physician substitute or other trained person the following activities related to donor eligibility and blood component collection, provided that the responsible physician or a physician substitute is on the premises at the collection site: (1) Determining and documenting donor eligibility, (2) collecting blood and blood components, (3) returning red blood cells to the donor during apheresis, (4) other activities authorized by the CBER Director, (5) the collection of Source Plasma in an approved collection program from a donor who is otherwise determined to be ineligible, and (6) the collection of a blood sample for testing required under § 640.65(b)(1)(i). Similar to collections of blood and blood components subject to delegations under § 630.5(b), § 630.5(c)(1)(i)(A)(*1*) through (c)(1)(i)(A)(*3*) provide that the responsible physician must not delegate specific responsibilities related to the assessment of donor blood pressure, donation frequency after red blood cell loss, donor pulse, and certain plasmapheresis collections from an ineligible donor. Section 630.5(c)(1)(i)(A)(*4*) and (c)(1)(i)(A)(*5*) provide that the responsible physician must not delegate the responsible physician's determination related to a donor's false-positive reaction to a serologic test for syphilis, or the responsible physician's determination to permit plasmapheresis of a donor with syphilis. In addition, § 630.5(c)(1)(ii) authorizes the responsible physician, who may or may not be present when these activities are performed, to delegate to a trained physician substitute the approval and signature for a plasmapheresis procedure and review and signature for accumulated laboratory data, the calculated values of each component, and the collection records. However, the responsible physician must not delegate the decision to reinstate a donor in accordance with § 640.65(b)(2)(i). These provisions in § 630.5(c)(1)(ii) were not expressly included in proposed § 630.5. We have included them here in order to state more clearly how the new delegation provisions in § 630.5 affect the existing responsibilities of the responsible physician.

With respect to donor immunization, consistent with the proposed rule, § 630.5(c)(2)(i) authorizes the responsible physician to delegate to a physician substitute or other trained person the administration of an immunizing agent other than red cells to a donor in an approved immunization program, provided that the responsible physician or physician substitute is on the premises. Section 630.5(c)(2)(ii) authorizes the responsible physician to delegate to a physician substitute the function of donor immunization with red blood cells, provided that the responsible physician has approved the procedure and is on the premises when the procedure is performed. Section 630.5(c)(3) authorizes the responsible physician to delegate to a physician substitute the administration of the medical history, physical examination (including examination before immunization), and informed consent required in § 630.15(b)(1), (b)(2), and (b)(5). The responsible physician is not required to be present at the collection site when the physician substitute performs these activities.

Section 630.5(c)(4) addresses delegations for collections from infrequent plasma donors, as defined in § 630.3(e). This section authorizes the responsible physician to delegate to a trained person the following activities related to collections from infrequent plasma donors: the activities listed in § 630.15(b)(1)(i) through (b)(1)(iii) and (b)(1)(v), and the administration of the informed consent under § 630.15(b)(2). The responsible physician or a physician substitute is not required to be present at the collection site provided that the responsible physician has delegated these activities to a trained person who is also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures. However, if Source Plasma is collected from an infrequent plasma donor and the donor is otherwise ineligible or is participating in an approved immunization program, the responsible physician may only delegate activities as described in § 630.5(c)(1) through (c)(3), as appropriate to that collection.

Section 630.5(d) requires that, for all collections, establishments must establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when medically necessary. In addition, establishments must assure that an individual (responsible physician, physician substitute, or trained person,

as defined in § 630.3) who is currently certified in cardiopulmonary resuscitation is located on the premises whenever the establishment is performing collections of blood or blood components.

Finally, we have added § 640.130 to new subpart M of 21 CFR part 640, entitled ''Definitions and Medical Supervision.'' Section 640.130 clarifies that the requirements for medical supervision established in § 630.5 supplement the regulations in part 640. We are adding this provision to aid the reader in identifying applicable requirements for medical supervision related to the collection of blood and blood components in accordance with part 640.

(Comment 36) One comment agreed that the responsible physician should direct and control the physician substitutes and trained personnel, and supported proposed provisions under which the responsible physician could authorize trained personnel, including physician substitutes, to determine the donor's eligibility and collect blood and blood components in the absence of a responsible physician.

(Response) We have finalized the proposed rule to permit delegation of blood collection activities to trained persons, including physician substitutes, who are adequately instructed and qualified to perform the delegated functions. This delegation provision is not intended to preempt more restrictive requirements under State or local law. We do not require the responsible physician to be on the premises, except for red blood cell immunizations, although State or local law may provide otherwise. We have also clarified the activities that the responsible physician may not delegate. Delegation is not permitted in these circumstances because the medical expertise of the responsible physician is necessary to assess whether the donor's health permits the collection.

(Comment 37) One comment requested clarification that designated physician substitutes and trained persons may perform the collection of platelets, Red Blood Cells and plasma (as distinct from Source Plasma) and may return red blood cells during an apheresis collection in the absence of the responsible physician. Another comment criticized a requirement for the presence of a physician substitute in the collection of Source Plasma, noting that red blood cells are now routinely returned by automated equipment during apheresis collections of plasma, Red Blood Cells, and platelets. The comment stated that, since modern apheresis devices return red blood cells to the donor through automated processes, the return of red blood cells does not pose a heightened risk relative to other procedures, and therefore there is no need for a responsible physician or physician substitute to be present during the return of red blood cells to apheresis donors. The comment suggested that the presence of a physician substitute or the responsible physician should only be required in the unlikely event that a Source Plasma establishment was returning red blood cells manually.

(Response) Section 630.5(b)(1)(iii) and (c)(1)(i)(A) of the final rule authorize the responsible physician to delegate to a physician substitute or other trained person the return of red blood cells to the donor during apheresis. Subject to an exception for certain plasmapheresis collections, the regulation does not require the responsible physician to be present at the collection site when red blood cells are returned to the donor during apheresis, provided that the responsible physician has delegated oversight of these activities to a trained person who is also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures. However, when this activity is performed in relation to the collection of plasma by plasmapheresis (other than a collection from an infrequent plasma donor), the regulation requires the responsible physician or physician substitute to be present at the collection site. We have determined that the presence of the responsible physician or of a physician substitute under the supervision of the responsible physician is necessary to help ensure the continued safety of plasmapheresis donors who are not infrequent donors, as defined in § 630.3(e). This is because such donors are permitted to donate up to two times every week, and larger volumes of fluid may be collected at each donation than from other donors. These factors may increase risks for the donor, and warrant the on-site presence of a physician substitute or the responsible physician.

(Comment 38) One comment noted that § 630.5(c) would permit a collecting establishment to authorize a physician substitute to perform the functions of a responsible physician in the collection of Source Plasma, except the responsible physician would be required to be present for red blood cell immunizations. The comment stated that they assume that FDA is requiring the presence of the responsible physician for the red blood cell immunization to assist the recipient of red blood cells if a life-threatening situation arises during the immunization process. The comment asserted that this is most likely based on the fact that potential life-threatening reactions most commonly occur within 10 to 15 minutes of the start of the transfusion with as little as 10 milliliters (mL) transfused.

The comment said that they understand the potential risks associated with red blood cell immunization. However, the comment stated that having a physician present during the immunization process does not protect against the single greatest risk to recipients of red blood cells, which is human error when identifying the blood product for administration to the recipient of red blood cells. Therefore, in protecting against this risk, the comment stated that it is imperative that plasma establishments have processes and procedures in place to assure that the correct red blood cell product is infused to the intended recipient. The comment reports that this is currently achieved by adherence to current good manufacturing practices. The comment recommended that FDA remove the requirement of having a physician present during immunization with red blood cells as long as current good manufacturing practices are followed.

(Response) We agree with the description of the risks of red blood cell immunizations. We also agree that Source Plasma establishments must adhere to Current Good Manufacturing Practice for Blood and Blood Components (21 CFR part 606), including § 606.100(b), which require establishments to establish, maintain, and follow written standard operating procedures for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, and further manufacturing purposes. However, adherence to current good manufacturing practices does not replace the medical oversight provided by the responsible physician, or the clinical expertise that a responsible physician can provide in the case of an emergency at the establishment. Accordingly, we require that the responsible physician must be present when a donor is immunized with red blood cells. Section 630.5(c)(2)(ii) authorizes the responsible physician to delegate to a physician substitute the function of donor immunization with red blood cells, provided that the responsible physician has approved the procedure and is on the premises at the collection site when the procedure is performed.

(Comment 39) A comment to proposed § 630.5(e) asserted that blood collection personnel should be trained in cardiopulmonary resuscitation and the use of automated external defibrillators, and should call 911 to transport donors to a medical facility for emergency care as soon as possible. Another comment noted that the final rule could require that collection staff be trained in cardiopulmonary resuscitation.

(Response) Final § 630.5(d) requires blood collection establishments to establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when necessary. In addition, blood collection establishments must assure that an individual (responsible physician, physician substitute, or trained person) who is currently certified in cardiopulmonary resuscitation is located on the premises whenever collections of blood or blood components are performed. We agree that the availability of such a person on the premises will provide important donor protections in the event they are needed. We are not including in the codified language a requirement for a person also to be trained in the use of automated external defibrillators because such devices are not always available at collection sites. However, we believe that the presence of automated external defibrillators may be helpful, and establishments may choose to provide training on available automated external defibrillators, in addition to assuring that a person currently certified in cardiopulmonary resuscitation is located on the premises during collections. As noted in our response to comment 40, we believe that establishments will incorporate the use of 911 services into their procedures for obtaining rapid emergency medical services for donors when necessary.

(Comment 40) One comment noted that proposed § 630.5(e) would have required establishments to establish, maintain, and follow standard operating procedure for providing emergency medical services for donors within 15 minutes. The comment agreed that SOPs should be established, maintained, and followed for the provision of emergency medical services but stated that ensuring a 15 minute response time would not be feasible in some communities and in any event is beyond the control of the blood establishment. Other comments also noted that local emergency medical service response time is community dependent. Blood centers cannot control how quickly emergency medical services respond and cannot guarantee a 15 minute response time.

(Response) After considering the comments, we have finalized this provision without referencing a 15 minute timeframe. We recognize that in many instances blood collection facilities must rely on the response time of emergency medical services available through local 911 services. Instead, we are requiring in § 630.5(d) that that establishments establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when necessary. In addition, the final rule requires that at least one person (responsible physician, physician substitute, or trained person) on the premises during the collection of blood and blood components be currently certified in cardiopulmonary resuscitation. FDA expects that procedures established by blood collection establishments for obtaining rapid emergency medical services will generally result in the provision of emergency medical services within 15 minutes. However, by not specifying a 15 minute response time (and instead calling only for a ''rapid'' response), we are recognizing that unanticipated circumstances that are outside the control of the blood establishment may delay such care. Establishments should consider the availability of emergency medical services and local response times, particularly when determining locations for mobile collections.

(Comment 41) One comment responded that proposed § 630.5(e) should be reworded to include public emergency medical services. The comment agreed that the establishment of standard procedures for providing emergency medical services within 15 minutes, if necessary, for donors seems appropriate.

(Response) We decline to include the term ''public'' prior to emergency medical services in § 630.5(d). We interpret emergency medical services to include an onsite responsible physician or access to emergency medical services available through 911. If an establishment determines that emergency medical services accessible through 911 may not be available rapidly, due to the location of the collection facility or mobile unit, the establishment should provide for a responsible physician to be present at the collection site.

J. General Donor Eligibility Requirements (§ 630.10)

This section includes requirements to ensure that blood and blood components are safe, pure and potent. It also includes requirements to determine that the donor is in good health and the donor's health will not be adversely affected by the donation. We require the establishment to provide the donor with certain educational material related to infectious disease risk so that the donor can self-defer, to check donor deferral records, to perform a limited physical assessment of the donor, to assess the donor for risk factors for relevant transfusion-transmitted infections and other factors that might adversely affect the donation or the donor's health, to obtain a donor acknowledgement that is signed or otherwise recorded, to defer ineligible donors, and to obtain proof of the donor's identity and a postal address where the donor may be contacted for 8 weeks after donation for purposes of donor notification under § 630.40.

We received comments on this section from individuals, blood establishments and trade organizations. We are finalizing this section largely as proposed, except that we have clarified the language in some sections and combined or revised other sections. We have combined proposed § 630.10(e), (f), and (g) covering various aspects of donor eligibility into one section, § 630.10(e). We have renumbered proposed § 630.10(h) into final § 630.10(f). Final § 630.10(f)(3) provides a modified standard for donor hemoglobin or hematocrit. Proposed § 630.10(i) is final § 630.10(g), and we have clarified proposed § 630.10(i)(2) Donor's written statement of understanding, now titled ''Donor's acknowledgement'' in § 630.10(g)(2). We also added § 630.10(h) to state more explicitly what an establishment must do when a donor is ineligible.

1. Section 630.10(a)

Consistent with FDA's long standing requirement that a donor be in good health at the time of donation to assure that blood, blood components and blood products manufactured from their donations will be safe, pure and potent, this section states that an establishment must not collect blood or blood components before determining that the donor is eligible to donate. We received no comments on this provision. We added language to explain that, to be eligible, a donor must be in good health and free from transfusion-transmitted infections as can be determined by the processes in this subchapter. The phrase ''as can be determined by the processes in this subchapter'' clarifies that blood establishments must assess a donor's eligibility in accordance with these regulations. Like the proposed rule, this section states that a donor is ineligible if the donor is not in good health or if the blood establishment identifies

factors that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components collected from the donor.

2. Section 630.10(b)

Section 630.10(b) requires that, before determining eligibility, an establishment must provide the donor with educational material in an appropriate format regarding certain relevant transfusion-transmitted infections when providing that information is necessary to assure the safety, purity, and potency of blood and blood components, such as for HIV risk factors. Currently, the only relevant transfusion-transmitted infection for which FDA has determined that providing such information is necessary to assure blood safety, purity, and potency is HIV. FDA first made this recommendation in 1983 (Ref. 30). The donor history questionnaires and accompanying materials found acceptable by FDA include blood donor educational material addressing HIV risk behaviors and signs and symptoms of HIV (Refs. 6, 7, 8). Providing this educational information in written or electronic format would meet the requirements of this section. In addition, the provision permits establishments to provide, in the educational material, information concerning the risks and hazards of donation. This provision differs from proposed § 630.10(b) in two significant ways: (1) In response to comments, we have clarified that blood collection establishments must provide information concerning certain, and not all, relevant transfusion-transmitted infections and (2) to provide greater flexibility and to accommodate existing practices, we have revised this section to expressly permit establishments to provide, in this educational material, information regarding the risks and hazards of the donation procedure to meet the requirements under § 630.10(g)(2)(ii)(E).

(Comment 42) Two comments raised concern that the proposal would require establishments to provide the donor with too much information about too many relevant transfusion-transmitted infections. Several comments suggested that the rule should not require the educational material to include signs and symptoms of a relevant transfusion-transmitted infection. Several comments suggested that providing the donor history questionnaire should be sufficient to meet this requirement, while several comments suggested that the donor history questionnaire should not include signs and symptoms of HIV.

(Response) FDA believes that providing educational material to donors protects the safety of the blood supply and donor health. FDA believes that self-deferral by at risk donors because of information provided in the educational materials has helped ensure blood safety (Refs. 6, 7, 8, 31, 32, 33). Blood establishments have voluntarily developed donor educational material in response to potential threats (Refs. 6, 7, 8, 31, 32, 33).

FDA agrees with the comments that educational materials should not describe all relevant transfusion-transmitted infections. Instead, this section requires establishments to provide donor information about a relevant transfusion-transmitted infection when necessary to assure the safety, purity, and potency of blood and blood components. As noted previously, currently HIV is the only relevant transfusion-transmitted infection for which providing such information is necessary. The longstanding practice of providing educational material about HIV, including information about signs and symptoms, would continue as a requirement under this provision.

FDA believes that establishments may choose to include in the donor educational material information to explain the collection procedure and the risks and hazards of the procedure, as required under § 630.10(g)(2)(ii)(E). This section expressly permits the incorporation of that information into the donor educational material, but does not require it.

3. Section 630.10(c)

Section 630.10(c) requires establishments to determine the donor's eligibility on the day of donation and prior to collection. Under § 630.10(c)(1), which is applicable to products that cannot be stored for more than 24 hours, an establishment may determine the donor's eligibility and collect a sample for testing required under § 610.40 no earlier than 2 calendar days before the day of donation. In § 630.10(c)(2), the final rule authorizes blood establishments to clarify a donor's response to a donor history question under § 630.10(e) or (g) in accordance with standard operating procedures and within 24 hours of the time of collection.

(Comment 43) Several comments stated that for components having a shelf life of 24 hours, collecting a sample for testing for infectious diseases one day before donation may not provide enough time to obtain the results. They requested that FDA allow the donor to be tested 3 days prior to collection of the donation or alternatively allowing the donation to be released under emergency provisions in § 610.40(g) or where appropriately labeled as from a donor who has been previously tested.

(Response) FDA agrees with that there is a need for some flexibility on the timing for collecting a sample for testing and making a donor eligibility determination for donors of blood components that cannot be stored for more than 24 hours. We have decided to finalize the proposed provision, now § 630.10(c)(1), and provide that ''when a donor is donating blood components that cannot be stored for more than 24 hours, you may determine the donor's eligibility and collect a sample for testing required under § 610.40 of this chapter, no earlier than 2 calendar days before the day of donation, provided that your standard operating procedures address these activities.'' We believe that this 2 calendar day timeframe will be adequate to accommodate donor testing before collection. We also note that current § 610.40(g) allows release of untested components in appropriately documented medical emergency situations.

(Comment 44) FDA received several comments requesting that FDA permit blood establishments to obtain answers to missing donor information for 24 hours after the collection occurred.

(Response) FDA realizes that sometimes blood establishments become aware that there are missing answers to donor history questions, or they need clarification of answers to certain donor history questions. In response to comments, and consistent with current FDA policy (Ref. 34), we are adding new § 630.10(c)(2) to the final rule. Section 630.10(c)(2) expressly authorizes establishments to clarify donor records after collection under these circumstances, ''In the event that, upon review, you find that a donor's responses to the donor questions before collection were incomplete, within 24 hours of the time of collection, you may clarify a donor's response or obtain omitted information required under paragraph (e) of this section, provided that your standard operating procedures (required under 21 CFR 606.100) address these activities.'' This applies only to responses to donor questions, and not to information that establishments are required to obtain as part of the physical assessment of the donor addressed in § 630.10(f).

4. Section 630.10(d)

Section 630.10(d) requires a blood establishment to determine the donor's eligibility before collection by performing four tasks: (1) Consulting the records of deferred donors maintained under § 606.160(e)(1) and (2). Because it

may not be feasible to review the cumulative record described in § 606.160(e)(2) prior to collection at all collection sites, the regulation provides that if pre-collection review is not feasible, the establishment must consult the cumulative record prior to release of any blood or blood component prepared from the collection; (2) assuring that the interval since the donor's last donation is appropriate; (3) assessing the donor's medical history; and (4) performing a physical assessment of the donor. We have finalized the description of the last two steps as proposed, and we have clarified the language used to describe the second step by omitting unnecessary language.

The first factor has been changed to reference the ''records of deferred donors maintained under § 606.160(e)(1) and (2) of this chapter'' instead of the proposed ''list of ineligible donors required under § 606.160(e)(2) of this chapter'', and to provide flexibility for consulting the cumulative record before release of blood or blood components when the record cannot be available at the collection site. We discuss final § 606.160(e) at comment 25. The review of the records of deferred donors may be accomplished by making an electronic query of a centralized database.

(Comment 45) One comment questioned the validity of donor deferral registries in ensuring the safety of the blood supply. For example, the comment asserted that requiring collection facilities to consult the donor deferral registry prior to donation would negatively affect mobile operations and impact other facilities when computer outages occur that would have a significant negative impact on blood availability.

(Response) The requirements in §§ 606.160(e) and 630.10(d)(1) will help assure that blood and blood components that are not suitable for use are not collected or distributed. These provisions protect donors from making donations that should not be collected, protect recipients from the release and use of unsuitable donations, and help establishments to conserve resources used in collecting, testing, and manufacturing blood and blood components. Moreover, since § 630.10(d)(1) helps to prevent the collection of unsuitable units, we believe that it will be feasible for establishments to comply with these requirements while at the same time maintaining adequate supplies of suitable blood and blood components. We believe that the requirements, as finalized, are similar to existing practices within blood establishments. Moreover, § 630.10(d)(1) of the final rule now provides additional flexibility so that if unusual circumstances prevail (for example, at a distant mobile collection, or when an establishment is having temporary technical difficulties), and pre-collection review is not feasible because the establishment cannot consult the cumulative record at the collection site, the establishment may collect from the donor, but must consult the cumulative record before release of any blood or blood component prepared from the collection.

5. Section 630.10(e)

The requirements of proposed § 630.10(e), (f), and (g) are interrelated. We have combined proposed § 630.10(e), (f), and (g) into one section, final § 630.10(e). This section requires establishments to conduct a medical history interview as described in this section to determine if the donor is in good health, to identify risk factors closely associated with exposure to, or clinical evidence of, a relevant transfusion-transmitted infection, and to determine if there are other conditions that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components or any product produced from the blood or blood components. Blood establishments must take a medical history as described in this section.

Section 630.10(e) also contains specific requirements for determining that the donor is in good health and free from risk factors for a relevant transfusion-transmitted infection. This assessment must include the following factors: (1) Factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection, including the factors described in § 630.10(e)(1)(i) through (vi) and (2) other factors described in § 630.10(e)(2)(i) through (vii) that may make the donor ineligible, including factors related to donor health or travel history.

Section 630.10(e) is intended to provide explicitly in our regulations for our current donor deferral recommendations and blood establishment practices. We discuss the comments received on that provision. We received no comments on our proposal in § 630.10(g)(7), under which a donor would be ineligible because she was pregnant at the time of, or within 6 weeks of, donation, and have finalized that proposal in § 630.10(e)(2)(v).

(Comment 46) Several organizations requested FDA not to finalize the provision in proposed § 630.10(e) that would have required an establishment to determine whether a health care practitioner ever told the donor not to donate blood.

(Response) We agree. We included this provision, in part, as a result of the anthrax exposures in 2001, where individuals may have been advised not to donate. However, prior advice not to donate blood may be based on a number of factors, including a transient infection, now cured, or blood loss due to an accident, from which the donor has long recovered. We have not included this provision in the final rule. Instead we require establishments to take a medical history, as described in § 630.10(e). Such a medical history would be focused on eliciting information related to potential and current risks, either to the donor, or to the safety of the donated blood product.

(Comment 47) We received comments stating that FDA has recognized uniform donor history questionnaires and should not add the criteria for deferral in proposed § 630.10(f).

(Response) FDA believes that use of a current and acceptable donor history questionnaire, such as the donor history questionnaires and accompanying materials found acceptable by FDA in guidance (Refs. 6, 7, 8), would meet these requirements. If the need arises, FDA will describe how to comply with these provisions in guidance documents issued in accordance with good guidance practices.

(Comment 48) One comment suggested that we abandon the term ''social'' in proposed § 630.10(f)(1), ''social behaviors associated with relevant transfusion-transmitted infections.''

(Response) We agree and have dropped the term ''social.'' Section 630.10(e)(1)(i) now refers simply to ''behaviors.''

(Comment 49) Other comments stated that FDA should not consider the behavior of men who have had sex with another man even one time since 1977 to be ''behaviors associated with relevant transfusion-transmitted infections'' under proposed § 630.10(f)(1).

(Response) This rule does not specify the circumstances under which FDA would consider men who have sex with another man to be a behavior associated with relevant transfusion-transmitted infections. Instead, that is an issue FDA has addressed in previous guidance related to the issue (Ref. 10). We are currently reviewing this policy. If we determine that modifications of any behavior-based donor deferral recommendations are warranted, we will issue new guidance to blood

establishments in accordance with good guidance practices.

(Comment 50) We received several comments suggesting that FDA change the following phrase in proposed § 630.10(f)(2), ''Medical treatments and procedures associated with exposure to relevant transfusion-transmitted infections.'' The comments stated that this criterion was too vague and suggested that the donor history questionnaire would provide a sufficient basis for determining whether the donor had risk exposures from medical procedures.

(Response) We agree with the comment in part and have made this criterion, now contained in § 630.10(e)(1)(ii), more specific. FDA recognizes that many medical procedures present some risk, which cannot be specifically quantified. Consequently, final § 630.10(e)(1)(ii) states, ''Receipt of blood or blood components or other medical treatments and procedures associated with possible exposure to a relevant transfusion-transmitted infection.'' In any event, we agree with comments that an acceptable donor history questionnaire, such as the donor history materials that are currently recognized in FDA guidances (Refs. 6, 7, 8), may be used to elicit information adequate to satisfy these provisions.

(Comment 51) One comment asked FDA to clarify how establishments would gather information related to signs and symptoms of relevant transfusion-transmitted infections under proposed § 630.10(f)(3).

(Response) In final § 630.10(e)(1)(iii), we require establishments to assess ''Signs and/or symptoms of a relevant transfusion-transmitted infection.'' For example, FDA has issued guidance on signs and symptoms of HIV (Refs. 10, 30). If a donor exhibits signs or symptoms of HIV, they would be deferred under this provision. We believe that an establishment would meet this requirement by determining that the donor is in good health, and using a currently acceptable donor history questionnaire. FDA has periodically issued new guidance recommending assessment for signs and symptoms of a new infectious agent or disease (Refs. 35, 36). FDA will issue guidance in accordance with good guidance practices in the event that different information is needed to satisfy the requirements of this section.

(Comment 52) Several comments asked FDA to reconsider the longstanding requirement for deferral of donors with a ''history of viral hepatitis.''

(Response) Neither the proposed nor the final rule refers to a ''history of viral hepatitis'' as a factor in determining donor eligibility. We are finalizing the donor eligibility requirements without reference to a requirement to defer donors with a history of viral hepatitis after the age of 11. Instead, under new § 630.3(h)(1)(ii) and (iii), HBV and HCV are relevant transfusion-transmitted infections. Under § 630.10(e)(1)(iii), an establishment must defer a donor exhibiting signs and/or symptoms of relevant transfusion-transmitted infections, including HBV and HCV. Reactive test results for these relevant transfusion-transmitted infections would result in donor deferral as described in § 610.41(a).

(Comment 53) One comment requested that that we not finalize the requirement in proposed § 630.10(f)(4) to determine whether a donor has been institutionalized in a correctional institution, preferring that this be addressed in guidance, not regulation. Another comment recommended that FDA clarify that deferral would be for institutionalization in a correctional institute for 3 days or more.

(Response) We have finalized a requirement in § 630.10(e)(1)(iv) that establishments determine whether a donor has been institutionalized in a correctional institution. We have rejected the suggestion that we leave this deferral to guidance because we concluded that this deferral is readily described and unlikely to change due to technological developments. We agree with the second comment and have further clarified that the deferral applies to donors who were institutionalized in a correctional institution for 72 consecutive hours or more in the 12 months before donation.

(Comment 54) We received comments asking us to revise the definition for ''intimate contact'' provided in proposed § 630.3(e), which was applicable to proposed § 630.10(f)(5), and to clarify that the deferral for ''intimate contact'' would only apply to those relevant transfusion-transmitted infections where such transmission occurs through intimate contact.

(Response) We agree in part with the comment. We have modified the defined term in § 630.3(f) so that it is now ''intimate contact with risk for a relevant transfusion-transmitted infection'' and clarified that this term refers to conduct that could result in the transfer of potentially infectious body fluids from one person to another. The provision that is now finalized in § 630.10(e)(1)(v) incorporates this clarified definition, and requires inquiry concerning such intimate contact with risk for a relevant transfusion-transmitted infection, which is defined in § 630.3(f) as having engaged in an activity that could result in the transfer of potentially infectious body fluids from one person to another. We have issued guidance when we believed that deferral for intimate contact with an individual infected with a relevant transfusion-transmitted infection or exposed to a relevant transfusion-transmitted infection was appropriate (Refs. 11, 37). FDA will issue a future guidance document as necessary for deferral of donors because of specific intimate contact with risk for a relevant transfusion-transmitted infection.

(Comment 55) One comment requested that we state that nonsterile percutaneous inoculation, as proposed in § 630.10(f)(6), be considered a basis for deferral only when the inoculation took place within 4 months of the donation.

(Response) We did not specify in the proposed regulation a timeframe for this deferral, stating that the blood establishment should defer the donor if the factor was ''still applicable'' at the time of donation, and we have not specified a timeframe in the final rule codifying this factor at § 630.10(e)(1)(vi). FDA's 1992 guidance entitled, ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,'' recommends a 1 year deferral for nonsterile percutaneous exposure, and this recommendation is still current (Ref. 10).

(Comment 56) We received several comments asking FDA to modify proposed § 630.10(g)(1), which identified ''Medical or dental treatment, or symptoms of a recent or current illness'' as a basis for ineligibility. These comments asked FDA to delete the reference to dental treatment.

(Response) We agree with these comments in part. In finalizing proposed § 630.10(g)(1), we have revised this provision and separated it into two sections. Section 630.10(e)(2)(i) now requires establishments to assess donors for symptoms of a recent or current illness. Section 630.10(e)(2)(ii) now requires establishments to assess donors for certain medical treatments or medications, such as a major surgical procedure, that indicates that the donor should not donate. We have omitted the requirement to defer donors for recent dental treatment.

(Comment 57) We received several comments asking FDA to delete the provision in proposed § 630.10(g)(1) through (g)(3) which refer to ineligibility because of medical treatment, medication, or major surgical procedure.

One comment suggested that the deferral be limited to the criteria and medications enumerated in current FDA guidance documents. Several comments asked FDA to identify major medical procedures.

(Response) We have finalized § 630.10(e)(2)(ii) to require blood establishments to assess donors for certain medical treatments or medications, such as a major surgical procedure, that indicate that the donor should not donate. This provision is intended to protect the health of the donor and ensure the safety and purity of the blood product. We note that we have issued guidance on donor deferral criteria for certain medications (Ref. 38). We believe that establishments can meet the requirements of this section by using current donor history questionnaire materials recognized as acceptable by FDA, or other approved donor history questionnaire. If our recommendations for deferral for medical procedures or specific medications change, we would issue guidance in accordance with good guidance practices.

(Comment 58) We received several comments asking FDA not to finalize proposed § 630.10(g)(4), under which a donor would be ineligible on the basis of travel to, or residence in, an area endemic for a transfusion-transmitted infection. The comments criticized the provision as vague and more appropriately dealt with in FDA guidance documents.

(Response) In finalizing this provision in § 630.10(e)(2)(iii), we have provided additional clarity by stating that a donor would be ineligible on the basis of such travel or residence only when such screening is necessary to assure the safety, purity, and potency of blood and blood components due to the risks presented by donor travel and the risk of transmission of that transfusion-transmitted infection by such donors. For example, in the future we may determine that screening donors under this provision for the Chickungunya virus, a transfusion-transmitted infection that is transmitted by mosquitoes, is necessary to assure the safety, purity, and potency of blood and blood components. If so, we would address deferral of donors with a travel history to an area endemic for Chickungunya in accordance with good guidance practices.

(Comment 59) Several comments suggested that we delete the provision in proposed § 630.10(g)(6), which would have required a determination of ineligibility due to exposure or possible exposure to a released disease or disease agent relating to a transfusion-transmitted infection, if it was known or suspected that such a release has occurred. The comments suggested that this provision was vague and better addressed in guidance when an event occurs.

(Response) In § 630.10(e)(2)(iv), we have finalized this provision as proposed. This factor only becomes relevant when a disease or disease agent for a transfusion-transmitted infection has been released. We expect this to apply in rare circumstances, such as after a serious accident or bioterrorism attack involving the release of such agents. FDA intends to issue guidance, as practicable, when a released disease or disease agent is identified and is of a nature or type that donor deferral would be warranted. We note that we previously issued guidance on the deferral of donors with possible exposure to anthrax due to a possible bioterrorism event (Ref. 39).

(Comment 60) We received several comments on proposed § 630.10(g)(8), which would have required blood establishments to determine to be ineligible donors who gave answers to medical history questions that appeared unreliable due to the apparent influence of drugs or alcohol, or due to another reason affecting the reliability of the donor's answers. The comments agreed with the deferral, but stated that blood establishment procedures were adequate to address this issue.

(Response) We combined donor suitability requirements from existing regulations for Whole Blood donations (§ 640.3) and Source Plasma donations (§ 640.63) in the final rule. Source Plasma regulations have had a longstanding requirement (§ 640.63(d)) that ''any donor who, in the opinion of the interviewer, appears to be under the influence of any drug, alcohol, or for any reason does not appear to be providing reliable answers to medical history questions, shall not be considered a suitable donor.'' Until now, there has not been a corresponding provision in the requirements for Whole Blood donors, even though a donor who does not provide reliable answers presents similar risks in that venue. We are finalizing this requirement for all donations in § 630.10(e)(2)(vi).

In the preamble to the proposed rule we gave, as an example of an unreliable answer, a donor who states that he or she is donating in order to be tested for infectious agents. This is because of our concern that the donor may be aware of some additional, undisclosed, risk factor that leads him or her to seek information on their infection status by presenting at a blood donation center. Such undisclosed risk factors endanger blood safety, particularly when the donor is in the ''window period'' when the donor is infected and infectious, but the infection cannot yet be detected by donor screening tests. We did not receive comments on this example. We have decided to expressly require the deferral of a donor who states they are seeking testing for a relevant transfusion-transmitted infection. We expect that blood establishments may then refer the donors to public health testing clinics and other venues providing testing.

(Comment 61) We received comments requesting that we not finalize the proposed requirement to determine a donor to be ineligible due to receipt of a xenotransplantation product, or intimate contact with such a recipient (proposed § 630.10(g)(5)).

(Response) In final § 630.10(e)(2)(vii), we require establishments to assess the eligibility of a donor on the basis of receipt of a xenotransplantation product. We finalized this provision to protect the health of the donor who received the xenotransplantation product and to address the risk of transmission of animal infectious agents by blood and blood products collected from such a donor. In 2002, we discussed those risks in a draft guidance entitled ''Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts'' (Ref. 37). We have not finalized the proposed requirement to require screening for intimate contact with a xenotransplantation recipient. If, in the future, we determine that donation by an individual who has had intimate contact with a recipient of a xenotransplantation product may affect that donor's health, or the safety, purity, or potency of the blood or blood component, or product produced from the blood or blood component collected from that donor, we will issue guidance to address these risks.

6. Section 630.10(f)

As we described earlier, we combined proposed § 630.10(e) through (g) into § 630.10(e) in the final rule. We have finalized proposed § 630.10(h) as final § 630.10(f).

The physical assessment criteria set forth in § 630.10(f)(1) through(6) in this final rule requires establishments to determine that a donor is in good health which helps to assure that blood and blood components collected are safe, pure, and potent. This section requires establishments to determine on the day of donation and prior to collection of blood or blood components that the

donor is in good health, indicated in part by a normal temperature, a blood pressure within acceptable limits, an acceptable hemoglobin or hematocrit level, a regular pulse, and a minimum weight requirement. Blood establishments are also required to perform an examination of the donor's phlebotomy site and the donor's arms and forearms.

a. *Temperature (§ 630.10(f)(1)).*

(Comment 62) We received no comments objecting to the requirement for measuring a donor's temperature. We received one comment asking whether we would specify a subnormal temperature.

(Response) We are finalizing the proposed requirement to determine that the donor's oral body temperature does not exceed 37.5 °C (99.5 °F), or the equivalent if measured at another body site, since an elevated temperature indicates that the donor is not in good health and may be a symptom of infection or other adverse condition. On the other hand, a temperature that is a few degrees lower than 37.5 °C (99.5 °F), is not necessarily indicative of poor health. We decline to specify a subnormal temperature at this time. Instead, we leave assessment of an apparently healthy donor who presents for donation with an unusually low temperature for blood establishments to address in their standard operating procedures.

b. *Blood Pressure (§ 630.10(f)(2)).*

(Comment 63) Several comments recommended that FDA should not finalize a requirement for determining the donor's blood pressure, while others recommended not specifying limits for systolic and/or diastolic blood pressure measurements, or addressing such bounds only in guidance. One comment stated that a baseline blood pressure for all donors at each donation is needed in the event of a reaction.

(Response) Current § 640.3(b)(2) requires that donors be in good health, as demonstrated by systolic and diastolic blood pressure within normal limits, unless the examining physician is satisfied that an individual with blood pressure outside these limits is an otherwise qualified donor. In the preamble to the proposed rule we had solicited comments requesting supporting scientific data regarding the necessity, or lack of necessity of requiring specific upper and lower blood pressure limits for a donor (72 FR 63416 at 63426 and 63427). We did not receive significant data. In November 2009, we asked the Blood Products Advisory Committee whether available data support the utility of obtaining pre-donation blood pressure measurements as predictors of risk of an adverse response to donation, and the majority responded that data did not establish pre-donation blood pressure as a predictor of risk of an adverse response. However, even though the vote did not support blood pressure measurement as a predictor of risk, many members of the committee stated that blood pressure measurement should be retained as part of the donor assessment. The committee members noted that studies examining adverse events and blood pressure have been restricted to donors with currently acceptable blood pressure levels. Several committee members were concerned that it was not safe for donors with blood pressures above 180 mm of mercury to donate. They noted the lack of data on the safety of blood donations in hypertensive donors and the potential for severe adverse events in such donors. Other committee members noted that low blood pressure could be predictive of adverse events in young female donors who have low blood volume.

We are finalizing a requirement to measure the donor's blood pressure before donation. If a donor's systolic blood pressure is outside the range of 90 to 180 mm of mercury, or if the donor's diastolic blood pressure is outside the range of 50 to 100 mm of mercury, establishments may permit the donor to donate only when the responsible physician has examined the donor and determined that the health of the donor would not be adversely affected by donating. Note that under § 630.5(b)(1)(i)(A) and (c)(1)(i)(A)(*1*), the responsible physician is not authorized to delegate this examination and determination of the health of the donor, and must personally perform this examination and determination. Final § 630.10(f)(2) is consistent with the proposed rule and largely consistent with the current requirement in § 640.3(b)(2), and will assure that donors who present with either unusually high, or unusually low, blood pressure will be examined by the responsible physician before they are permitted to donate. We are establishing these criteria in the regulation, rather than providing a flexible standard, because we have determined that establishing clear criteria will be more protective of donor health. We note that, under the limits provided in § 630.10(f)(2), donors with blood pressure readings above 140/90 would be eligible to donate, even though such donors may be hypertensive (Ref. 40). However, experience to date indicates that donors with blood pressures in the range provided in this rule may safely donate (Refs. 41, 42).

(Comment 64) In response to our request for comments on the accuracy of blood pressure measurements, one comment stated that ''Many factors can influence blood pressure along with pulse such as stress, exercise, and caffeine intake. In addition, interobserver differences are found with measurements that rely on sphygmomanometers and stethoscopes. Therefore, a general preference for automated devices is found not only among donor centers but also among clinics, hospitals, and for use at home. These devices are commercially available and approved for sale. We recommend that FDA acknowledge the acceptance of automated devices in either the preamble to the final rule or in guidance. FDA also notes that an isolated measurement of blood pressure may not reliably assess acceptability for donation.''

(Response) We are not requiring that a specific type of device to be used to measure blood pressure. Establishments may use manual or automated devices as long as such use is consistent with the applicable standards or current good manufacturing practices, and their own standard operating procedures.

(Comment 65) The comment recommended that FDA provide the following, or similar, guidance: ''Firms should have a procedure for re-measuring the vital signs if there is reason to believe stress or other factors have affected the initial measurement.''

(Response) We are not issuing guidance on this issue at this time. We recognize that stress and other factors may affect initial measurements of the donor's blood pressure and pulse, required under § 630.10(f)(2) and (f)(4). In accordance with § 606.100(b)(2), establishments must have standard operating procedures for taking a donor's blood pressure and pulse before collection. However, these requirements do not prevent a blood collection establishment from providing in those standard operating procedures for taking and relying upon a second measurement of blood pressure if there is reason to believe stress or another factor affected the initial measurement and taking a second measurement is consistent with medical practice.

c. *Hemoglobin or hematocrit determination (§ 630.10(f)(3)).*

We proposed to require that a donor's hemoglobin level or hematocrit value be determined using a sample of blood obtained by fingerstick, venipuncture or by a method that provides equivalent results. Blood obtained from the earlobe is not acceptable. We received no

comments on this provision and are finalizing this provision as proposed. This section was proposed as § 630.10(h)(3)(i); we now finalize it as the first paragraph of § 630.10(f)(3). We further proposed to retain the existing requirement for autologous donations that a donor's hemoglobin level be no less than 11 grams of hemoglobin per deciliter of blood or a hematocrit value of 33 percent. We received no comments on this provision and are finalizing this provision as proposed. In addition, for allogeneic donations, we proposed to retain existing requirements that a donor's hemoglobin level be no less than 12.5 grams of hemoglobin per deciliter of blood or a hematocrit value of no less than 38 percent. We also solicited comments (72 FR 63416 at 63427) on:

- Changing the minimum acceptable hemoglobin level to 12.0 grams per deciliter of blood or hematocrit of 36 percent for female allogeneic donors, or whether a decision to collect from donors with such levels should be left to the discretion of the medical director of the collecting establishment on a case-by-case basis;
- The possibility of adverse effects caused by the collection of blood and blood components from female allogeneic donors with a minimum level of 12.0 grams of hemoglobin per deciliter of blood or a hematocrit value of 36 percent;
- The possibility of adverse effects caused by the collection of blood and blood components from allogeneic donors with a minimum level of 12.5 grams of hemoglobin per deciliter of blood or a hematocrit value of 38 percent;
- Establishing a more stringent interdonation interval; and
- The use of copper sulfate solution based methods as an appropriate method to determine acceptable hemoglobin levels.

Since the proposed rule was published, FDA has brought up issues related to blood donation, hemoglobin levels, and iron depletion in donors for discussion at two Blood Products Advisory Committee meetings on September 10, 2008 and July 27, 2010 (Refs. 43, 44). In addition, the Department of Health and Human Services, Public Health Service, Advisory Committee on Blood Safety and Availability discussed iron depletion and donor informed consent at its December 17, 2008 meeting (Ref. 45). In co-sponsorship with the Department of Health and Human Services, National Heart, Lung and Blood Institute, AABB, America's Blood Centers and Plasma Protein Therapeutics Association, FDA held a workshop entitled ''Public Workshop: Hemoglobin Standards and Maintaining Adequate Iron Stores in Blood Donors'' on November 8–9, 2011 (November 2011 Workshop) (Ref. 46).

At the July 2010 Blood Products Advisory Committee meeting, following the discussion of hemoglobin qualification standards and iron depletion in donors, the committee voted unanimously (10 yes votes, 0 no votes, 1 abstention) in support of raising the hemoglobin level for men, but did not support a change in the hemoglobin level for women (10 no votes and 1 abstention) (Ref. 44). The shortcomings of relying solely on hemoglobin measurement and the need to study measures to mitigate iron deficiency in blood donors were discussed at both meetings of the Blood Products Advisory Committee (Refs. 43, 44) and at the November 2011 Workshop (Ref. 46). After reviewing those discussions and the data presented at those meetings, we have decided to promulgate different standards for male and female donors, but not to alter the current 8 week interval between donations of Whole Blood and single donations of apheresis Red Blood Cells. Recognizing that research in this area continues and that data may be developed to support a change in donor hemoglobin standards, we have provided for greater flexibility in donor hemoglobin standards.

Section 630.10(f)(3)(i) now requires that allogeneic donors must have a hemoglobin level or hematocrit value that is adequate to assure donor safety. In addition, we establish minimum standards. The minimum standard established for female allogeneic donors in § 630.10(f)(3)(i)(A) is consistent with the current standard: A hemoglobin level that is equal to or greater than 12.5 grams per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent. However, we recognize that a lower hemoglobin/hematocrit level is also within the normal range for female donors. Since hemoglobin levels are influenced by the male hormone testosterone, female donors typically have lower hemoglobin levels than male donors. The fact that a female donor's hemoglobin/hematocrit level is lower than that of a male of similar age does not necessarily mean that the female donor has low iron stores, which the body uses to replace hemoglobin lost to blood donation (Refs. 47, 48). For this reason, in the preamble to the proposed rule we specifically requested comment on whether to permit collections from female allogeneic donors with a hemoglobin level of 12.0 grams per deciliter of blood or a hematocrit value of 36 percent. We are not establishing that minimum level at this time. However, § 630.10(f)(3)(i)(A) provides that an establishment may collect blood from female allogeneic donors who have a hemoglobin between 12.0 and 12.5 grams per deciliter of blood, or hematocrit value between 36 and 38 percent, provided that the establishment takes additional steps to assure that the lower value is adequate with respect to donor safety, in accordance with a procedure that has been found acceptable for this purpose by FDA. FDA has not yet recognized any such procedures, and awaits the development of data related to these issues. Conceivably, these steps might include a pre-donation measure of iron stores by means of a ferritin test, or iron replacement therapy and monitoring of iron stores. We have determined that standard collections from a donor with a hemoglobin level as low as 12.0 grams per deciliter of blood or hematocrit value of 36 percent would meet minimum potency levels based on calculated hemoglobin content.

Section 630.10(f)(3)(i)(B) of the final rule establishes a minimum standard for male allogeneic donors of 13.0 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 39 percent. This standard aligns more closely with the low range of normal levels for men, and is higher than the current regulation's minimum standard of 12.5 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent (Ref. 48). We requested comment in the preamble to the proposed rule on the possibility of adverse effects on male donors with a minimum hemoglobin level of 12.5 grams per deciliter of blood or a hematocrit value of 38 percent. We solicited these comments, in part, because of our concern about possible adverse effects of collecting blood from male donors with below normal hemoglobin or hematocrit levels, and reports about iron depletion resulting from blood donation (Refs. 46, 49, 50). Males with below normal hemoglobin or hematocrit levels may have a higher incidence of iron deficiency due to frequent blood donations or undiagnosed conditions such as gastrointestinal bleeding due to colon cancer. Since the proposed rule published, the results of a study sponsored by the Department of Health and Human Services, National Heart, Lung and Blood Institute, the Retrovirus Epidemiology Donor Study-II (REDS–II)

Donor Iron Status Evaluation Study (REDS–II–RISE study) on hemoglobin levels in donors have become available (Refs. 49, 50). The results of the REDS–II–RISE study amplified existing concern about frequent donation and iron depletion. In this rule, we are establishing higher minimum hemoglobin/hematocrit levels for male donors after reviewing that study and considering the comments submitted.

(Comment 66) We received numerous comments asking FDA not to make changes in acceptable hemoglobin and hematocrit levels for male and female donors until the REDS–II–RISE study on hemoglobin levels in donors was completed.

(Response) We are finalizing this rule after reviewing the results of the REDS–II–RISE study. Preliminary results of the REDS–II–RISE study were presented at the July 2010 Blood Products Advisory Committee meeting. At the conclusion of that discussion, the advisory committee voted unanimously that the available scientific evidence supported raising the minimum hemoglobin/hematocrit levels for male donors. The committee did not support lowering minimum standards for female donors (Ref. 44). The REDS–II–RISE study published on October 10 and 24, 2011, and the results were discussed at a November 2011 Workshop (Ref. 46). Results from the REDS–II–RISE study were published in an article entitled, ''Iron deficiency in blood donors: The REDS–II Donor Iron Status Evaluation (RISE) Study,'' (Ref. 50). The authors reported a high prevalence of iron depletion in frequent blood donors. As recommended by the comments, FDA has considered the results of the REDS–II–RISE study in determining appropriate hemoglobin standards for this rule. We agree that the study provides important new information on hemoglobin levels in donors, and supports increasing the minimum hemoglobin/hematocrit requirements for male donors. We recognize that this is an important donor safety issue, and we will continue to review the scientific data as we consider these issues in the future.

(Comment 67) We received one comment supporting lowering the hemoglobin level for women and one opposing lowering the hemoglobin level for women. The comment supporting a lower minimum hemoglobin level stated that a hemoglobin level of 12.0 grams per deciliter of blood was normal for women, and allowing such donors to donate would improve blood availability. The comment opposing lowering the minimum hemoglobin level stated that this practice would make more women susceptible to anemia and iron deficiency.

(Response) For female allogeneic donors, the current minimum hemoglobin/hematocrit levels remain the default minimum levels under this rule. In the event that an establishment takes additional steps that are adequate to assure donor safety an establishment may collect from female donors with normal, but lower, hemoglobin levels, between 12.0 and 12.5 grams per deciliter of blood, or a hematocrit value between 36 and 38 percent, provided the establishment has taken additional steps to assure that this alternative standard is adequate to ensure that the health of the donor will not be adversely affected due to the donation, in accordance with a procedure that has been found acceptable for this purpose by FDA. We have not yet found such a procedure adequate for this purpose. However, we recognize that, in the future, new data may support revised hemoglobin/hematocrit standards for female allogeneic donors, particularly if it becomes possible to measure other values, including iron stores, before donation. In determining or recognizing an alternative measure, FDA intends to consider other evidence related to donor health, including iron stores. Until then, establishments must follow the current standard for female allogeneic donors: A hemoglobin level of 12.5 grams per deciliter of blood or a hematocrit value of 38 percent.

(Comment 68) One comment stated that changing the hemoglobin level could affect cleared devices as some are cleared based on a specified hemoglobin/hematocrit lower limit.

(Response) We recognize that some operator's manuals for apheresis devices describe the minimum hemoglobin level of 12.5 grams per deciliter of blood, or a hematocrit value of 38 percent, and that these references would need to be updated to reflect the new minimum standard for male donors. In addition, related changes to apheresis device software may be needed.

d. *Pulse (§ 630.10(f)(4)).*

Current regulations require that a donor of Source Plasma have a normal pulse, but do not specify a related requirement for donors of Whole Blood or other blood components. We proposed in § 630.10(h)(4) to require that all donors have a regular pulse that measures between 50 and 100 beats per minute. A donor with an irregular pulse or measurements outside these limits would be permitted to donate only when the responsible physician has examined the donor and determines and documents that the health of the donor would not be adversely affected by donating. We have finalized this provision in § 630.10(f)(4) with one change. The final rule provides that a donor with an irregular pulse or measurements outside these limits may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating. This determination may be made by the responsible physician on the basis of an assessment of the donor's information (for example, the responsible physician may conclude that the donor's low pulse rate is due to regular marathon running). This provision thus does not require that the responsible physician personally examine the donor. Note that under final § 630.5(b)(1)(i)(B) and (c)(1)(i)(A)(*2*), the responsible physician cannot delegate this determination that the donor's health would not be adversely affected by donating.

(Comment 69) Several comments opposed adding a requirement for determining that the donor has a regular pulse between 50 and 100 beats per minute. One comment indicated that the physician should examine the donor for any irregularity in their pulse, not just a pulse outside the proposed limits.

(Response) To assure that donors are in good health and will not be adversely affected by donating, we are finalizing the requirement to measure the donor's pulse and assess eligibility based on pulse rate and regularity. In November 2009, FDA asked the Blood Products Advisory Committee if available data support the utility of obtaining pre-donation pulse measurements as predictors of risk of adverse response to donation. The majority of the committee agreed (10 yes votes, 8 no votes) that pulse measurement was a predictor of risk of adverse response to donation. In particular, high pulse rates may be associated with higher rates of vasovagal reactions. We also agree with the comment that an irregular pulse can indicate that a donor is not in good health (Ref. 51). Therefore, final § 630.10(f)(4) requires that the donor's pulse must be regular and between 50 and 100 beats per minute—no less than 50 beats per minute, and no more than 100 beats per minute. A donor with an irregular pulse or measurements outside these limits is ineligible unless the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(Comment 70) One comment asserted that a phone consultation between the blood collection center and the responsible physician should be sufficient to determine whether a donor

with an irregular pulse can donate, rather than the proposed requirement that responsible physician actually ''examine'' the donor. For example, the comment stated that their blood collection center routinely permits the responsible physician on-call to give phone authorization for donors with pulse rates between 40 and 50 beats per minute to donate, when it is ascertained by the donor's history that the donor is an athlete.

(Response) We agree with the comment. A donor with an irregular pulse or measurements outside the limits provided in final § 630.10(f)(4) may be permitted to donate when the responsible physician has determined that the health of the donor would not be adversely affected by donating. We have not finalized a requirement that the responsible physician must examine the donor, and we provide that in appropriate circumstances the responsible physician may make a determination of whether a donor's health would be adversely affected by donating blood or blood components. Such a determination may be reached by a phone consultation between the establishment and the responsible physician, though under § 630.5(b)(1)(i)(B) and (c)(1)(i)(A)(*2*), the responsible physician cannot delegate the determination that the donor's health would not be adversely affected by donating.

e. *Weight (§ 630.10(f)(5)).*

We proposed in § 630.10(h)(5) that a donor weigh a minimum of 50 kilograms (110 pounds) and not have any unexplained loss of greater than 10 percent of body weight within the past 6 months. We are finalizing the requirement that donors weigh at least 110 pounds, but have not finalized the requirement related to unexplained weight loss.

(Comments 71) Several comments suggested deleting the requirement to assess the donor's weight because most blood establishments do not currently weigh donors. Several comments said there was no justification for the 110 pounds lower weight limit and that deferrals based on the overall health of the donor were better addressed through the donor history questionnaire.

(Response) Section 630.10(f)(5) does not require blood establishments to weigh Whole Blood donors. Blood establishments may make this determination by asking a donor whether the donor weighs at least 110 pounds.

f. *Skin examination (§ 630.10(f)(6)).*

In proposed § 630.10(h)(6) we proposed requirements that: (1) The donor's phlebotomy site be free of evidence of infection, inflammation, lesions, and pitted skin and (2) the donor's arms and forearms be free of punctures and scars indicative of injected drugs of abuse. We have finalized these provisions, except that we have deleted the reference to ''pitted skin''.

(Comment 72) One comment recommended that FDA not include the term ''pitted skin'' from the final rule. The comment stated frequent plasmapheresis donors would be expected to have pitted areas of their skin due to the needle punctures for their donations as frequently as twice per week. The comments asserted that a close examination for pitted skin could lead to deferral of committed donors.

(Response) We agree with the comment that frequent donors often have pitted areas of their skin due to needle punctures. Therefore, we do not include the term pitted skin in § 630.10(f)(6) of the final rule, and require only that the donor's arms must be free of infection, inflammation, and lesions. We note that pitted skin may be more difficult to decontaminate, which may affect the choice of the phlebotomy site.

7. Section 630.10(g)

a. *Proof of identity and postal address (§ 630.10(g)(1)).*

We proposed in § 630.10(i)(1) that collection establishments obtain, before donation, proof of the donor's identity and a mailing address where the donor may be contacted for 8 weeks following donation. Establishments are currently required to maintain a record of this address in the donor record as required under § 606.160(b)(1)(x) (redesignated in this rule as § 606.160(b)(1)(ix)). Establishments may use this information to contact the donor to communicate regarding test results for evidence of infection, as required under § 630.40. We are finalizing this provision as proposed, except that the final rule specifies that the donor's mailing address must be a postal address.

(Comment 73) One comment suggested that the donor's name and last four digits of their Social Security Number (United States) or Social Insurance Number (Canada), with proof of an address, would be adequate proof of a donor's identification. Another comment stated that it is not always possible to obtain photographic identification, stating that members of certain groups are reluctant to have their photographs taken. The comment stated that FDA should allow for other means of identifying the donor.

(Response) We have finalized the rule to require that blood establishments obtain proof of identity of the donor prior to donation. However, we have not specified the means of establishing proof. We believe that photographic identification, a valid driver's license, validated biometric means, or other means can be useful in establishing the donor's identity. Establishments must include procedures for establishing donor identity in their standard operating procedures under § 606.100(b). We also note that, while this provision establishes a requirement for Whole Blood donors, § 640.65(b)(3) has long required Source Plasma establishment to have a donor identification system in place. For Source Plasma establishments, § 630.10(g)(1) does not add new requirements.

(Comment 74) We received several comments objecting to the requirement to obtain an address where the donor may be contacted for 8 weeks after donation. One comment stated that this provision would have an impact on blood collection on college campuses due to the movement of college students to other addresses for the summer. One comment referenced information from the United States Postal Service, indicating that most individuals who move do leave a forwarding address. The comment suggested that donors can be contacted through this mechanism. The comment further suggested that newer communication technologies such as email and cell phones can be used for notification purposes when necessary.

(Response) We have finalized the rule to require that blood establishments obtain a postal address where the donor may be contacted for 8 weeks after donation. This provision supports effective communication on issues that may be important to the donor and his or her contacts. We recognize that, when the donors are found ineligible prior to collection, they are deferred and notified of the reasons for their deferral at the blood center. However, communication with the donor becomes necessary after donation due to reactive or positive test results obtained on the donation. We believe that most establishments invite the donor back to the donor center to inform the donor of reactive or positive infectious disease test results on the donation. We do not believe that the provision improperly burdens blood establishments because of college students and other mobile populations. Student donors would provide the postal address where they expect to be in residence if they plan to leave school during the 8 weeks

following donation. We recognize that other means of contact, such as email or telephone, may permit more rapid communication. Establishments may also request an email address or telephone number, although the rule does not require establishments to collect this information. If the donor has been successfully contacted by other means, then we do not require that contact be made using the postal service.

b. *Donor acknowledgement (§ 630.10(g)(2)).*

In proposed § 630.10(i)(2), we proposed to require establishments to provide the donor with a written statement of understanding to be read and signed by the donor. The establishment would be required to use procedures to assure that the donor understands the material provided in the statement, which must not include language that would waive any of the donor's legal rights and must address seven elements: (1) The donor statement that he or she has reviewed the educational material required by § 630.10(b); (2) the donor's agreement not to donate if the donation could put the blood supply at risk; (3) testing of the donor's blood; (4) additional testing of the donor's blood if initial tests are reactive; (5) the consequences if the donation is determined not to be suitable, or if the donor is ineligible; (6) the risks and hazards of the specific donation procedure or of immunization, if applicable; and (7) the donor's opportunity to ask questions and withdraw consent at any time.

We have modified the provision after considering comments received to the proposed rule and the recommendations made from the Blood Products Advisory Committee at the April 28–29, 2011, meeting (Ref. 52). For clarity, we now call this ''Donor's acknowledgement,'' instead of the proposed ''Donor's written statement of understanding.'' The statement does not have to be in a written form only, although it must provide for a signature or other documented acknowledgement.

In proposed § 630.10(i)(2)(iv), we proposed to require that the donor be informed that a blood sample will be tested for specified relevant transfusion-transmitted infections and that the further testing might be required for reactive donations. Although we are finalizing the requirement that the donor be informed of infectious disease testing, following the recommendation of the Blood Products Advisory Committee at the April 2011 meeting (Ref. 52), we are not finalizing a requirement that the donor acknowledge that infectious disease testing may include additional testing of reactive samples (proposed § 630.10(i)(2)(iv)). We are not including this detailed requirement in the final rule, and are finalizing 6 out of the 7 proposed requirements.

We have also clarified the requirement that the donor be informed of the risks and hazards of the donation procedure. We now require in § 630.10(g)(2)(ii)(E) that the donor acknowledgement include acknowledgment that the donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure that the donor will undergo. This is required for every donation of blood and blood components, including Source Plasma and other donations by apheresis. We are finalizing this section with the additional modifications discussed in our responses to comments.

(Comment 75) One comment questioned the use of the term ''understanding'' as used in ''written statement of understanding'' in proposed § 630.10(i)(2).

(Response) We have revised the provision to require that the donor acknowledge that the donor has read the material provided. Accordingly, we now designate this as ''Donor's acknowledgement''.

(Comment 76) We were also asked how this section relates to other sections of the existing Source Plasma regulations on informed consent.

(Response) For collections of plasma and platelets for apheresis, §§ 630.15(b) and 640.21(g) require establishments to engage the donor at least annually in an informed consent dialogue. See discussion in comments 86 and 117. The requirement to obtain a donor acknowledgement applies to every collection of blood and blood components, including apheresis collections of plasma and platelets. The donor's acknowledgement must be obtained at each donation.

(Comment 77) Several comments objected to a requirement that the donor ''sign'' a statement and urged FDA to allow an electronic signature.

(Response) We agree that this requirement can be satisfied by an electronic signature. Final § 630.10(g)(2)(i) requires that the donor's acknowledgement be provided by signature or other documented acknowledgement.

8. Section 630.10(h)

We have added § 630.10(h) to make explicit a requirement in the proposed regulation. Section 630.10(h) provides that a blood establishment must not collect from a donor found, before collection, to be ineligible, unless an exception exists. In addition, we incorporated existing requirements to defer donors found to be ineligible and to notify the donors of their deferral as required in § 630.40(a).

K. Donor Eligibility Requirements Specific to Whole Blood, Red Blood Cells and Plasma Collected by Apheresis (§ 630.15)

Section 630.15(a) establishes donor eligibility requirements for the collection of Whole Blood and Red Blood Cells collected by apheresis, and § 630.15(b) establishes donor eligibility requirements for collections of Source Plasma and plasma collected by plasmapheresis. These requirements are in addition to those in § 630.10.

For donors of Whole Blood and Red Blood Cells collected by apheresis, this rule requires that donation frequency be consistent with protecting the donor's health, describes minimum intervals between donations, and addresses donations by donors undergoing therapeutic phlebotomy. We have added references to Red Blood Cells collected by apheresis to the heading and at several points in this section to clarify the applicability of § 630.15(a) to Red Blood Cells collected by apheresis.

For donors of Source Plasma and plasma collected by plasmapheresis, the rule requires the responsible physician, subject to § 630.5(c), to conduct an appropriate medical history and physical examination of the donor. Additionally, blood establishments are required to weigh the donor before each plasmapheresis procedure and to assess the donor's total protein level prior to each donation. This provision includes a requirement in § 630.15(b)(1)(ii) to defer a plasmapheresis donor found to have a medical condition that would place the donor at risk from plasmapheresis, and to defer a donor because of red blood cell loss as described in the rule. This section also contains informed consent requirements for donors of Source Plasma and plasma collected by plasmapheresis. These provisions complement other requirements for the collection of plasma by plasmapheresis in part 640 and part 630, including restrictions on frequency of collection as specified in §§ 640.32 and 640.65. In addition § 630.15(b)(1) cross-references certain exceptions provided for plasmapheresis collections from infrequent plasma donors in § 630.25.

1. Section 630.15(a)

Consistent with the proposed rule, final § 630.15(a)(1) requires that for a

collection resulting in a single unit of Whole Blood or Red Blood Cells collected by apheresis, the donation frequency must be no more than once in 8 weeks. For an apheresis collection resulting in two units of Red Blood Cells, the donor must not donate more than once in 16 weeks. These limitations on donation frequency reflect long standing donation interval practices established to protect the donor from potential health risks associated with frequent donations of Whole Blood or Red Blood Cells. The purpose of these provisions is to protect the health of the donor and allow time for red blood cell recovery. In § 630.15(a)(1)(ii), we provide two exceptions to the donation interval: (1) The donation is for autologous use as prescribed by the donor's physician and the responsible physician determines and documents that the donation may proceed or (2) the donation is a dedicated donation based on the intended recipient's documented exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating. In the final rule, we added the term ''exceptional'' to clarify that this exception to donation frequency should apply only in those rare situations where the recipient's need for a component from a donor with particular characteristics is exceptional. For example, it may be appropriate to rely on this exception in the event that a recipient needs a blood component that is negative for a rare blood cell antigen. Under this exceptional medical need provision, the responsible physician must examine the donor and determine and document that the health of the donor would not be adversely affected by donating. Under § 630.5(b)(1)(i), the responsible physician is not authorized to delegate the examination of the donor or the determination that the health of the donor would not be adversely affected by donating.

For clarity, the requirements regarding therapeutic phlebotomy have been consolidated in the final rule in § 630.15(a)(2).

(Comment 78) One comment stated that the applicability of proposed § 630.15 to Red Blood Cells collected by apheresis was unclear. The comment stated that ''double unit collection programs,'' often have additional and different donor eligibility requirements, as described in proposed § 630.15(a)(1).

(Response) Final § 630.15(a) now more expressly includes Red Blood Cells collected by apheresis. Final § 630.15(a)(1) establishes minimum time intervals between collections of Whole Blood, and single and double units of Red Blood Cells by apheresis. These time intervals are consistent with existing regulations and guidance. This addition makes explicit what was less directly stated in the proposed rule. Proposed § 630.15(a)(1) referred to ''double unit collection programs,'' which are double Red Blood Cell collections by apheresis. Moreover, proposed § 640.12 required establishments to determine the eligibility of donors of Red Blood Cells in accordance with §§ 630.10 and 630.15.

(Comment 79) One comment stated that FDA should not specify 8 and 16 week donation intervals. Instead, the comment recommended that a blood establishment determine donation frequency without reference to a specific donation interval, taking into account the donor history, the results of a limited physical examination, the participation of a medical director or his or her designee, and the blood center's procedures. Another comment recommended that a physician be allowed to authorize more frequent collection by certifying that the prospective donor has recovered from the prior donation without evidence of residual effects or to allow the physician to simply certify that the prospective donor meets his/her requirements for a repeat donation on the day of the examination.

(Response) FDA regulations have long specified a minimum interval of 8 weeks between Whole Blood donations, unless a physician examines the donor and certifies the donor to be in good health. FDA is finalizing minimum donation intervals in this rule to protect the health of donors of Whole Blood and Red Blood Cells collected by apheresis because too frequent donation may adversely affect a donor's health (Refs. 47, 48). In the final rule at § 630.15(a)(1), we are retaining a minimum requirement for an 8 week interval between the donation of a unit of Whole Blood or donation of a single unit of Red Blood Cells by apheresis, and requiring a 16 week interval after a double collection of Red Blood Cells. A 16 week interval following a double collection of Red Blood Cells is recommended in current FDA guidance (Ref. 53). Blood establishments are free to establish longer donation intervals.

We have provided a limited exception to these donation intervals to allow for more frequent collections for: (1) An autologous donation as prescribed by the donor's physician only when the donor has been examined by the responsible physician who determines and documents that the donation may proceed and (2) a dedicated donation based on the intended recipient's documented exceptional medical need, only when the responsible physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating.

(Comment 80) Several comments requested that we clarify in the final rule that donors with hereditary hemochromatosis can donate more frequently than the 8 week interval set forth in proposed § 630.15(a)(1) and also to clarify that more frequent donations from such donors may be collected more frequently without an exception or alternative under § 640.120.

(Response) Final § 630.15(a)(2) states clearly that a donation may be collected from a donor more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or 16 weeks for apheresis collections resulting in a double collection of Red Blood Cells, when the donor is determined to be eligible under § 630.10 and the collection is a physician-ordered therapeutic phlebotomy of a donor, including a donor with hereditary hemochromatosis. Establishments do not need an exception or alternative under § 640.120 to make a collection under this provision if the requirements set forth in § 630.15(a)(2) are met.

(Comment 81) One comment recommended that the term ''iron overload'' should be substituted for the term ''hereditary hemochromatosis'' in the provision providing an exception to the requirement to label a collection with the disease state of a donor undergoing therapeutic phlebotomy.

(Response) We decline to substitute the term ''iron overload'' for the term ''hereditary hemochromatosis'' in final § 630.15(a)(2). The term, ''iron overload'' describes imprecisely the donors for whom establishments would perform phlebotomies without charge. However, we agree with the comment that this provision may, at some time in the future, appropriately be applied to collections from donors whose therapeutic phlebotomy is necessitated by a disease or condition other than hereditary hemochromatosis. Accordingly, final § 630.15(a)(2) provides that no labeling for the disease or condition is required if: (i) The donor meets all eligibility criteria; (ii) the donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider treating the donor for (A) hereditary hemochromatosis; or (B) another disease or condition, when the health of a donor with that disease or condition will not be adversely

affected by donating, the donor's disease or condition will not adversely affect the safety, purity, and potency of the blood and blood components collected, or any products manufactured from them, and the collection is in accordance with a procedure that has been found acceptable for this purpose by FDA; and (iii) the establishment performs without charge therapeutic phlebotomies for all individuals with that disease or condition. Labeling to identify the disease state or condition that necessitated the therapeutic phlebotomy is still required when these criteria are not met.

(Comment 82) Another comment suggested that the final rule should not require a physical examination by a responsible physician at the time of donation for individuals presenting a prescription for therapeutic phlebotomy for medical reasons. The comment observed that the 2001 guidance document entitled, ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis,'' (Ref. 54) did not provide for such a physical examination for exceptions or alternatives granted in accordance with that guidance document.

(Response) We agree with this suggestion. The final rule does not require that an individual undergoing a prescribed therapeutic phlebotomy to promote the donor's health be examined by a responsible physician at the time of donation. The physical assessment required for all donors under § 630.10(f) still applies, however.

(Comment 83) One comment supported the proposal that disease labeling would not be required for blood and blood components donated by an individual with hereditary hemochromatosis if the donor meets all eligibility criteria and the collecting establishment performs therapeutic phlebotomies without charge for all individuals with hereditary hemochromatosis, including those who need therapeutic phlebotomy but do not wish or are not eligible to donate. However, the comment recommended that the final rule authorize blood establishments to accept grants and gifts from third parties, including partial insurance coverage, related to the costs of phlebotomy.

(Response) The final rule provides that blood establishments do not have to label donations from a donor with hereditary hemochromatosis with the donor's disease state if the donor is eligible and the establishment does not charge anyone with hereditary hemochromatosis (or another disease or condition, if the conditions in the regulation are met) for therapeutic phlebotomy. This provision is intended to remove the incentive for an individual with hereditary hemochromatosis to provide untruthful answers to donor eligibility questions for a blood donation in order to receive the benefit of a phlebotomy without charge. If a blood establishment charged a fee for an ineligible donor to undergo a therapeutic phlebotomy, but not for an eligible donor with hereditary hemochromatosis, the ineligible hereditary hemochromatosis donor would have an incentive to deny risk conditions that might preclude cost-free donation (Ref. 55). This policy is in part based on recommendations of the Advisory Committee on Blood Safety and Availability (Ref. 56). We decline to modify this provision to address the acceptance of grants, gifts, or insurance payments. We note that we did not propose such a provision, and we believe that a reference to grants, gifts, or insurance payments could confuse patients seeking a therapeutic phlebotomy.

(Comment 84) One comment suggested that hospitals that transfuse suitable blood and blood components labeled with the donor's iron overload disease state should include a statement to that effect in their informed consent for transfusion.

(Response) This rule does not address the content of hospital discussions related to informed consent for transfusion. Final § 630.15(a)(2) authorizes blood establishments to collect blood and blood components only from donors, including donors with hereditary hemochromatosis, determined to be eligible. Blood from hereditary hemochromatosis donors has been used for transfusion in other countries without reports of adverse events in recipients (Refs. 57, 58, 59).

1. Section 630.15(b)

We revised proposed § 630.15(b)(1), formerly entitled ''Physical examination and informed consent,'' by dividing it into two sections. This clarifies that separate requirements apply for the medical history and physical examination (final § 630.15(b)(1)) and for obtaining informed consent (final § 630.15(b)(2)). As a result, proposed § 630.15(b)(2) through (b)(7) are finalized as § 630.15(b)(3) through (b)(8).

a. *Medical history and physical examination (§ 630.15(b)(1)).*

This section, titled ''Physical examination and informed consent'' in the proposed rule, is now titled ''Medical history and physical examination.'' Informed consent requirements are now addressed in § 630.15(b)(2). The new heading more accurately describes the assessment required under this section. As proposed, we would have required the responsible physician to examine the donor for medical conditions that would place the donor at risk during plasmapheresis. We intended for this physical examination to include conducting an appropriate medical history and physical examination to identify medical conditions that may place the donor at risk from plasmapheresis.

(Comment 85) One comment stated that FDA should not require a responsible physician to examine the donor before the initial donation and at least annually thereafter. The comment asserted that plasmapheresis collection has been in place for years without risk to donors. The comment also stated that an annual and initial exam is unnecessary for infrequent plasma donors and donors not participating in immunization programs.

(Response) Examination by a qualified licensed physician is already required under current § 640.63(b) for all Source Plasma donors, and we believe that the requirement to conduct a medical history and physical examination before the first donation, and at least annually thereafter, contributes to the safety record of these collections. We have modified this requirement by authorizing the responsible physician in § 630.5(c)(3) to delegate this activity to a physician substitute, as defined in § 630.3(g). During the annual physical, donors may be examined for a variety of conditions, such as heart disease, seizures, trouble breathing, allergies, recent medical operations, or medications, in order to ensure that donating will not adversely affect the health of the donor. Such evaluations would include a physical examination and medical history which might identify medications or underlying medical conditions that would lead to donor deferral. Because frequent donation by plasmapheresis of plasma for transfusion raises similar donor safety concerns, this requirement now applies to collections from frequent plasmapheresis donors, and not only to Source Plasma donors.

However, we agree with the comment that an annual and initial examination is unnecessary for an infrequent plasma donor, as defined in § 630.3(e). Final § 630.25 provides certain exceptions from donor eligibility requirements for infrequent plasma donors, including the requirement for an enhanced medical history and physical examination under § 630.15. These donors remain subject to

the requirements for medical history and physical assessment under § 630.10.

b. *What requirements apply to obtaining informed consent? (§ 630.15(b)(2)).*

(Comment 86) Several comments stated that for plasmapheresis donors, the distinction between the written statement of understanding and informed consent should be clarified.

(Response) We have clarified that the written statement of understanding, renamed and revised as the donor's acknowledgement in final § 630.10(g)(2), applies to the collection of all blood and blood components, including Source Plasma and plasmapheresis collections. Informed consent for Source Plasma donation has long been required under current § 640.61, and this rule continues those requirements for Source Plasma and plasmapheresis collections. In recognition that the donation of Source Plasma and plasma by plasmapheresis may present additional and potentially greater risks to the donors, § 630.15(b)(2) requires the responsible physician to obtain the informed consent of such a donor on the first day of donation or no more than 1 week before the first donation. Section 630.5 addresses the authority of the responsible physician to delegate this task. The responsible physician must explain the risks and hazards of the procedure to the donor. The explanation must be made in such a manner that the donor may ask questions of the responsible physician. The explanation must also give the donor a clear opportunity to refuse the procedure. This informed consent process involves a dialogue between the donor and the responsible physician. The establishment must obtain informed consent from these donors at least once every year. If a donor does not return for 6 months, the establishment must obtain informed consent again. If new risks and hazards are identified, or if the donor is enrolled in a new program such as an immunization or special collection program, then a new informed consent, addressing the specific risks and hazards of that program, must be obtained. The informed consent requirements in § 630.15(b)(2) are in addition to the donor acknowledgement, which under § 630.10(g)(2), must be obtained from the donor at each donation.

c. *Weight (§ 630.15(b)(3)).*

Section 630.15(b)(2) of the proposed rule would have required that establishments determine a donor's weight at each donation of plasma by plasmapheresis. We received several comments regarding this provision, which we address in this rule, and are finalizing this provision in § 630.15(b)(3) as proposed.

(Comment 87) Two comments asserted that weighing a donor at each donation is not useful. One comment further stated that donors are not weighed prior to plateletpheresis procedures, and there is no evidence that asking the donor to state their weight, as opposed to weighing donors, has been unsafe. The comment further asserted that it would not make sense to require a donor to be weighed prior to a co-collection of plasma and platelets by apheresis as donors are currently not weighed prior to triple plateletpheresis procedures, and there have been no adverse events.

(Response) We are finalizing this provision as proposed, and require establishments to weigh a donor before collecting plasma by plasmapheresis. A current weight measurement permits the collecting establishment to calculate accurately the plasma volumes to be collected based on a weight specific nomogram. The need for accurate measurement applies to all collections by plasmapheresis, whether Source Plasma, or frequent or infrequent plasmapheresis collection. We have not included a requirement to weigh plateletpheresis donors. The instructions for use for the apheresis devices used for such collections vary concerning whether they require the user to weigh the donor. Instead, establishments would address donor weight in their standard operating procedures for plateletpheresis collection in a manner that is consistent with the instructions for use (operator's manual) for the apheresis devices used by the establishment to collect platelets.

When there is a co-collection including plasma by apheresis, this provision requires the establishment to weigh the donor because the collection of plasma by apheresis will be based on the donor's weight. In addition, the instruction for use, including the operator's manual of the device used to collect platelets by apheresis, may include an instruction to determine the donor's weight for co-collections with plasma.

(Comment 88) One comment also recommended that in addition to weighing donors at Source Plasma establishments, the donor's height be taken once a year. The comment suggested that conversion of the measurement of height and weight to lean body mass should be the basis for the quantity of plasma removed.

(Response) Measuring the donor's height combined with measuring a donor's weight may be useful in identifying and using a more accurate nomogram to determine the maximum quantity of plasma that should be collected from the donor by plasmapheresis. However, we believe donors are able to accurately report their height, which is less likely to fluctuate over time than their weight. Therefore, § 630.15(b)(3) requires establishments to weigh each donor prior to each donation, while permitting reliance on a donor's self-reported height when needed to determine an accurate nomogram for the maximum quantity of plasma that should be collected. We note that under current § 606.65(e) establishments must follow the device instructions for use and operators manual of the apheresis collection device.

d. *Total protein level (§ 630.15(b)(4)).*

We are finalizing the requirement for collection establishments to test the donor's blood sample for total plasma protein, and that the donor have a value of no less than 6.0 grams per deciliter and no more than 9.0 grams per deciliter. Consistent with current § 640.63(c)(5) and proposed § 630.15(b)(4), this section requires establishments to continue the practice of assessing protein levels before each plasmapheresis procedure. In addition, we are maintaining the existing requirement in current § 640.65(b)(1)(i), which requires establishments to assess a Source Plasma donor's total protein levels, and to perform a plasma or serum protein electrophoresis or quantitative immuno-diffusion test or an equivalent test to determine immunoglobulin composition of the plasma or serum, on the day of the first medical examination or plasmapheresis, and at least every 4 months thereafter. Final § 640.65(b)(2)(i) requires the responsible physician to review the accumulated laboratory data, including any tracings of the plasma or serum protein electrophoresis pattern, the calculated values of the protein composition of each component, and the collection records within 14 calendar days after the sample is drawn to determine whether or not the donor should be deferred from further donation. Comments on § 640.65(b)(2)(i) are discussed at comment 118.

(Comment 89) Several comments questioned the validity of the proposal to require 9.0 grams protein per deciliter value for the upper limit for total plasma protein. One comment stated the requirement for total protein should specify that the donor's total plasma or serum protein must have a value of no less than 6.0 grams per deciliter and that the acceptable upper limit may be established based on applicable

statistical analysis of test results on their donors.

(Response) After further consideration, we are finalizing these limits largely as proposed. We consider the lower limit, no less than 6.0 grams protein per deciliter, and the total upper limit of 9.0 grams protein per deciliter in a plasma or serum sample, as appropriate measurement parameters to ensure the donor's health. We have determined that the reference ranges for testing protein in serum and plasma are comparable (Ref. 60); the final rule now applies these lower and upper limits whether testing is performed on either a plasma or serum sample. Although the comments questioned the value of an upper limit, we consider an upper limit to be necessary to ensure donor health, because high protein levels can be associated with adverse health conditions, such as plasma cell dyscrasias (Ref. 61).

(Comment 90) Another comment suggested FDA should consider a flexible regulation to allow for the development of an acceptable alternative to the current procedures.

(Response) We have not identified a need to provide for a variable standard in this rule. An establishment that proposes to use a different standard may submit a request for an exception or alternative under § 640.120.

e. *Examination before immunization (§ 630.15(b)(5)).*

We have finalized § 630.15(b)(5) to be consistent with proposed § 630.15(b)(4), but we have revised the language for clarity. This section requires the responsible physician, subject to § 630.5, to conduct an appropriate medical history and physical examination of the donor no more than 1 week before the first immunization injection of a donor for the production of high-titer antibody plasma. This requires that the responsible physician conducts an appropriate medical history and physical examination, as described in § 630.15(b)(1), before the first immunization. It further provides an opportunity to obtain an informed consent specific for participation in an immunization program, as required in § 630.15(b)(2)(iv) (Ref. 62). However, it is not necessary to repeat the medical history and physical examination required in § 630.15(b)(1) if the immunized donor's plasma is collected within 3 weeks of the first immunization injection. Under § 630.15(b)(5)(ii), establishments are not required to re-examine a donor before immunizing the donor for the production of high-titer antibody plasma if the donor is currently participating in a plasmapheresis collection program and is eligible under § 630.10.

f. *Deferral of donors due to red blood cell loss (§ 630.15(b)(6)).*

For the safety of the donor, we are requiring establishments to defer donors from donating Source Plasma and plasma collected by plasmapheresis following red blood cell loss due to a donation of Whole Blood or Red Blood Cells collected by apheresis. Establishments must also ensure that the cumulative red blood cell loss resulting from previous donations does not adversely affect the health of the donor.

Under final § 630.15(b)(6)(i), establishments must defer a donor from donating plasma by plasmapheresis for 8 weeks following a donation of Whole Blood or a single unit of Red Blood Cells by apheresis. However, establishments may collect Plasma by plasmapheresis 48 hours after a donation of Whole Blood or a single unit of Red Blood Cells, provided the extracorporeal volume of the apheresis collection device is less than 100 mL (§ 630.15(b)(6)(i)). We authorize collection under these circumstances because the risk of red blood cell loss in the donor is lower. The limited volume of the extracorporeal circuit limits the donor's potential red blood cell loss in routine apheresis collection. In addition, under § 630.15(b)(6)(ii), plasma donors must be deferred for 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure. Final § 630.15(b)(6)(iii) requires deferral for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

We have not finalized the provisions in the proposed rule that would have required deferral after red blood cell loss of equal to or greater than 200 mL (proposed § 630.15(b)(5)(i) and (b)(5)(iii)). We recognize that it is difficult to measure the amount of blood lost in order to determine whether the volume is equal to or greater than 200 mL. Instead, we are finalizing the requirement in § 630.15(b)(6)(iii) to defer the donor if the donor's cumulative red blood cell loss in any 8 week period could adversely affect donor health. We have addressed deferral due to red blood cell loss in guidance (Ref. 63) and intend to issue future guidance on the impact of the cumulative red blood cell loss following frequent apheresis procedures.

(Comment 91) One comment noted that FDA's guidance, ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods,'' which published in December 2007 during the comment period for the proposed rule, contained recommendations for 16 week deferral of platelet donors who experienced losses of red blood cells of 300 mL or more. The comment recommended that 16 week deferrals for larger red blood cell loss should be included for plasma donors in this final rule.

(Response) We agree with this comment about the relevance of FDA's recommendations in ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods,'' hereafter, referred to as the ''2007 Guidance'' (Ref. 64). Because the risks associated with red blood cell loss are comparable for donors of plasma and platelets by apheresis, § 630.15(b)(6)(iii) requires establishments to defer for 16 weeks plasma donors who donate two units of Red Blood Cells during a single apheresis procedure.

(Comment 92) Another comment stated that specific deferral periods are unnecessarily restrictive, and that there should be a provision similar to that in the proposed rule at § 640.21(e), to the effect that collection of plasma by apheresis should be permitted following a donation of Whole Blood or other red cell loss, if the extracorporeal red blood cell volume for the apheresis device is less than or equal to 100 mL. The comment noted that most of the plasma collected by apheresis from volunteer blood donors is plasma collected concurrently with apheresis platelets. The comment stated that since FDA recognizes that plateletpheresis collection is safe in this circumstance, it does not make sense to have more restrictive criteria for the collection of plasma by apheresis during plateletpheresis, as the red blood cell loss would be the same for these procedures.

(Response) We recognize that a co-collection of Plasma and Platelets may occur and we agree that the risks associated with red blood cell loss for collections of Source Plasma and Plasma by apheresis are similar to those for collections of Platelets by apheresis. The requirements for deferral of Plasma donors due to red blood cell loss following Whole Blood or Red Blood Cell donation or inadvertent red blood cell loss are addressed in this section. Separately, we are finalizing a corresponding provision for the deferral of Platelet donors due to Whole Blood or Red Blood Cell donation or red blood cell loss in § 640.21. We intend for the deferrals for red blood cell loss to be the same for all collections of Plasma and Platelets by apheresis, including co-collections, because we consider the

risks of red blood cell loss to be the same.

In the final rule, we require the deferral of plasmapheresis donors following the donation of Whole Blood and Red Blood Cells, and because of cumulative red blood cell loss over time. Consistent with the final requirements for Platelets in § 640.21, § 630.15(b)(6)(i) permits the collection of Source Plasma and Plasma by plasmapheresis 2 days after a donation of Whole Blood or a single unit of Red Blood Cells, provided the extracorporeal volume of the apheresis collection device is less than 100 mL.

g. *Exceptions to deferral due to red blood cell loss (§ 630.15(b)(7)).*

Final § 630.15(b)(7) provides an exception to deferral due to red blood cell loss for certain Source Plasma donors. While the introductory paragraph of proposed § 630.15(b)(6) referred to participation in a plasmapheresis program instead of to Source Plasma collections, we finalized this exception using the more explicit term ''Source Plasma.'' In proposed § 630.15(b)(6)(i), the responsible physician would have been required to conduct an examination and ''certify'' the donor's good health; final § 630.15(b)(7)(i) requires that the responsible physician examine the donor at the time of the current donation and determine and document that the donor is in good health and the donor's health permits the plasmapheresis. Under § 630.5(c)(1)(i)(A), the responsible physician is not authorized to delegate this examination and determination. In proposed § 630.15(b)(6)(ii), this exception would apply when the ''donor possesses an antibody that is transitory, of a highly unusual or infrequent specificity, or of an unusually high titer.'' In final § 630.15(b)(7)(ii), the exception is reserved for donors whose plasma possesses a property such as an antibody, antigen, or protein deficiency, that is transitory, of a highly unusual or infrequent specificity, or of an unusually high titer. This reference to the donor's plasma, instead of the narrower reference to an ''antibody'' in the plasma is repeated in final § 630.15(b)(7)(iii), which requires the establishment to document the special characteristics of the donor's plasma and the need for plasmapheresis of that donor. We altered this provision to refer more generally to the unusual characteristics of the plasma, rather than to a specific antibody, because we recognized that this exception should be available under appropriate circumstances where the donor's plasma has other unusual characteristics, such as a rare antigen. As additional protection against additional red blood cell loss in a collection under this provision, final § 630.15(b)(7)(iv) provides that the extracorporeal volume of the apheresis device used to collect plasma under this provision must be less than 100 mL. We note that donors who donate subject to this exception must be advised of the risks and hazards related to this donation under §§ 630.10(g)(2) and 630.15(b)(2), or under § 630.15(b)(2)(iv), if the donor is newly enrolled in the program.

(Comment 93) One comment asserted that the statement in the proposed rule at § 630.15(b)(6)(ii), ''the donor possesses an antibody that is transitory. . .'' requires modification. The comment stated that the usual antibody characterized this way would be anti-Jka or -Jkb. The comment continued that it would be difficult to determine whether the plasma was collected from someone who has an antibody that is transitory before it is collected. The comment recommended the language be changed to state, ''donor's plasma contains an antibody. . .''

(Response) We are retaining the word ''transitory'' in final § 630.15(b)(7), although it now refers to a transitory property in the donor's plasma, rather than specifically to a transitory antibody. This provision is meant to apply to collections of plasma from individuals with specific transitory properties. These provisions apply only when an establishment knows that the donor's plasma has a particular property that is transitory.

h. *Malaria (§ 630.15(b)(8)).*

Consistent with proposed § 630.15(b)(7), final § 630.15(b)(8) does not require Source Plasma donors to be free from risk of malaria (for example, based on residence in or travel history to a malaria endemic area). We do not require establishments to screen Source Plasma donors for malaria risk factors because Source Plasma undergoes further manufacturing steps to effectively remove or inactivate pathogens such as the malaria parasite, and licensed plasma derivatives manufactured from Source Plasma have not transmitted malaria.

(Comment 94) Several comments agreed with our proposal to not require freedom from malaria risk for Source Plasma donors.

(Response) We are finalizing this provision as proposed.

(Comment 95) In response to our request for comments with supporting data concerning whether this provision should be expanded to donors of plasma for transfusion (72 FR 63416 at 63429), one comment supported not requiring an assessment of malaria risk, but did not provide supporting data. The comment stated that there is very low residual red blood cell contamination in a plasmapheresis product, and that the thawing process renders the malaria parasite non-viable. The comment also cited the lack of historical malaria transmission from Fresh Frozen Plasma.

(Response) The malaria parasite resides in red blood cells, and we recognize most red blood cells are removed from plasma collected by apheresis. There are limited data on the viability of malaria parasites in plasma and the residual red blood cells contained in plasma. However, plasma intended for transfusion, unlike Source Plasma used to manufacture plasma derivatives, does not undergo further manufacturing steps to remove or inactivate pathogens. Absent data demonstrating that the risk of transfusion-transmitted malaria is eliminated with plasma products intended for transfusions as well as a licensed test for malaria, we require that all donors, except Source Plasma donors, be assessed for risk of malaria.

(Comment 96) Two comments responded to our request for comments concerning whether Source Plasma donors should be screened for other parasitic diseases. The comments recommended that Source Plasma donors not be screened for other parasitic diseases, since, due to the nature of Source Plasma donation and the manufacturing process, these have no impact on product quality or safety. One comment urged FDA to distinguish between plasma collected for transfusion and plasma collected for further manufacture, and consider the intended final use of the products. The comment recommended that donors should not be screened for any pathogen that can be removed by filtration.

(Response) We are not including in this final rule a specific exemption for assessing Source Plasma donors for risk of all parasitic diseases; nor are we eliminating donor screening for pathogens that can potentially be removed by filtration or other manufacturing methods. Insufficient data were submitted in support of these proposals. We intend to address recommendations for donor screening and testing for specific new diseases identified as relevant transfusion-transmitted infections on a case by case basis. We recently chose not to recommend screening or testing of Source Plasma donors for Chagas disease, another parasitic infection (Ref. 24). We intend to continue such

individual assessments and issue appropriate recommendations in the future.

L. Exceptions for Certain Ineligible Donors (§ 630.20)

Section 630.20 permits, under certain circumstances, the collection of blood and blood components from individuals who do not meet one or more of the eligibility requirements under §§ 630.10 or 630.15, or are deferred under § 610.41. In finalizing this provision, we made several changes. In the first sentence, we make clear a requirement that was implicit in the proposed rule: That collection authorized under this provision may proceed only after the establishment performs the required donor assessments and determines a donor to be ineligible under any provision of §§ 630.10(e) and (f) or 630.15(a). We have not included the reference to donors deferred under § 610.41 because of a reactive screening test for a relevant transfusion-transmitted infection in final § 630.20. We determined that the provision was unnecessary to include here because §§ 610.40(h)(2)(i) and 610.41(a)(5) already authorize autologous collections from reactive donors, and §§ 610.40(h)(2)(ii) and 610.41(a)(2) and (3) authorize plasmapheresis collections under a special collection program. For a collection from a reactive donor outside these provisions, a blood establishment would first file a request under § 640.120. We expect that such requests would occur only in extraordinary medical circumstances. We also reorganized the section and clarified the responsible physician's role and responsibilities for all collections authorized under § 630.20.

Final § 630.20(a) permits establishments to collect from certain ineligible donors donating only for autologous use, as prescribed by the donor's physician. Autologous donors have long been permitted to donate blood for their own use even though they do not meet eligibility criteria, including a reactive result on a donor screening test. This section provides additional protections for an ineligible, autologous donor who may not be in good health: The donor must have a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent, and the responsible physician must determine and document before the collection that the health of the donor permits the collection. Under § 630.5(b)(1)(ii), the responsible physician must not delegate the determination of the donor's health. Note that § 630.20(c)(1) of the proposed rule stated that this exception would be available when ''[t]he donation is for autologous use . . . and is not for allogeneic transfusion or for further manufacturing use.'' Final § 630.20(a) defines the scope of this exception in fewer words that are intended to have the same meaning, ''The donation is for autologous use *only*'' (emphasis added).

Also consistent with the proposed rule, final § 630.20(b) permits the collection of plasma from donors participating in an approved Source Plasma program to collect plasma for further manufacturing use into in vitro products for which there are no alternative sources. One example of such products is plasma collected from donors with relevant transfusion-transmitted infection(s) or other diseases; the plasma may be used to develop positive controls for infectious disease test kits. The collection must take place under the medical oversight specified in the approved plasmapheresis program, and for each collection the donor must meet the criteria in § 630.10(f)(1) through (6) and the responsible physician must determine and document that the donor's health permits the collection procedure. Under § 630.5(c)(1)(i)(A)(*2*), the responsible physician must not delegate the determination that the donor's health permits the collection procedure.

Final § 630.20(c) provides an exception when the donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need, and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue risk to the transfusion recipient. This is similar to proposed § 630.20(c)(3), but we have clarified that this applies to the collection of blood components for transfusion (not further manufacturing use), and that the medical need of the transfusion recipient must be exceptional. Consistent with final § 630.15(a)(1)(ii)(B), we added the term ''exceptional'' to clarify that this exception to donor eligibility should apply only in those rare situations where the recipient's need for a component from a donor with particular characteristics is exceptional.

(Comment 97) Two comments recommended that the language throughout this section refer to ''responsible physician or physician substitute'' instead of to ''responsible physician.''

(Response) We decline to add the extra words requested here. Section 630.5 addresses the activities which the responsible physician may delegate.

(Comment 98) Two comments asserted that it was unnecessary and burdensome to require the responsible physician to examine and certify the good health of an autologous donor before allowing a collection under this exception. The comments noted that autologous donors are under the care of their personal physicians, and these collections take place pursuant to prescription or physician's order. Autologous donors may wish to donate at facilities geographically distant from the facility where the blood establishment's responsible physician is located. The comments stated that the rule should therefore not require examination by the responsible physician. Some comments also criticized the proposed requirements that the responsible physician examine the donor and certify in writing that the donor's health permits the collection procedure for special collection programs and directed donations.

(Response) We have revised proposed § 630.20. For collections under these exceptions, the final rule requires that the responsible physician determine and document that the donor's health permits the collection procedure, and additionally for directed donations under § 630.20(c), that the donation presents no undue medical risk to the transfusion recipient. We note that this determination will be made after the applicable donor eligibility assessments required under § 630.10 and § 630.15 are performed. The responsible physician can make these determinations based on information developed during the donor eligibility assessments, rather than during an additional examination of the donor, and, consistent with § 630.5(b)(1)(i)(B) through (b)(1)(i)(C) and (c)(1)(i)(A)(*2*) through (c)(1)(i)(A)(*3*), can make this determination from another geographic location. The responsible physician's determination must be documented. In accordance with § 606.100, blood establishments must have written standard operating procedures for collections under these provisions.

We also note that establishments must have prior written approval from the Director, CBER for special collections under § 630.20(b). FDA will review donor selection criteria for these programs, as well as the provision for medical oversight of collections, and must approve the procedures before such collections may proceed. In some circumstances, FDA may require additional donor protections to be in place. For example, FDA may determine that collections from donors with

clotting factor deficiencies may proceed only if the responsible physician examines the donor before each donation and is present to oversee the collection. These terms would be addressed in FDA's review and approval of the special collection program. In additional, final § 630.20(b) requires that ineligible donors who are permitted to donate under this section must meet the criteria in § 630.10(f)(1) through (6).

For collections under § 630.20(c), the responsible physician is not authorized to delegate the determination that the donor's health permits the collection procedure, or that the donation presents no undue medical risk to the transfusion recipient. Because the collection and transfusion of blood and blood components from such collections may present risks to both the donor and the transfusion recipient, we have determined that these determinations must be made by the responsible physician, who may make these determinations from an offsite location.

(Comment 99) One comment emphasized the importance of directed platelet donations, and urged FDA to rely on the blood establishment to determine whether to collect platelets from a donor with a hematocrit value of 37 percent (just below the value of 38 percent referenced in current regulations) when the collection is intended for a specific recipient based on documented medical need.

(Response) We agree that dedicated platelet donations are important. Final § 630.20(c) would permit dedicated donations based on documented exceptional medical need, provided that the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

M. Exceptions From Certain Donor Eligibility Requirements for Infrequent Plasma Donors (§ 630.25)

We are finalizing this provision largely as proposed. For greater clarity, we have included a definition of ''infrequent plasma donor'' in new § 630.3(e), and we use that defined term in this section. An infrequent plasma donor is a donor who has not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks, and who has not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year. Final § 630.25 provides exceptions for collections from infrequent plasma donors who are not participating in an immunization program. This reflects our determination that, for these collections, it is not necessary for establishments to assess infrequent plasma donors using the medical history and physical examination required in § 630.15(b)(1); to perform the test for total protein required to be performed prior to collection under § 630.15(b)(4) and periodically under § 640.65(b)(1)(i); or to perform a plasma or serum protein electrophoresis or quantitative immuno-diffusion test or an equivalent test to determine immunoglobulin composition of the plasma or serum, as required under § 640.65(b)(1)(i). Further, it is not necessary for the responsible physician to review the laboratory data as required in § 640.65(b)(2)(i).

We have added the term ''medical history'' in the first sentence of final § 630.25(a), to make clear that this provision may provide an exception to the requirements in § 630.15(b)(1) to conduct both the medical history and physical examination required for Source Plasma or frequent plasma collection. However, blood establishments are still required to perform the medical history and physical assessment required under § 630.10. In addition, as discussed in response to comment 102, we have directly addressed the applicability of this exception to donors who previously donated a co-collection of plasma and another blood component by apheresis.

(Comment 100) One comment stated that the donor eligibility requirements for frequent plasma donors are unnecessary for infrequent donors.

(Response) Our regulations have long provided additional donor eligibility requirements for Source Plasma donors (see current § 640.63) to address potential risks associated with frequent plasmapheresis donation, and this rule incorporates those long-standing provisions. However, we agree that infrequent plasma donors are not exposed to the same risks as frequent donors. In final § 630.25, we provide exceptions from certain donor eligibility requirements for infrequent plasma donors.

(Comment 101) One comment recommended that the exceptions in § 630.25 should be applicable to donors who donate plasma more frequently than once in 4 weeks if the donor's physician determines the donor to be in good health.

(Response) We decline to accept this comment. The conduct of a medical history and physical exam, the pre-collection review of total protein levels, and the periodic review of protein composition and other laboratory data as required by §§ 630.15(b)(1), (b)(4), and 640.65(b) are necessary to protect the health of plasma donors who are not infrequent plasma donors, as defined in § 630.3(e) (Refs. 65, 66).

(Comment 102) One comment requested clarification concerning whether the exceptions proposed in § 630.25 should be available when a donor made a recent platelet donation by apheresis. Another comment stated that this provision would unnecessarily restrict infrequent plasma collections after red blood cell loss. The comment noted that proposed § 630.25 did not address the applicability of this exception after recent donation of platelets by apheresis. The comment noted that most of the plasma collected by apheresis from volunteer blood donors is plasma collected at the same time as apheresis platelets. The comment stated that the criteria for the collection of plasma at the same time as collection of platelets by apheresis should be similar.

(Response) Final § 630.25 provides exceptions for infrequent plasma donors, as defined in § 630.3(e), who are not participating in an immunization program. In response to the comment, we have not included in final § 630.25 the references to red blood cell loss due to apheresis and Whole Blood collections, which we included in proposed § 630.25(a). Instead, final § 630.25 provides for more narrow exceptions to the provisions that relate to the risks of frequent plasmapheresis. We address the deferral of plasma donors for red blood cell loss in § 630.15(b)(6) and (7), and the deferral of platelet donors for red blood cell loss in § 640.21(f).

We agree with the comment that the effects of a recent co-collection of plasma with platelets or another blood component by apheresis should be considered in determining whether the exceptions in § 630.25 are available. Accordingly, § 630.25 applies only to infrequent plasma donors, and § 630.3(e) excludes from the definition of infrequent plasma donor a donor who has donated a co-collection of plasma with another blood component by apheresis in the preceding 4 weeks. This reflects our determination that, like donations of plasma by plasmapheresis, co-collections of plasma and platelets or another blood component by apheresis during the previous 4 weeks should not be subject to these exceptions. In this way, FDA provides protection to donors from the risks associated with frequent donation of plasma by apheresis (Ref. 64).

N. Donation Suitability Requirements (§ 630.30)

We have finalized requirements in § 630.30(a) to define when a donation is suitable, and in § 630.30(b) to state what an establishment must do when a donation is not suitable.

Under final § 630.30(a)(1) through (4), a donation is suitable when: (1) The establishment determines that the donor is not currently deferred from donation as determined by review of the records of deferred donors described in § 606.160(e); (2) the results in accordance with §§ 630.10 through 630.25 indicate that the donor is in good health and procedures were followed to ensure that the donation would not adversely affect the health of the donor; (3) the results in accordance with § 630.10(e) indicate that the donor is free from risk factors for, or evidence of, relevant transfusion-transmitted infections and other factors that make the donor ineligible to donate; (4) the donor's blood has been tested in accordance with § 610.40 and, unless an exception applies, is negative or nonreactive; and (5) the donation meets other requirements in subchapter F. The final rule now specifies in § 630.30(a)(1) that an establishment must determine that the donor is not currently deferred from donation by reviewing the donor records described in § 606.160(e). Final § 630.30(a)(2) clarifies that the determination of the donor's good health must also include a finding that procedures were followed to ensure that the donation would not adversely affect the health of the donor.

Proposed § 630.30(a)(5) would have required an establishment to determine as part of its review of the suitability of platelet components that ''you have taken adequate steps to assure that the donation is tested for bacterial contamination and found negative.'' After further consideration we have determined that this provision, which concerns a current good manufacturing practice, should be codified in part 606, which is titled ''Current Good Manufacturing Practice for Blood and Blood Components.'' Accordingly, we discuss comments to proposed § 630.30(a)(5) at comments 13 through 24 (discussing final § 606.145). Consistent with proposed § 630.30(a)(6), § 630.30(a)(5) in the final rule states that a donation is suitable when the donation meets other requirements in subchapter F.

We have made several changes from the proposal in finalizing § 630.30(b), titled ''What must you do when the donation is not suitable?'' Final § 630.30(b)(1) now provides ''You must not release the donation for transfusion or further manufacturing use unless it is an autologous donation, or an exception is provided in this chapter.'' This provision is revised to state more explicitly a clear consequence of finding that a donation is not suitable.

Final § 630.30(b)(2), consistent with the proposed rule, requires a blood establishment to defer the donor of an unsuitable donation. However, although the proposed rule would have required deferral of all donors of platelets found to be bacterially contaminated, § 630.30(b)(2) of the final rule requires deferral only when the establishment determines in accordance with new § 606.145 that the bacterial contamination is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor. We made this change in response to comments, which are discussed at comment 103. In addition, we discuss the requirement to determine whether contaminating bacteria are likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor at comment 103.

We are not finalizing the provision (proposed § 630.30(b)(3)) that would have required establishments to enter information about deferred donors into the cumulative record of deferred donors. As discussed at comments 25 through 28, we are finalizing the requirements related to the cumulative record of deferred donors more narrowly and new § 606.160(e)(2), not this section, specifies the information required to be included in that record.

Consistent with the proposed rule, we require establishments to notify deferred donors in accordance with final § 630.40. However, although we reiterated the reasons for deferral and notification in the language of proposed § 630.30(b)(4), in final § 630.30(b)(4) we are taking the simpler approach of cross-referencing the donor notification requirements in § 630.40. This is not a substantive change.

(Comment 103) Several comments opposed a broad requirement to defer and notify donors when their platelet component is identified as bacterially contaminated. Some comments observed that the presence of bacteria on a donor's skin is expected and typically is not an indication of illness in the donor. Most instances of bacterial contamination of platelets occur due to the limitations of collection facility practices, which may permit the introduction of skin flora or other contaminants into the collection. On the other hand, in some instances, the presence of certain bacterial contaminants in a platelet component could indicate an underlying bacteremia, and potentially a serious illness in the donor. One comment also asserted that donor deferral based on a bacterial culture positive result may be appropriate if: (1) The positive culture is an indication of an underlying donor pathology that may be cause for deferral (for example, a donor who cultured positive for *Streptococcus bovis* who later was found to have colonic pathology) or (2) the positive culture may indicate a higher risk of future contaminated collections.

One comment would support notification only when a local investigation completely ruled out collection facility practices as the source of contamination. Another comment asserted that while identification of the bacterial contaminant is likely to be performed to aid the medical director in evaluating the potential risk to transfusion recipient or donor, the extent of this identification may be limited to ''coagulase negative *Staphylococcus*'' or ''*Bacillus* species, not *anthracis*.'' The comment went on to state that further identification of the species of the bacterial contaminant should not be required.

(Response) We agree that most instances of bacterial contamination of platelets occur because of limitations to aseptic methods of collection. If we were to require deferral and notification of all donors who donated platelets that subsequently tested positive for bacterial contamination, we would unnecessarily alarm many fully qualified donors. We further agree with the comments noting that a subset of the findings of contamination are linked to bacteria-associated illness in the donor, such as a colonic malignancy which may be signaled by the presence of *Streptococcus bovis* in the donated platelets (Ref. 19). Accordingly, we have narrowed the proposal related to donor deferral and notification. Under § 630.30(b)(3), a collection establishment must defer the donor of bacterially contaminated platelets when the contaminating organism is identified in accordance with § 606.145 as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor. This reference to endogenous infection is intended to refer to bacteria that originate from the bloodstream of an asymptomatic donor, and not to bacteria that are typically found on the surface of the skin.

This rule does not require donor deferral when the presence of bacteria is due to contamination with the skin flora, or other contamination at the collection site. We have similarly limited donor notifications related to

platelet contamination. Final § 630.30(b)(4) requires establishments to notify donors in accordance with § 630.40. As noted at comment 107, § 630.40(a) now requires an establishment to make reasonable attempts to notify any donor whose donated platelets have been determined under § 606.145(d) to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor.

(Comment 104) Several comments stated that they consider the decision whether to defer and notify the donor to fall within the purview of the collection facility's medical director. They stated that regulation is not required in this area. Another comment stated that blood establishments already have a defined policy for how to investigate situations where a blood component contains a contaminant in the unit that might suggest the presence of a systemic infection in the donor, and that the donor should be notified and then investigated, counseled and/or treated as appropriate by a knowledgeable physician. The comment asserted that AABB has in place a logical and medically sound approach to these issues and that current procedures set forth by the industry organization and establishments are sufficient.

(Response) We recognize that numerous blood establishments already defer and notify donors in accordance with the policies embodied in this regulation. However, others do not, and donors at those facilities may not receive information that is important to their health. In order to protect these donors, we are requiring donor deferral and notification when the responsible physician for the collection establishment determines that the contaminating organism is likely to be associated with bacterial infection that is endogenous to the bloodstream of the donor.

(Comment 105) Another comment recommended that FDA not finalize these donor deferral and notification provisions. The comment urged FDA to instead provide separate guidance after FDA approves a bacterial release test. The comment asserted that guidance was needed to address the deferral period and the reason for deferral.

(Response) Since the proposed rule was published, the tools for bacterial testing of platelets have improved and notification practices have evolved. FDA has cleared several devices for quality control testing of platelets, including two culture-based systems and two non-culture-based rapid tests. One test has also been cleared as a safety measure following testing with an early culture. In the United States, culture of apheresis platelets by collection centers is virtually universal. Approximately 65 percent of Whole Blood-derived platelets are pooled early in storage (pre-storage pooling) at the collection center and are all cultured; the remaining 35 percent are pooled just prior to transfusion by the transfusion service and are typically tested with a rapid test (information obtained at the AABB July 2012 workshop) (Ref. 20). In addition, AABB published industry standards requiring follow-up of positive samples to identify the organism (Ref. 17). A practice of notifying donors after finding endogenous bacteria with clinical consequences, such as *Streptococcus bovis,* has been reported by the American Red Cross, among others (Refs. 18, 19). These circumstances support even more strongly the donor deferral and notification provisions we proposed. Accordingly, we decline the comments' request that we delay finalizing these provisions. We will issue additional guidance as appropriate.

(Comment 106) Another comment stated that a lookback procedure with respect to all cases of bacterial contamination would not be appropriate; rather, reasonable medical judgment should be applied in these instances.

(Response) We are not requiring a lookback procedure in this rule.

O. Requalification of Previously Deferred Donors (§ 630.35)

We received no comments on proposed § 630.35. On our own initiative, we have restructured this provision to more clearly identify situations where a prior deferral will not prevent future donations by an eligible donor. This section continues to provide that a previously deferred donor may donate again if that donor meets donor eligibility criteria at the time of the current collection, and if the collecting establishment determines that the basis for the previous deferral is no longer applicable.

In final § 630.35(a), we make clear that the basis for a previous deferral is no longer applicable if the deferral was for a defined period of time and that time period has passed, or if the deferral was otherwise temporary, such as those deferrals based on eligibility criteria described in final § 630.10(f)(1) through (5) or § 630.15(b)(4). These sections require deferral for individual donor conditions that may change over time: temperature, blood pressure, hemoglobin or hematocrit, pulse, weight, and for plasmapheresis donors, total protein levels.

Final § 630.35(b) makes clear that when the basis for the deferral is no longer applicable, donors who were deferred for reasons other than under § 610.41(a) may be found to be eligible to donate under a requalification method or process found acceptable for such purpose by FDA. For example, donors who were deferred under § 630.10(e)(1)(vi) for tattooing involving nonsterile percutaneous skin inoculation could be requalified after 12 months if they meet all other donor eligibility criteria (Ref. 67). FDA intends to recognize additional methods and processes in guidance documents issued in accordance with good guidance practices. In addition, to respond to individual requests or a public health need, FDA may also authorize alternative procedures related to donor requalification under § 640.120. We note that reentry of donors deferred under § 610.41(a) is already addressed in current § 610.41(b), which remains in effect.

P. Requirements for Notifying Deferred Donors (§ 630.40)

We have finalized § 630.40(a) consistently with the proposed rule, in which we proposed to move the existing donor notification provision from §§ 630.6 to 630.40, and to add a requirement for notifying donors whose platelet component has tested positive for a bacterial contamination that is likely due to an infection endogenous to the bloodstream of the donor. In addition, the proposed and final rules incorporate updated references to notification after deferral due to ineligibility under new §§ 630.10 and 630.15. While existing § 630.6(a) requires notification of a donor determined not to be suitable based on suitability criteria under § 640.3 or § 640.63, those provisions are being replaced by the donor eligibility criteria in §§ 630.10 and 630.15. Throughout final § 630.40, we also made conforming changes to certain terminology to be consistent with terms used elsewhere in this final rule.

(Comment 107) Several comments, discussed at comments 104 through 106, raised concerns about deferral and notification of donors whose platelet component has tested positive for bacterial contamination that is likely due to an infection endogenous to the bloodstream of the donor. A few comments stated that it would be difficult to notify donors whose platelets indicate evidence of bacterial infection in the donor because FDA has

not issued guidance regarding how to identify such situations.

(Response) As noted at Comment 20, we now require in § 606.145(d) that the responsible physician for the collection establishment determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor. Donor deferral and notification are required only after the responsible physician has made this determination, based on medical judgment, in accordance with the blood collection establishment's SOP.

Q. Platelets: Eligibility of Donors (§ 640.21)

In this final rule, we have revised requirements for collection of Platelets based on comments. We published the proposed rule in November 2007 and subsequently in December 2007 issued the 2007 Guidance (Ref. 64), as we discussed in comment 91. Many of the comments criticized provisions of the proposed rule, while supporting recommendations made in the 2007 Guidance. We have finalized this section to be more consistent with our recommendations in the 2007 Guidance document.

Consistent with proposed § 640.21(a)(1), final § 640.21(a) requires establishments to determine the eligibility of platelet donors in accordance with §§ 630.10 and 630.15, except as expressly modified in § 640.21. We received no comments on this provision and are finalizing it as proposed.

Proposed § 640.21(b) stated that a donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function. We have finalized this provision in two sections. Final § 640.21(b) states that a plateletpheresis donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function. This is because a donor of platelets collected by plateletpheresis will typically be the sole source of platelets provided in a therapeutic transfusion, and the effects of any drugs on platelet function will not be mitigated by pooling the affected platelets with platelets from other donors who have not taken the drug. Final § 640.21(c) states that a Whole Blood donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function, unless the platelet unit is labeled to identify the ingested drug. We made this change because we recognize that establishments frequently pool multiple units of Whole Blood platelets in order to mitigate the effects of a single unit collected from a donor who ingested a drug that adversely affects platelet function.

In final § 640.21(d), we require establishments to assess and monitor the donor's platelet count. Establishments: (1) Must take adequate and appropriate steps to assure that the donor's platelet count is at least 150,000 platelets/μL before plateletpheresis begins. If an establishment does not have records of a donor's platelet count from prior donations and is not able to assess the donor's platelet count either prior to or immediately following the initiation of the collection procedure, the establishment must not collect 9.0×10^{11} or more platelets in that donation; (2) must defer from platelet donation a donor whose pre-donation platelet count is less than 150,000 platelets/μL until a subsequent pre-donation platelet count indicates that the donor's platelet count is at least 150,000 platelets/μL; and (3) must take appropriate steps to assure that the donor's intended post-donation platelet count will be no less than 100,000 platelets/μL. We revised these provisions in response to comments that proposed § 640.21(c) was too prescriptive.

Final § 640.21(e) addresses frequency of plateletpheresis collection in a manner that is largely consistent with the proposed rule. Consistent with proposed § 640.21(c)(4)(i), final § 640.21(e)(1) provides that a donor may donate no more than a total of 24 plateletpheresis collections during a 12-month rolling period. Proposed § 640.21(c)(4)(ii) authorized no more than 2 single component collections of platelets by plateletpheresis within a 7 calendar day period, with a minimum of 2 calendar days between procedures, and proposed § 640.21(c)(4)(iii) would have authorized no more than one double or triple component collection procedure within a 7 calendar day period. However, the proposed rule did not provide numerical values to distinguish among single, double, and triple collections. Final § 640.21 provides one value, 6×10^{11} platelets, to identify collections that warrant a longer deferral period between donations. Final § 640.21(e)(2) provides that when an establishment collects fewer than 6×10^{11} platelets, the establishment must wait at least 2 days before any subsequent plateletpheresis collection. The establishment must not attempt to collect more than 2 collections within a 7 day period. Final § 640.21(e)(3) provides that when an establishment collects 6×10^{11} or more platelets, the establishment must wait at least 7 days before any subsequent plateletpheresis collection (proposed § 640.21(c)(4)(iii)).

Consistent with proposed § 640.21(d), final § 640.21(e)(4) provides an exception to these limits. For a period not to exceed 30 days, a donor may serve as a dedicated plateletpheresis donor for a single recipient as often as is medically necessary, provided that the donor is in good health, as determined and documented by the responsible physician, and the donor's platelet count is at least 150,000 platelets/μL, as measured at the conclusion of the previous donation or before initiating plateletpheresis for the current donation. Current § 610.40(c)(1) addresses the frequency of donor testing for such dedicated plateletpheresis donors.

Final § 640.21(f) addresses the deferral of plateletpheresis donors due to red blood cell loss in a manner that is generally consistent with proposed § 640.21(e). Proposed § 640.21(e) referred to deferral ''for a period of 8 weeks after donating a unit of Whole Blood or after losing a volume of whole blood equal to or greater than 450 mL, or red blood cells equal to or greater than 200 mL, cumulatively over an 8 week period; or . . . for a period of 16 weeks after donating a double Red Blood Cells unit collection.'' Final § 640.21(f)(1) finalizes a requirement to defer a donor from donating plateletpheresis or a co-collection of platelets and plasma by apheresis for 8 weeks following donation of a unit of Whole Blood or a single unit of Red Blood Cells by apheresis. Consistent with proposed § 640.21(e), and in recognition that certain apheresis collection devices limit potential losses of red blood cells and whole blood, the rule provides an exception to this 8 week deferral, this section permits such apheresis collections 2 calendar days after a donation of Whole Blood or a single unit of Red Blood Cells, provided that the extracorporeal volume of the device is less than 100 mL. While proposed § 640.21(e) did not reference the collection of Platelets with Plasma in this exception, we are responding to comments by addressing that collection in final § 640.21(f)(1). Final § 640.21(f)(2) finalizes a 16 week deferral after a donation of a double Red Blood Cells collection. We have not finalized the proposed requirement to defer a donor based on cumulative loss of whole blood or red blood cells over an 8 week period, because it may be difficult for the establishment to assess cumulative blood loss. Instead, final § 640.21(f)(3) requires an establishment to defer a donor for 8 weeks or more if

the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

Proposed § 640.21(a)(2) would have required blood collection establishments to include a statement that the ''long-term effects of frequent apheresis are unknown'' in the platelet donor's statement of understanding (finalized as the donor acknowledgement in § 630.10(g)(2)). Instead of finalizing that provision, we have incorporated the informed consent requirements found in current § 640.21(c), into final § 640.21(g). As with Source Plasma donation, the responsible physician must obtain the informed consent of a plateletpheresis donor on the first day of donation, and at subsequent intervals no longer than 1 year. Informed consent for plateletpheresis would involve a dialogue between the plateletpheresis donor and the responsible physician. The responsible physician must explain the risks and hazards of the procedure to the donor; that explanation must be made in such a manner that the donor may give consent, but also has a clear opportunity to refuse the procedure. Authorization to delegate this task to a trained person is addressed in § 630.5(b)(1)(iv). This requirement is different from and is in addition to the requirement in § 630.10(g) to obtain a donor's acknowledgement at every donation.

(Comment 108) One comment suggested that we use the term ''platelet apheresis'' throughout this provision.

(Response) We use the term ''plateletpheresis'' in this rule to describe the process of using automated methods to collect Platelets while returning other blood components to the donor. The use of this term is consistent with our current regulations and the 2007 Guidance.

(Comment 109) Two comments stated that proposed § 640.21(b) should be finalized consistently with the recommendations on deferring donors of apheresis platelets who have ingested drugs that inhibit platelet function.

(Response) The recommendations for deferring plateletpheresis donors for ingesting platelet-inhibiting drugs that are contained in the 2007 Guidance are consistent with this final rule (Ref. 64).

(Comment 110) One comment stated that donors of Whole Blood-derived platelets should not be deferred for ingesting platelet-inhibiting drugs. The comment stated that a Whole Blood-derived platelet component collected from a donor who has ingested platelet inhibitory drugs would not be given as a single unit dose, and platelet-inhibiting effects of the ingested drugs would be very limited.

(Response) Final § 640.21(b) states that a plateletpheresis donor must not serve as a source of platelets for transfusion if the donor has recently ingested drugs that adversely affect platelet function. Final § 640.21(c) now states that a Whole Blood donor must not serve as the source of Platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function unless the labeling of the unit identifies the ingested drug that adversely affects platelet function. This information will enable the transfusion service to make an informed decision when selecting a single unit of Whole Blood platelets for a small dose transfusion (for example, to a neonate), and will provide useful information to collection establishments and transfusion services when selecting units to pool for a standard dose for the transfusion of platelets. We are not prescribing a specific method for labeling these units. Currently available methods include providing the information on the unit label, as a sticker placed on the unit, or in labeling such as a tie-tag attached to the unit.

(Comment 111) Several comments observed that the proposal in § 640.21(c)(1) applicable to frequent platelet collections, which would require a platelet count before commencing a collection by apheresis, is not consistent with the 2007 Guidance, which recommended that historic averages or default counts may be used in lieu of an actual platelet count. The comments supported those alternatives to a requirement to obtain an actual platelet count, which might not be available at mobile collection sites. Other comments suggested that the regulation should permit reliance on platelet counts taken at other times, including an average of the donor's last three venous platelet counts, the donor's last post-donation platelet count, the platelet count obtained from a pre-collection venous blood sample from the donor's previous donations, the average pre-platelet counts for local donor populations, and the default count for the collection equipment being used. One comment noted that first time donors at mobile collection sites would not have a record of previous platelet counts, but should still be permitted to donate.

(Response) Although we recommend that blood establishments obtain a pre-donation sample from a donor for a platelet count when feasible, we agree that under some conditions it may not be possible to measure a donor's platelet count before commencing the collection of platelets by apheresis. We have revised the final rule accordingly. Final § 640.21(d) requires the collecting establishment to assess and monitor the donor's platelet count for all collections of Platelets by plateletpheresis. However, we do not require an actual measurement of the donor's platelet count before initiating an apheresis collection of Platelets, unless the establishment suspects that the donor's platelet count is less than 150,000 platelets/μL. Instead, § 640.21(d)(1) requires establishments to take adequate and appropriate steps to assure that the donor's platelet count is at least 150,000 platelets/μL before initiating plateletpheresis collection. We believe that the recommendations in the 2007 guidance (Ref. 64), which address the use of historic values or the default machine setting when an actual platelet count cannot be obtained in advance of a donation, would currently satisfy the requirement in § 640.21(d)(1) to take such adequate and appropriate steps. If an establishment does not have records of a donor's platelet count from prior donations and is not able to assess the donor's platelet count either prior to or immediately following the initiation of the collection procedure, the establishment may collect platelets by plateletpheresis, but must not collect 9.0×10^{11} or more platelets from that platelet donor. Final § 640.21(d)(2) requires establishments to defer a donor whose pre-donation platelet count is less than 150,000 platelets/μL until a subsequent pre-donation count indicates that the donor's platelet count is at least 150,000 platelets/μL. This provision requires an actual measurement of the donor's platelet count before initiating another collection of platelets.

(Comment 112) One comment asked whether the proposal that the post-donation count be no less that 100,000 platelets/μL would require blood centers to perform a post-donation platelet count. The comment stated that performing a post-donation count is burdensome. Another comment said that post-collection counts should never be required. The comment stated that apheresis collection device settings can be validated to reliably avoid post-collection counts below 100,000 platelets/μL.

(Response) Final § 640.21(d)(3) requires a collecting establishment to take appropriate steps to assure that the donor's intended post-donation platelet count will be no less than 100,000 platelets/μL. We expect that establishments will implement this requirement by validating the settings on their apheresis collection devices to

avoid post-collection counts below 100,000 platelets/μL.

(Comment 113) One comment suggested that FDA specify that in the event the donor's post-donation platelet count is less than 100,000 platelets/μL, the donation should be reviewed by the Medical Director, who, based on the donor's history, may deem the donor to be eligible for future donations.

(Response) Because § 640.21(d)(3) requires establishments to take appropriate steps to assure that a platelet donor's intended post-donation platelet count will be no less than 100,000 platelets/μL, we believe that this situation will occur rarely. If the donor returns to donate platelets, § 640.21(d) would require the establishment to assess and monitor the donor's platelet count, and, under § 640.21(d)(1), would require the establishment to take adequate and appropriate steps to assure that the donor's platelet count is at least 150,000 platelets/μL before initiating plateletpheresis collection. A donor whose pre-donation count is less than 150,000 platelets/μL must be deferred under § 640.21(d)(2).

(Comment 114) Several comments suggested that limitations on frequency of plateletpheresis collections should not be finalized. They criticized as unnecessary the limitations to 24 collections in a 1 year period and the requirement for a 2 day interval between each collection. Some comments stated that there is no evidence to support a requirement for a 7 day donation interval following the donation of a double or triple component. One comment asserted that other protections (such as following instructions for use on apheresis collection devices) are adequate to protect the donor.

(Response) We have finalized these requirements in § 640.21(e). Some studies have demonstrated a higher incidence of iron deficiency in frequent plateletpheresis donors. In a United Kingdom study of serum ferritin levels of frequent plateletpheresis donors, there was a direct correlation between plateletpheresis donation frequency and iron depletion. The authors suggested that the iron depletion in these donors is due to blood loss that can occur with each plateletpheresis donation (Ref. 68). In addition, frequency of donation may affect the donor's ability to replace platelets adequately (Ref. 69). For this reason, in order to protect the health of the donor, we have finalized limits on the frequency of platelet donation in § 640.21(e). We agree that collection of more than a single replacement dose of platelets is generally safe. However, the specified interdonation intervals are prescribed to assure that plateletpheresis donors have time to recover their platelet counts between collections.

We also note that § 640.21(e)(4) provides an exception that may be available when a donor serves as a dedicated plateletpheresis donor for a single recipient. Under this exception a healthy donor may donate more frequently during a 30 day period, in order to provide platelets for a recipient in need of multiple transfusions of platelets.

(Comment 115) One comment noted that the proposed deferrals of plasma donors for red blood cell loss contained in proposed § 630.15(b)(5) were different from the deferrals for platelet donors for red blood cell loss in proposed § 640.21(e).

(Response) We have harmonized the deferrals for red blood cell loss in final § 640.21(f) based on comments regarding co-collection of Platelets and Plasma by apheresis, discussed at comment 92.

(Comment 116) One comment recommended that a Whole Blood donor should have to wait 8 weeks before donating by plateletpheresis, unless the instrument used is designed to collect less than 100 mL of red blood cells, regardless of the donor's hematocrit, when the donor is not fully re-infused. The comment stated that there is a potential for plateletpheresis donors to lose more than 100 mL of red blood cells based on the type of machine used and the donor's hematocrit, and identified one apheresis device with an extracorporeal blood volume greater than 200 mL.

(Response) Final § 640.21(f)(1) allows an establishment to collect either platelets by apheresis or platelets with Plasma by apheresis 48 hours after a donation of Whole Blood or Red Blood Cells, only if the extracorporeal volume of the apheresis collection device is less than 100 mL. An establishment could not collect platelets by apheresis using the device with an extracorporeal volume greater than 200 mL identified by the comment under this provision.

(Comment 117) Two comments criticized proposed § 640.21(a)(2), which would have required the statement of understanding to include a statement that the long-term effects of frequent apheresis are unknown. One comment suggested that there is adequate published literature that would indicate that the effects of long-term frequent apheresis are known. Another similar comment asserted that no long-term adverse effects have been reported with frequent apheresis, and it is not necessary to include a statement with information provided to the donor.

(Response) Final § 640.21(g) requires the responsible physician to explain the risks and hazards of the procedure to the donor as part of the informed consent process. In addition, § 630.10(g)(2)(ii)(E) requires that, at every donation, the donor acknowledge that the donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure. These regulations do not require that the donor be informed that the long term effects of frequent apheresis are unknown; we recognize that, as knowledge improves, such a statement may no longer be accurate. However, even though the current literature does not answer all questions concerning the long term consequences of frequent plateletpheresis (Ref. 70), the informed consent must address long term risks and hazards associated with frequent apheresis, such as iron depletion (Refs. 71, 72). The donor's informed consent is required before the first plateletpheresis donation, and at least yearly thereafter.

R. Source Plasma: Plasmapheresis (§ 640.65(b))

We have finalized these sections largely as proposed. Final § 640.65(b)(1)(i) and (b)(2)(i) now reference § 630.25, incorporating those exceptions related to collections from infrequent plasma donors. This reflects our determination, as described in the section addressing § 630.25, certain provisions are not necessary for these collections. Final § 640.65(b)(2)(i) also requires that plasmapheresis donors be tested every 4 months to assure that they have a total protein of no less than 6.0 grams per deciliter, and no more than 9.0 grams per deciliter in a plasma sample or a serum sample. We received comments on this protein standard, which is also incorporated in § 630.15(b)(4). We discuss those comments at comment 89. Final § 640.65(b)(2)(i) further requires the responsible physician to review the accumulated laboratory data, including any tracings of the plasma or serum protein electrophoresis pattern, the calculated values of the protein composition of each component, and the collection records to determine if the donor should be deferred from further donation. This section further requires that if the review is not completed within 14 calendar days after the sample is drawn, the collection establishment must defer the donor pending the review. This will assure that establishments do not take additional collections from an ineligible

donor in the event that this review is delayed.

(Comment 118) A few comments to proposed § 640.65(b)(2)(i) recommended that the review time for determining whether a donor would be deferred from further donation should remain at 21 days, not 14 days as proposed. The comment stated that the current 21 day allowance is needed to ensure adequate time for testing, return of test results to the laboratory and medical review. The comment stated that FDA should note that Canadian health authorities recently changed their requirement to 21 days.

(Response) We decline to provide a 21 day timeframe for review. This change from 21 days to 14 days reflects changes on how samples are submitted for testing, and how test results are transmitted. These changes permit faster receipt and review of test results. As we noted in the proposed rule, current § 640.65(b)(2)(i) requires this review to take place within 21 days; we are reducing the time period to 14 calendar days because results are typically transmitted and recorded electronically, permitting faster access. Requiring medical review of these laboratory test results within 14 days is one of the important protections this rule provides to Source Plasma donors.

S. Source Plasma: General Requirements (§ 640.69)

We have finalized two sections as final § 640.69(e) and (f). These provisions incorporate industry practices known as the Qualified Donor Standard and Inventory Hold. Final § 640.69(e) provides that establishments must ensure that Source Plasma donated by paid donors is not used for further manufacturing into injectable products until the donor has a record of being found eligible to donate in accordance with § 630.10, and a record of negative test results on all tests required under § 610.40(a), on at least two occasions in the past 6 months. Because the regulation requires the establishment to determine a paid donor to be eligible on at least two occasions, but does not require that a unit be collected at the time of the initial eligibility determination, the regulation permits establishments that prefer to establish a donor's qualification by screening the donor and collecting a blood sample, but not a full donation, for testing in accordance with § 610.40(a).

We have finalized the inventory hold provision proposed in § 640.69(f) to require establishments to hold Source Plasma donated by paid donors in quarantine for a minimum of 60 days before it is released for further manufacturing use to make an injectable product. In addition, we now state explicitly the conditions that would prevent an establishment from distributing Source Plasma from quarantine. Under final § 640.69(f), an establishment must not distribute quarantined donations if the donor is subsequently deferred under § 610.41 because of a reactive screening test for evidence of infection due to a relevant transfusion-transmitted infection, or if the establishment subsequently determines the donor to be ineligible under § 630.10 due to risk factors closely associated with exposure to, or clinical evidence of, infection due to a relevant transfusion-transmitted infection. Since Source Plasma would be placed in quarantine under this section after the donation has been determined to be suitable under § 630.30, this section describes the information, typically obtained in connection with a subsequent Source Plasma donation by the donor, which would disallow the distribution from quarantine of that donor's prior donations. We added this language so that establishments would understand that, under this section, post-donation information would prevent the distribution of quarantined donations if that information consisted of a reactive screening test on a subsequent donation or a subsequent donor deferral due to risk factors associated with relevant transfusion-transmitted infection. Other donor information would not prevent distribution of previously quarantined units, even if it led to deferral of the donor from current collections. For example, information related to a donor's health on the day of a future donation (see, for example, § 630.10(f)(1) through (f)(6)) would not affect the distribution from quarantine of previously collected units.

(Comment 119) Two comments noted that proposed § 640.69(e) and (f) would codify existing, voluntary practices used in Source Plasma establishments. The comments urged FDA not to mandate voluntary industry standards. The comments noted that the Qualified Donor Standard and Inventory Hold were developed before nucleic acid testing was available to identify HIV as well as certain other relevant transfusion-transmitted infections, and that the use of nucleic acid testing significantly improves the identification of recent infections in the donor. According to the comments, incorporating these industry standards in regulation could inhibit the development of new practices based on new technology, and otherwise limit flexibility in the future.

(Response) As we explained in the proposed rule, these provisions are intended to provide additional mitigations of the risk of infectious disease transmission presented by collections from paid Source Plasma donors. Since the 1970s, it has been documented that paid Source Plasma donors are at higher risk than volunteer blood donors for certain relevant transfusion-transmitted infections (Ref. 73). In a 1998 report, the General Accounting Office (GAO) compared the incidence rates (positives per 100,000 person years) between paid and volunteer plasma donors, reporting ''we found that the incidence rates for HIV, HBV, and HCV were much higher for paid donors. HIV incidence rates were 19 times higher among paid donors (61.8 versus 3.3 for volunteer donors), while HBV and HCV rates were 31 times (245.5 versus 8.0) and 4 times higher (63.5 versus 14.9), respectively.'' The GAO concluded, ''there is a consistent pattern of higher marker rates among paid donors than among volunteer donors.'' The GAO further recognized the Qualified Donor Standard and Inventory Hold help to mitigate the risks of infection from plasma pools used for manufacturing plasma derivative products. Accordingly, in consideration of the additional risks presented by the paid Source Plasma donors, both industry and the GAO have recognized the importance of these practices in increasing the safety of products manufactured from Source Plasma. Although donor testing has improved with the advent of nucleic acid testing, Source Plasma collectors have continued to incorporate the Qualified Donor Standard and Inventory Hold into their quality standards, as reflected, for example, by the Plasma Protein Therapeutics Association, Quality Standards of Excellence, Assurance and Leadership (QSEAL) Certification Program (Ref. 74).

We solicited comments and supporting data in the proposed rule on whether other requirements would achieve the same results as these practices. We did not receive responsive comments and data. FDA appreciates that, in the future, new standards and practices may develop, which could replace the Qualified Donor Standard and Inventory Hold. However, such alternatives have not yet been identified. If appropriate alternative standards become available in the future, FDA could allow the use of those appropriate alternative standards as alternative procedures under § 640.120,

as well as revise this regulation when warranted.

(Comment 120) One comment asked that the wording in § 640.69(e) be revised to state that Source Plasma may be released once a donor has two sets of negative/non-reactive/not implicated viral marker test results. The comment further asserted that it should not be a requirement that the samples sent for testing be drawn at the same time the donor donates Source Plasma.

(Response) Under the final rule, an establishment may draw samples for testing under § 610.40(a) without collecting Source Plasma at the same time.

(Comment 121) One comment questioned the requirements in § 640.69(f), asserting that a proposal to require Source Plasma collectors to store the plasma at the collection center during the 60-day Inventory Hold would be unduly burdensome. The comment noted that the voluntary industry standard for the 60-day hold gives the manufacturer the flexibility to determine the most appropriate place for storage. Moreover, the comment stated that a requirement to use interim ''quarantine'' labeling on individual Source Plasma collections would add cost. The comment also stated that the term ''Quarantine'' should not be used because it implies that the plasma being placed in the 60-day hold is violative, when the product is simply held in inventory as part of the standard routine process.

(Response) The language of the proposed rule would not have required that Source Plasma be stored at the collection site, nor did it require establishments to label individual collections of Source Plasma as ''Quarantined.'' Rather the proposed rule simply required that the product be ''held in quarantine.'' The final rule requires that Source Plasma be held for a minimum of 60 days and prohibits distribution of certain units ''after placing a donation in quarantine.'' Final § 640.69(f) does not specify where an establishment must store the product. The establishment is not required to store the product at the collection site, and an establishment may store the product at an appropriate off site facility during the 60-day Inventory Hold. Nor does this provision require individual labeling of units. Instead, it simply requires that the establishment be able to identify any units that may not be distributed because of post-donation information received during the 60-day hold, and to identify when the 60-day hold has expired for a unit. We believe that establishments can meet these requirements by employing a variety of methods, including physical segregation, labeling (units, cases, or other packing units), or by electronic means (such as by computerized inventory). Finally, we disagree that the use of the term ''quarantine'' in this context suggests that the product subject to the Inventory Hold is violative. Rather, the term merely implies that the establishment is restricted from distributing the quarantined product while it is subject to the Inventory Hold.

(Comment 122) One comment objected to the use of ''paid'' to describe donors of Source Plasma subject to this provision. The comment asserted that paid Source Plasma donors are compensated for the time it takes to fulfill their commitment to donate. The comment stated that donating blood and plasma should be encouraged and that it is often necessary to reward donors for their donation.

(Response) We have finalized the rule incorporating the term ''paid donor.'' This usage is consistent with current § 606.121(c)(8)(v)(A), which is applicable to transfusable blood and blood components. That section defines a paid donor as a person who receives monetary payment for a blood donation.

T. Source Plasma: Records (§ 640.72)

In proposed § 640.72(a)(2) through (a)(4), we proposed several changes to current § 640.72 in order to conform to changes in this rule. We have finalized this section largely as proposed.

(Comment 123) One comment asked FDA to authorize establishments under § 640.72(a)(3) to maintain as an electronic record the records of the plasma donor's informed consent to participate in the plasmapheresis program, and where applicable, to participate as an immunized donor. This informed consent is required under § 630.15(b)(2). The comment stated that informed consent requirements should be consistent with proposed § 630.10(i)(2), which allows for a ''signature or acceptable substitute for a signature to indicate that understanding''.

(Response) We note that the donor acknowledgement, which the establishment is required under final § 630.10(g)(2) to obtain at each donation, requires a signature or other documented acknowledgement. The donor acknowledgement record is required to be maintained in accordance with § 606.160(a). For informed consent, obtained at the intervals specified in § 630.15(b)(2), final § 640.72(a)(3) now requires establishments to maintain the original or a clear copy or other durable record which may be electronic, of the donor's consent for participation in the plasmapheresis program or immunization.

(Comment 124) Several comments questioned the reference in proposed § 640.72(a)(4) to documentation by the responsible physician that the donor is in good health under §§ 630.10 and 630.15 on the day of examination. The comments stated that trained persons would be capable of making assessments under §§ 630.10 and 630.15.

(Response) We agree with the comment that reference to §§ 630.10 and 630.15 in proposed § 640.72(a)(4) was misplaced. Instead, under final § 640.72(a)(4) we require that records of the medical history and physical examination of the donor, conducted in accordance with § 630.15(b)(1) and, where applicable, § 630.15(b)(5), must address the eligibility of the donor as a plasmapheresis donor and, if applicable, an immunized donor. Delegation of this examination and determination is addressed in § 630.5(c)(3).

U. Source Plasma: Reporting of Donor Reactions (§ 640.73)

We are not finalizing § 640.73 in this rule. Instead, FDA intends to finalize this section when FDA finalizes the proposed rule, ''Safety Reporting Requirements for Human Drug and Biologicals'' (68 FR 12406, March 14, 2003) (Ref. 75). We will address in that final rule the comments received on proposed § 640.73 in this docket. By doing so, we intend to consolidate the safety and reporting requirements of all human drugs and biologicals under this chapter into one comprehensive regulation.

V. Alternative Procedures (§ 640.120)

We are finalizing proposed § 640.120 which separates and revises current § 640.120(a) into proposed § 640.120(a) and (b), and revises and redesignates current § 640.120(b) as § 640.120(c). Under proposed § 640.120(a), a blood establishment could request that the Director, CBER, approve a proposed exception or alternative to any requirement in Title 21 of the CFR, Chapter I, subchapter C (21 CFR parts 200 through 299; these include drug regulations, such as current good manufacturing practice regulations, that are applicable to blood products) and F (21 CFR parts 600 through 680), regarding blood, blood components, or blood products. Current § 640.120(a) authorizes exceptions or alternatives to regulations in subchapter F but omits reference to subchapter C; proposed § 640.120(a) addressed this omission. Under proposed § 640.120(a)(1), an establishment could request an

exception or alternative in writing, or, if there are difficult circumstances and submission of a written request is not feasible, as an oral request under proposed § 640.120(a)(2). We also proposed in § 640.120(b) to permit the CBER Director to issue an exception or alternative to these regulations in the event of a public health emergency which impacts blood and blood product establishments or blood availability. We proposed to redesignate current § 640.120(b) as § 640.120(c), and to revise it to state that FDA would publish alternative procedures and exceptions periodically on the CBER Web site rather than in the **Federal Register**, as our current regulations provide.

We are finalizing this provision largely as proposed, while making some clarifying changes. In final § 640.120(a), we no longer refer to our *approval* of an exception or alternative procedure. Instead, we refer to *issuing* an exception or alternative. This is consistent with the use of the term ''issue'' in proposed § 640.120(b).

In § 640.120(b), we proposed that the Director be authorized ''in a public health emergency'' to issue exceptions or alternatives if ''necessary to assure that blood, blood components, or blood products will be available in a specified location to respond to an unanticipated immediate need for blood, blood components or blood products.'' Final § 640.120(b) authorizes the Director ''to respond to a public health need'' by issuing a notice of exception or alternative if an exception or alternative is ''necessary to assure that blood, blood components, or blood products will be available in a specified location or locations to address an urgent and immediate need for blood, blood components, or blood products or to provide for appropriate donor screening and testing.'' We made these two changes to emphasize that this authority will be available to address urgent and immediate needs for blood, blood components, and blood products. The use of this provision is not contingent on whether that need could have been anticipated. In addition, we made explicit the Director's authority to issue exceptions or alternatives to provide for appropriate donor screening and testing. In recent years, we have confronted shortages and near-shortages of important donor tests. These situations have caused us to recognize the importance of being able to protect donors and recipients by permitting the use of alternative, but adequate, testing algorithms.

(Comment 125) FDA received two comments on proposed § 640.120. Both comments concerned § 640.120(b), relating to alternative procedures during a public health emergency. The comments urged FDA to be more specific about which regulatory provisions in subchapters C and F of Title 21 of the CFR would potentially be the subject of exceptions or alternative procedures during a public health emergency. One comment further indicated that blood establishments would be better able to prepare facilities and train staff if CBER provided more specific information about exceptions and alternative procedures which may be used during a public health emergency.

(Response) The Agency does not agree that potential variances should be listed within the regulation. Whether or not an exception or alternative is appropriate will depend on the specific situation. The scope, duration, and nature of a specific situation, how it impacts blood establishments, and the extent to which blood and blood products continue to be available, will determine whether a particular provision in subchapter F of title 21 of the CFR would be an appropriate subject for an exception or alternative procedure to address the public health need. Current § 610.40(g) authorizes release or shipment of blood or blood components prior to testing in appropriately documented medical emergency situations. Moreover, CBER has posted on its Web site a document entitled ''Exceptions and Alternative Procedures Approved Under 21 CFR 640.120'' (Ref. 76), which provides examples of exceptions and alternatives permitted under current § 640.120(a). Blood establishments may find this information to be useful for emergency planning purposes. In addition, FDA intends to continue to work with stakeholders on how to assure the continued availability of safe, pure, and potent blood and blood products during emergencies and other situations that may warrant a variance under this section.

W. Reagent Red Blood Cells (§§ 660.31, 660.32)

We are not finalizing proposed § 660.31, which proposed that donors of peripheral blood for Reagent Red Blood Cells, used as diagnostic substances for laboratory tests, must meet all the criteria for donor eligibility under §§ 630.10 and 630.15, and we are deleting current § 660.31. We are also deleting § 660.32, which addressed the collection of blood for Reagent Red Blood Cells from donors of peripheral blood. We are taking this action because blood collection establishments in the United States are fully subject to the requirements for donor eligibility, testing, and donation suitability discussed at length in this rulemaking, and these requirements are duplicative for such collections. Moreover, Reagent Red Blood Cells are licensed products subject to licensing standards to assure that the product is safe, pure, and potent. FDA assures that all licensed Reagent Red Blood Cells meet standards for safety, purity, and potency.

(Comment 126) One comment asked FDA not to reference in § 660.31 the criteria for donor eligibility in §§ 630.10 and 630.15. The comment stated that Reagent Red Blood Cells are not used for transfusion and are further processed for reagent use only; it is not necessary for donors of these products to meet the criteria in §§ 630.10 and 630.15.

(Response) We do not agree that donor eligibility provisions should not apply to donors of Red Blood Cells to be manufactured into Reagent Red Blood Cells. Blood collection establishments in the United States must comply with §§ 630.10 and 630.15, and we will require manufacturers of licensed Reagent Red Blood Cells to comply with applicable standards. However, we are deleting §§ 660.31 and 660.32 from the final rule as duplicative.

X. Quality System Regulation: Scope (§ 820.1)

We did not receive any comments on this section and we are finalizing the section as proposed.

Y. Technical Amendments

As has been noted elsewhere in this document, we are making a number of technical changes. These include changes in terminology in certain provisions as follows:

- We are removing the terms ''communicable disease agent'', ''communicable disease agents'', and ''communicable disease agent(s)'' wherever they appear and adding in their place ''relevant transfusion-transmitted infection'', ''relevant transfusion-transmitted infections'', and ''relevant transfusion-transmitted infection(s)'' to be consistent with the new definition of ''relevant transfusion-transmitted infection'' in § 630.3(h). These changes occur throughout 21 CFR part 610 subpart E, as well as in the following provisions: §§ 606.121(c)(11), (c)(12), and (i)(5), 606.122(e), 630.40(b)(3), (d)(1), (d)(1)(i), (d)(1)(iii), 640.5(f), and 640.67;
- We are removing the terms ''qualified licensed physician'', ''licensed physician'', and ''physician on the premises'' and adding in their place ''responsible physician'' to be consistent with the new definition of

''responsible physician'' in § 630.3(i). These changes occur in the following provisions: §§ 606.110(a), 640.65(b)(1)(i), (b)(1)(ii), (b)(2)(i), (b)(2)(iii), and (b)(2)(iv), 640.66, and 640.71(b)(1);

• We are removing the terms ''suitable'' or ''suitability'' and adding in their place ''eligible'' or ''eligibility'' to be consistent with the new definition of ''eligibility of a donor'' in § 630.3(d). These changes occur in the following provisions: §§ 606.40(a)(1), 606.100(b)(1), 606.121(i)(5), 606.160(b)(1)(x), 610.40(h)(2)(iv)(A), 610.41(a)(3), (a)(4), and (b), 630.40(a), (b), (b)(1), and (c), 640.12, 640.31, and 640.51;

• We also are removing ''supplemental test'' and ''supplemental (additional, more specific) test'', or similar wording, and adding in their place ''further testing'' to be consistent with the further testing requirements in § 610.40(e). These changes occur in the following provisions: §§ 610.40(e)(2), 610.46(a)(2), (a)(3), (a)(4), (b)(2), and (b)(3), 610.47(a)(2), (a)(3), (a)(4), (b)(2), and (b)(3), 630.40(a), (b)(3), and (d)(1)(iii);

• We are removing the term ''certified in writing'' and adding in its place ''determined and documented'' to be consistent with the requirement to determine and document in § 640.21(e)(4). This change occurs in § 606.110(a); and

• We are removing the reference to ''Health Care Financing Administration'' and replacing the reference with this Federal Agency's current name, ''Centers for Medicare and Medicaid Services'' in § 610.40(f).

As part of this final rule, we also are removing certain provisions from the CFR because the provisions are superseded or replaced by provisions in the final rule. These include: §§ 610.40(c)(2) and (i), 640.3, 640.27, 640.61, 640.62, and 640.63. For the same reasons, we are removing and reserving §§ 640.4(a), 640.5(a), and 640.64(a). With these changes, we need to make conforming changes when these removed provisions are referenced elsewhere in the CFR.

• § 610.40(i): The final rule removes from the CFR 610.40(i), which addresses syphilis testing, because syphilis testing is now addressed in § 610.40(a). Accordingly, as part of this final rule, we are removing references to § 610.40(i) that appear in: §§ 610.40(d), (g), and (h)(1), 610.41(a) and (a)(5), and 610.42(a). In removing the reference to § 610.40(i) from §§ 610.40(d), 610.41(a) and (a)(5), and 610.42(a), we are also removing the text ''or by a serological test for syphilis'', which modifies the reference to § 610.40(i). In removing the reference to § 610.40(i) in § 610.40(h)(2)(vi), we are adding in its place a reference to § 610.40(a), and, because of the changes to § 640.5, we are removing the related reference to performing syphilis testing under § 640.5. In § 610.40(h)(2)(vii), we are removing the reference to § 610.40(i), and replacing it with references to §§ 640.65(a)(2)(ii) and(b)(1)(i), which address syphilis testing for Source Plasma donors. We are also removing § 640.65(b)(2), and replacing it with the more precise citation to § 640.65(b)(2)(ii) through (b)(2)(iv).

• § 640.3: The final rule removes from the CFR 640.3, which addresses suitability requirements for Whole Blood donors. This subject is now addressed in part 630. Accordingly, as part of this final rule, we are removing the reference to § 640.3 that appears in § 606.121(i)(5) and adding in its place a reference to § 630.10. We are removing the reference to § 640.3 that appears in § 640.4(e) and adding in its place a reference to § 630.10. We are removing the references to § 640.3 that appear in §§ 640.12, 640.31(a) and 640.51(a), and substituting references to §§ 630.10 and 630.15. We are removing the reference to § 640.3 as part of our changes to newly designated § 630.40(a), and adding in its place the reference to §§ 630.10 and 630.15.

• § 640.62: The final rule removes from the CFR 640.62, which addresses medical supervision in Source Plasma situations. This subject is now addressed in part 630. Accordingly, as part of this final rule, we are removing references to § 640.62 that appear in §§ 640.22(c), 640.32(b), and 640.52(b). To clarify that § 630.5 applies to medical supervision for the collection of Source Plasma and other collections addressed in part 640, we have added § 640.130 in new subpart M. This section states that the requirements for medical supervision established in § 630.5 supplement the regulations in part 640.

• § 640.63: The final rule removes from the CFR 640.63, which addresses suitability requirements for Source Plasma donors. This subject is now addressed in part 630. Accordingly, as part of this final rule, we are removing the reference to § 640.63 that appears in § 606.110(b) and adding in its place a reference to §§ 630.10 and 630.15. We also are removing the reference to § 640.63 as part of our revisions to newly designated § 630.40(a), and adding in its place a reference to §§ 630.10 and 630.15. As part of our changes to §§ 640.31(b) and 640.51(b), we also are removing references to § 640.63 and adding in their place a references to §§ 630.10 and 630.15. Similarly, as part of our revisions to § 640.72, we are removing the reference to § 640.63 in § 640.72(a)(2) and adding in its place a reference to §§ 630.10 and 630.15. We also are removing the reference to § 640.63(b)(3) in § 640.72(a)(4) and adding in its place references to § 630.15(b)(1) and (b)(5), among other changes.

III. Legal Authority

FDA is issuing this rule under the authority of sections 351 and 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 262 and 264), and certain provisions of the FD&C Act (21 U.S.C. 201 *et seq.*).

The establishment of these criteria for determining the eligibility of a donor of blood and blood components and the suitability of blood and blood components for transfusion or for further manufacturing is intended to assure that donations are safe, pure, and potent including preventing unsafe units of blood or blood components that may transmit a relevant transfusion-transmitted infection from entering the blood supply, while safeguarding the health of donors.

FDA has been delegated authority under section 361 of the PHS Act to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Intrastate transactions affecting communicable disease transmission may also be regulated under section 361 of the PHS Act (*Independent Turtle Farmers of Louisiana, Inc.* v. *United States,* 703 F.Supp.2d 604, 620–21 (W.D. La. 2010); *Louisiana* v. *Mathews,* 427 F. Supp. 174, 176 (E.D. La. 1977)).

It is important to recognize that, in the past, blood transfusion and manufacturing of blood derivatives presented significant risks of transmission of communicable diseases such as HBV and HIV. Risks of transmission of infectious diseases still remain from emerging infectious agents. As FDA has previously noted, section 361 of the PHS Act, ''is designated to eliminate the introduction of communicable disease, such as hepatitis, from one state to another. Of necessity, therefore, this authority must be exercised upon the disease causing substance within the state where it is collected, manufactured, or otherwise found. Thus, the Commissioner of Food and Drugs may promulgate current good manufacturing practice regulations for

intrastate blood banking, pursuant to the [PHS Act], as hepatitis is a communicable disease. Without proper controls, it is likely to spread on an interstate basis.'' (39 FR 18614, May 28, 1974). These statements are equally true today, where the spectrum of diseases transmitted by blood has increased to include, for example, HIV agents that cause AIDS, and HCV, an additional cause of hepatitis as well as emerging infectious agents. We understand communicable diseases to include those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. Preventing the spread of communicable disease is the important purpose underlying the comprehensive regulations for blood establishments now in place, which this final rule modifies and modernizes.

Under section 361 of the PHS Act, FDA is authorized to enforce the regulations it issues to prevent the introduction, transmission, or spread of communicable disease interstate through such means as inspection, disinfection, sanitation, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection in human beings, and other measures that may be necessary. In addition, under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted. For organizational defendants, fines range up to $200,000 and $500,000. Individuals and organizations also face possible alternative fines based on the amount of gain or loss (18 U.S.C. 3559 and 3571(b) through (d)). Federal District Courts also have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. (See *Califano* v. *Yamasaki,* 442 U.S. 682, 704–05 (1979); *United States* v. *Beatrice Foods Co.,* 493 F.2d 1259, 1271–72 (8th Cir. 1974), *cert. denied,* 420 U.S. 961 (1975).)

Blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351 of the PHS Act, which requires that such products be licensed (42 U.S.C. 262). Section 351 of the PHS Act further authorizes FDA, by delegation, to establish requirements for such biologics licenses (42 U.S.C. 262(a)(2)(A)). In addition to its authority under section 361 of the PHS Act, FDA relies on this authority when the final regulations are applied to products subject to biologics license. To obtain a license, applicants must show that the biological product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards designed to assure the continued safety, purity, and potency of the blood and blood components. FDA license revocation regulations provide for the initiation of revocation proceedings if, among other reasons, the establishment or the product fails to conform to the standards in the license application or in the regulations designed to ensure the continued safety, purity, or potency of the product (§ 601.5).

Violations of section 351 are punishable by a 1-year term of imprisonment, a fine as described in the preceding paragraph, or both (42 U.S.C. 262(f), 18 U.S.C. 3571). Blood and blood components are also drugs or devices, as those terms are defined in sections 201(g)(1) and (h) of the FD&C Act (21 U.S.C. 321(g)(1) and (h); see *United States* v. *Calise,* 217 F. Supp. 705, 708–09 (S.D.N.Y. 1962)); 42 U.S.C. 262(j) (''The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) applies to a biological product subject to regulation under this section, except that a product for which a license has been approved . . . shall not be required to have an approved [new drug] application . . . .''). Since blood and blood components are drugs or devices generally subject to the FD&C Act, in issuing these regulations, FDA relies on the FD&C Act's grant of authority to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)). The FD&C Act requires blood establishments to comply with the FD&C Act's current good manufacturing practice provisions and related regulatory scheme. Under section 501 of the FD&C Act (21 U.S.C. 351), drugs, including blood and blood components, are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing, or holding do not conform with current good manufacturing practice (21 U.S.C. 351(a)(2)(B)). Devices are deemed ''adulterated'' if the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with current good manufacturing practice requirements established by FDA in regulations (21 U.S.C. 351(h) and 360j(f)(1)). The provisions of this rule are critical aspects of current good manufacturing practice. The regulation requires collection establishments to assure that donors of blood and blood components meet the essential criteria for eligibility, and that blood and blood components are suitable for transfusion or further manufacturing. Blood and blood components not manufactured in accordance with current good manufacturing practice, including the provisions of this rule, and other provisions in the CFR, would be considered adulterated under 21 U.S.C. 351(a)(2)(B) or 21 U.S.C. 351(h) and 360j(f)(1), and collection establishments and blood and blood components would be subject to the FD&C Act's enforcement provisions for violations of the FD&C Act. These include seizure of violative products (21 U.S.C. 332), injunction against ongoing and future violations, and criminal penalties (21 U.S.C. 333 and 18 U.S.C. 3571). The FD&C Act punishes both misdemeanor and felony violations of the FD&C Act. Misdemeanor violations are punishable by a term of imprisonment of up to 1 year, a fine as described previously, or both. (21 U.S.C. 333(a)(1), 18 U.S.C. 3571). Individuals convicted of felony violations may be sentenced to a term of imprisonment of up to 3 years, a fine of up to $250,000, or both. Organizations convicted of felony violations may be sentenced to a fine of up to $500,000. Individuals and organizations also face possible alternative fines based on the amount of gain or loss (18 U.S.C. 3571(b) through (d)).

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs associated with this rule are expected to be minimal, the Agency certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an

assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in a 1-year expenditure that would meet or exceed this amount.

This rule sets forth requirements for donor eligibility and donation suitability to ensure the safety, purity, and potency of the blood and blood components used for transfusion or for further manufacture. Costs estimated in this analysis include costs related to the SOPs and bacterial testing requirements for blood collection establishments and transfusion services. The total upfront costs are $16,042,628, and include costs related to the review, modification, and creation of standard operation procedures. The mean annual costs of $892,233 include costs related to the bacterial testing and speciation of platelets. We anticipate that this final rule will preserve the safety, purity, and potency of blood and blood components by preventing unsafe units of blood or blood components from entering the blood supply, and by providing recipients with increased protection against communicable disease transmission. The requirements set forth in this rule will also help to decrease the number of blood transfusion related fatalities that are associated with the bacterial contamination of platelets. The annual value of additional fatalities averted related by testing of Whole Blood-derived platelets is estimated to be approximately $27 million to $90 million and the annual value of averted nonfatal sepsis infections is estimated to be $3.19 million to $4.91 million.

The full discussion of economic impacts is available in Docket No. FDA–2006–N–0040 (formerly Docket No. 2006N–0221) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (Ref. 77).

V. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have 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. Accordingly, FDA has concluded that the final rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting, recordkeeping, and disclosure burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use.

Description: FDA is amending the regulations applicable to blood and blood components, including Source Plasma, to make donor eligibility and testing requirements more consistent with current practices in the blood industry, to more closely align the regulations with current FDA recommendations, and to provide flexibility to accommodate advancing technology. The following information collection provisions are for recordkeeping, and third party disclosure.

In this final rule, under § 606.100(b), FDA requires establishments to establish, maintain, and follow written SOPs for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, autologous transfusion, and further manufacturing purposes. Under this provision, FDA also clarifies that establishments must establish, maintain, and follow written SOPs for all steps in the investigation of product deviations related to § 606.171; and for all steps in recordkeeping related to current good manufacturing practice and other applicable requirements and standards. FDA has separated the requirements for procedures for donor deferral and donor notification, previously provided under § 606.100(b)(20), into the requirement for procedures for donor deferral under § 606.100(b)(20) and the procedures for donor notification under § 606.100(b)(21). In addition, under § 606.100(b)(22), blood collection establishments and transfusion services must have procedures to control the risk of bacterial contamination of platelets, including all steps required under § 606.145.

FDA continues to require, under § 606.160(b)(1)(i), collection establishments to maintain donor records that include donor selection, including medical interview and examination and where applicable, informed consent. The regulations in this final rule that pertain to the requirements to maintain donor records under § 606.160(b)(1)(i), are as follows:

- § 606.110(a)(2) allows for the use of plateletpheresis and leukapheresis procedures provided that the procedure is performed under the supervision of a responsible physician who is aware of the health status of the donor, and the physician has determined and documented that the donor's health permits plateletpheresis or leukapheresis.
- § 630.5(b)(1)(i) allows the responsible physician to delegate to a physician substitute or other trained person the activity of determining the eligibility of a donor and documenting assessments related to that determination (with certain specified exceptions).
- § 630.10(f)(2) allows a donor with blood pressure measurements outside of the established limits to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.
- § 630.10(f)(4) allows a donor with an irregular pulse or measurements outside of the established limits to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.
- § 630.10(g)(2)(i) requires that prior to each donation, collection establishments must provide information to the donor addressing the elements specified in § 630.10(g)(2)(ii)(A) through (g)(2)(ii)(E) and obtain the donor's

acknowledgement that the donor has reviewed the information.

- § 630.15(a)(1)(ii)(A) requires that when a donation is for autologous use, the responsible physician must determine and document that the donation may proceed.
- § 630.15(b)(2) requires that: (1) The responsible physician must obtain the informed consent of a plasma donor on the first day of donation or no more than 1 week before the first donation, and at subsequent intervals of no longer than 1 year; (2) the responsible physician must obtain the informed consent of a plasma donor who does not return within 6 months of the last donation; (3) the responsible physician must explain the risks and hazards of the procedure to the donor; (4) if a donor is enrolled in a new program, such as an immunization or special collection program, the responsible physician must again obtain an informed consent specific for that program.
- § 630.15(b)(7)(i) requires that the responsible physician determines and documents that the donor is in good health and the donor's health permits the plasmapheresis.
- § 630.15(b)(7)(iii) requires that special characteristics of the donor's plasma and the need for plasmapheresis of the donor under § 630.20(b) are documented at the establishment.
- § 630.20(a) allows for the collection of blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a), if the donation is for autologous use only as prescribed by the donor's physician, and the donor has a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent, and the responsible physician determines and documents that the donor's health permits the collection procedure.
- § 630.20(b) allows for plasma to be collected under a Source Plasma collection program for further manufacturing use into in vitro products for which there are no alternative sources from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a), if the donor meets the criteria in § 630.10(f)(1) through (6) and the responsible physician determines and documents for each donation that the donor's health permits the collection procedure, and the collection takes place under the medical oversight specified in the approved plasmapheresis program.
- § 640.21(e)(4) allows, for a period not to exceed 30 calendar days, a donor to serve as a dedicated plateletpheresis donor for a single recipient, in accordance with § 610.40(c)(1), as often as is medically necessary, provided in part, that the donor is in good health, as determined and documented by the responsible physician.

FDA redesignated § 606.160(b)(1)(ix) to § 606.160(b)(1)(x), and redesignated § 606.160(b)(1)(x) to § 606.160(b)(1)(ix). Also, FDA replaced previous cross-reference to § 630.6 with new cross-reference to § 630.40 in § 606.160(b)(1)(x) and (b)(1)(xi).

FDA revised § 606.160(e) to require establishments to maintain two records to include the following sections: (1) A record of all donors found to be ineligible or deferred at that location; so that blood and blood components from an ineligible donor are not collected and/or released while the donor is ineligible or deferred and (2) establishments must maintain at all locations operating under the same license or under common management a cumulative record of donors deferred from donation were reactive for evidence of infection due to HIV, HBV, or HCV. In addition, establishments other than Source Plasma establishments must include in this cumulative record donors deferred for evidence of infection due to HTLV or Chagas disease; (3) the cumulative record must be updated at least monthly to add donors newly deferred for the reasons described herein; (4) in addition, establishments must revise the cumulative record to remove donors who have been requalified under § 610.41(b).

Under final § 606.145(c), in the event a transfusion service identifies platelets as bacterially contaminated, the transfusion service must not release the product and must notify the blood collection establishment that provided the platelets. In addition, the transfusion service must take appropriate steps to identify the organism; these steps may include contracting with the collection establishment or a laboratory to identify the organism. The transfusion service must further notify the blood collection establishment either by providing information about the species of the contaminating organism when the transfusion service has been able to identify it, or by advising the blood collection establishment when the transfusion service has determined that the species cannot be identified.

Under final § 630.5(d), collection establishments must establish, maintain, and follow SOPs for obtaining rapid emergency medical services for donors when medically necessary. Under final § 630.10(b), collection establishments must provide educational material concerning relevant transfusion-transmitted infections to donors before donation when donor education about that relevant transfusion-transmitted infection is necessary to assure the safety, purity, and potency of blood and blood components.

Under § 630.10(c)(1) and (2), collection establishments may perform certain activities, provided that these activities are addressed in their SOPs.

FDA requires under § 630.15(a)(1)(ii)(B), that for a dedicated donation based on the intended recipient's documented exceptional medical need, the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

Under § 630.15(a)(2) collection establishments may collect more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or once in 16 weeks for apheresis collections resulting in two units of Red Blood Cells, when the donor is determined under § 630.10 to be eligible to undergo a therapeutic phlebotomy, provided that the container label conspicuously states the disease or condition of the donor that necessitated phlebotomy. However, no disease state labeling is required when the conditions under § 630.15(a)(2)(i) through (iii) are met.

Under § 630.20(c), a collection establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a), if the donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need, and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

FDA redesignated § 630.6 to § 630.40, which requires collection establishments under § 630.40(a) to make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s), as required under § 610.41(a); or any donor who has been deferred as required under § 630.30(b)(3) because their donated platelets have been determined under § 606.145(d) to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of

the donor; and any donor who has been determined not to be eligible as a donor based on eligibility criteria under §§ 630.10 and 630.15.

Under § 640.21(c), a Whole Blood donor must not serve as the source of platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function, unless the unit is labeled to identify the ingested drug that adversely affects platelet function.

FDA separated § 640.72(a)(2) into § 640.72(a)(2)(i) and (ii), and redesignated the cross-reference previously provided in § 640.72(a)(2) from § 640.63 to § 630.10, and added cross-reference to § 630.15. Final § 640.72(a)(2)(i) requires establishments that collect plasma to maintain records, including a separate and complete record of initial and periodic examinations, tests, laboratory data, and interviews etc., as required in §§ 630.10, 630.15, 640.65, 640.66, and 640.67, except as provided in § 640.72(a)(2)(ii). Final § 640.72(a)(2)(ii) provides that negative results for testing for evidence of infection due to relevant transfusion-transmitted infections required in § 610.40, and the volume or weight of plasma withdrawn from a donor need not be recorded on the individual donor record if such information is maintained on the premises of the plasmapheresis center where the donor's plasma has been collected.

Under § 640.72(a)(4), collection establishments must maintain records of the medical history and physical examination of the donor conducted in accordance with § 630.15(b)(1) and, where applicable, § 630.15(b)(5), and must document the eligibility of the donor as a plasmapheresis donor, and, when applicable, as an immunized donor.

Description of Respondents: Licensed and unlicensed, registered blood establishments that collect blood and blood components for transfusion, licensed blood establishments that collect Source Plasma, and registered and unregistered transfusion services.

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule (72 FR 63416 at 63434).

Based on information received from FDA's database systems, there are approximately 1,265 licensed blood collection establishments and approximately 416 licensed Source Plasma establishments, for a total of 1,681 licensed blood collection establishments. Also, there are approximately 680 total unlicensed, registered blood collection establishments. The approximate total of 2,361 collection establishments, includes the 1,265 licensed blood collection establishments, 416 licensed Source Plasma establishments, and 680 total unlicensed, registered blood collection establishments. FDA estimates that there are 4,961 total transfusion services. Most of these transfusion services are not required to register with FDA.

The recordkeeping and third party disclosure estimates are based on information provided by industry, CMS, GAO, HHS, and FDA experience. Based on this information, FDA estimates that collection establishments annually collect approximately 40 million units of Whole Blood and blood components, which includes approximately 25 million donations of Source Plasma from approximately 2 million donors, and approximately 15 million [1] donations of Whole Blood and apheresis Red Blood Cell donations from approximately 10.9 million donors, including approximately 225,000 (1.5 percent of 15 million) autologous donations. Assuming each autologous donor makes an average of 2 donations, FDA estimates that there are approximately 112,500 autologous donors.

FDA estimates the information collection burden as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
606.100(b) (Maintenance of SOPs) [2]	2,361	1	2,361	24	56,664
606.100(b) (Maintenance of SOPs) [3]	4,961	1	4,961	10	49,610
606.160(b)(1)(i) [4]	2,361	16,942	40,000,000	0.17	6,800,000
630.15(a)(1)(ii)(B)	1,945	1	1,945	1	1,945
630.20(c)	1,945	1	1,945	1	1,945
640.72(a)(4)	416	4,808	2,000,000	0.08	160,000
Total					7,070,164

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (2) are included in the estimate for § 606.100(b).
[3] The recordkeeping requirements in § 606.100(b)(22) is included in the estimate for § 606.100(b).
[4] The recordkeeping requirements in §§ 606.110(a)(2); 606.160(e); 630.5(b)(1)(i); 630.10(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (a)(1)(ii)(B); 630.15(b)(2), (b)(7)(i) and (b)(7)(iii); 630.20(a) and (b); and 640.21(e)(4), are included in the estimate for § 606.160(b)(1)(i).

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Hours per record	Total hours
606.100(b) (Review and Modify SOPs) [2]	1,574	1	1,574	40	62,960
606.100(b) (Review and Modify SOPs) [2]	787	1	787	60	47,220
606.100(b) (Review and Modify SOPs)	4,961	1	4,961	16	79,376
606.100(b)(22) (Establish SOPs)	1,488	1	1,488	16	23,808

[1] These estimates are based on the 2011 National Blood Collection and Utilization Survey Report, which estimated that a total of 15,721,000 Whole Blood and Red Blood Cell units were collected in 2011. The 2011 report noted a decline in the numbers of Whole Blood and Red Blood Cell units collected and transfused.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Hours per record	Total hours
Total					213,364

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 606.171; 630.5(d); and 630.10(c)(1) and (2), are included in the estimate for § 606.100(b).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
606.145(c)	4,961	0.28	1,400	0.02	28

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping: As shown in table 1, under § 606.100(b), FDA estimates that for the 2,361 recordkeepers, which includes approximately 1,265 licensed blood collection establishments, approximately 416 licensed Source Plasma establishments, and approximately 680 total unlicensed, registered blood collection establishments, it will take approximately 24 hours annually to review and maintain SOPs. The recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (2) are included in the estimate for § 606.100(b).

In addition, the information collection burden under § 606.100(b)(22), for the transfusion services to maintain their SOPs is included in the information collection burden estimate under § 606.100(b).

The information collection burden for §§ 606.110(a)(2); 606.160(e); 630.5(b)(1)(i); 630.10(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (B); 630.15(b)(2), (b)(7)(i) and (b)(7)(iii); 630.20(a) and (b); and 640.21(e)(4), refer to the requirement to maintain records for donor selection under § 606.160(b)(1) specifically § 606.160(b)(1)(i) and are included in the information collection burden estimate under this regulation.

In table 1, under § 630.15(a)(1)(ii)(B) and § 630.20(c), FDA calculates the information collection burden that for the 1,945 recordkeepers, which includes approximately 1,265 licensed blood collection establishments and approximately 680 registered blood collection establishments. The donation would be used solely by a specified recipient based on documented medical need, and thus would occur rarely. Consequently, the burden to collection establishments is minimal.

The revisions to § 606.160(b)(1)(ix) through (xi) are technical amendments and do not result in any new information collection burden. The information collections for these sections have been approved under OMB control number 0910–0116.

FDA is not calculating the information collection burden for final § 606.100(b)(20) and (21) because these regulations have not been changed only redesignated. The information collection for final § 606.100(b)(20) and (21) have been approved under OMB control number 0910–0116.

Under § 606.160(e), FDA is not calculating the information collection burden specifically for establishments to maintain donor records because there is either minimal or no additional burden associated with the final § 606.160(e) because establishments have either been maintaining these records or providing access to these records at locations operating under the same license or under common management under current regulation(s) or guidance(s), or as part of their usual and customary business practice. In addition, the number of ineligible donors for which the establishments must maintain records has been decreased from the proposed rule in this final rule, which reduces the information collection burden for this requirement. The information collection for § 606.160(e) have been approved as part of § 606.160 under OMB control number 0910–0116.

FDA is not calculating the information collection burden for § 640.72(a)(2)(i), because the information collection for maintaining a complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., for final § 630.10 (redesignated from § 640.63) and §§ 640.65, 640.66, and 640.67 have been approved under OMB control number 0910–0116. In addition, the information collection cross-referenced under § 630.15, is included in the information collection burden estimate for § 606.160(b)(1)(i). FDA is not calculating the information collection burden for § 640.72(a)(2)(ii), because there is no additional burden and is covered under OMB control number 0910–0116.

As shown in table 2, under § 606.100(b), FDA estimates that for the 2,361 recordkeepers, two-thirds or 1,574 of the collection establishments will each expend, as a one-time burden, to reconcile their SOPs with the requirements. FDA estimates for the remaining one-third or 787 of the collection establishments each will expend additional time to establish and reconcile their SOPs with the requirements. The one-time recordkeeping requirements in §§ 606.171, 630.5(d), and 630.10(c)(1) and (2) are included in the estimate for § 606.100(b).

In table 2, under § 606.100(b)(22), FDA estimates that for the 4,961 transfusion services potentially impacted by this rule, 40 percent are following the voluntary standards for testing, speciation, and notifying the blood establishment, as usual and customary practice. For the remaining 60 percent (2,977) transfusion services, approximately one-half (1,488) would be impacted by the rule and each of these would expend, as a one-time burden, and to create SOPs consistent with the requirements.

Third Party Disclosure: In table 3, under § 606.145(c), FDA estimates that for the approximate 4,961 transfusion services, there would be 1,400 total notifications per year to blood collection establishments (700 notifications per year that platelets are bacterially contaminated and 700 notifications per year concerning the identity or non-identity of the species of the contaminating organism).

The labeling requirements under § 630.15(a)(2), are consistent with the

current requirement under § 640.3(d) that donations from a donor ''shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor's disease that necessitated withdrawal of blood.'' FDA is not calculating the information collection burden for § 630.15(a)(2) because the burden is included in the calculation for § 640.3(d). In addition, § 630.15(a)(2) reduces the information collection burden by not requiring labeling under the conditions specified in the regulation. The information collection burden in § 630.40(d) is approved under OMB control number 0910–0116.

Under § 630.10(b), FDA requires collection establishments to provide the donor with educational material. FDA is not calculating the information collection burden for this regulation because establishments collecting blood and blood components perform this activity as a usual and customary business practice and there is minimal new information collection burden for this requirement.

The information collection burden in final § 630.40 resulting from the redesignation of § 630.6 has been approved under OMB control number 0910–0116. Under final § 630.40, FDA considers the changes in text from ''*communicable disease*'' to ''*relevant transfusion-transmitted infection(s)*'', ''*suitable*'' to ''*eligible*'', and ''*suitability*'' to ''*eligibility*'', to be technical amendments that do not confer any new burden. FDA is not calculating the information collection burden under § 606.145(d) for the additional requirement that establishments that collect blood or blood components make reasonable attempts to notify any donor whose donated platelets have been determined to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, because establishments perform this activity as a usual and customary business practice and there is minimal new information collection burden for this requirement. The third party disclosure burden under § 630.30(b)(4), is covered under § 630.40.

Under § 640.21(c), FDA requires the establishments to label donations received from platelet donors who have recently ingested a drug that adversely affects platelet function to identify the ingested drug. FDA is not calculating the information collection burden for this regulation as there is minimal additional burden for this requirement because establishments collecting blood and blood components perform this activity as a usual and customary business practice.

The collections of information under § 640.120 has been approved under OMB control number 0910–0338. FDA is not calculating information collection burden for § 640.120, because the changes that were made will not have an impact on the current burden estimated for industry.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Parts 610 and 660

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 630

Blood, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

■ 1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. In § 606.3, revise paragraphs (a) and (c) to read as follows:

§ 606.3 Definitions.

* * * * *

(a) *Blood* means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

* * * * *

(c) *Blood component* means a product containing a part of human blood

separated by physical or mechanical means.

* * * * *

§ 606.40 [Amended]

■ 3. In § 606.40(a)(1), remove ''suitability'' and add in its place ''eligibility''.

■ 4. Amend § 606.100 as follows:

■ a. Revise paragraph (b) introductory text;

■ b. In paragraph (b)(1), remove ''suitability'' and add in its place ''eligibility'';

■ c. Revise paragraph (b)(20); and

■ d. Add paragraphs (b)(21) and (b)(22).

The revisions and additions read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) Establishments must establish, maintain, and follow written standard operating procedures for all steps in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for allogeneic transfusion, autologous transfusion, and further manufacturing purposes; for all steps in the investigation of product deviations related to § 606.171; and for all steps in recordkeeping related to current good manufacturing practice and other applicable requirements and standards. Such procedures must be available to the personnel for use in the areas where the procedures are performed. The written standard operating procedures must include, but are not limited to, descriptions of the following, when applicable:

* * * * *

(20) Procedures for donor deferral as prescribed in § 610.41 of this chapter.

(21) Procedures for donor notification and notification of the referring physician of an autologous donor, including procedures for the appropriate followup if the initial attempt at notification fails, as prescribed in § 630.40 of this chapter.

(22) Procedures to control the risks of bacterial contamination of platelets, including all steps required under § 606.145.

* * * * *

§ 606.110 [Amended]

■ 5. Amend § 606.110 as follows:

■ a. In paragraph (a), remove ''qualified licensed physician'' and add in its place ''responsible physician'' and remove ''certified in writing'' and add in its place ''determined and documented''; and

■ b. In paragraph (b), remove ''640.63'' and add in its place ''630.10, 630.15''.

§ 606.121 [Amended]

■ 6. Amend § 606.121 as follows:

■ a. In paragraph (c)(11) remove ''communicable disease agents'' and add in its place ''relevant transfusion-transmitted infections''; and remove ''§§ 610.40(i) and 640.65(b)'' and add in its place ''§ 640.65(b)'';

■ b. In paragraph (c)(12) remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s)'';

■ c. In paragraphs (h)(2) and (3), remove ''640.5(a), (b),'' and add in its place ''640.5(b)''; and

■ d. In paragraph (i)(5), remove ''suitability'' and add in its place ''eligibility''; remove ''§ 640.3'' and add it its place ''§ 630.10''; and remove ''communicable disease agents'' and add in its place ''relevant transfusion-transmitted infections''.

§ 606.122 [Amended]

■ 7. In § 606.122(e), remove ''communicable disease agents'' and add in its place ''relevant transfusion-transmitted infections''.

■ 8. Add § 606.145 to subpart H to read as follows:

§ 606.145 Control of bacterial contamination of platelets.

(a) Blood collection establishments and transfusion services must assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA.

(b) In the event that a blood collection establishment identifies platelets as bacterially contaminated, that establishment must not release for transfusion the product or any other component prepared from the same collection, and must take appropriate steps to identify the organism.

(c) In the event that a transfusion service identifies platelets as bacterially contaminated, the transfusion service must not release the product and must notify the blood collection establishment that provided the platelets. The transfusion service must take appropriate steps to identify the organism; these steps may include contracting with the collection establishment or a laboratory to identify the organism. The transfusion service must further notify the blood collection establishment either by providing information about the species of the contaminating organism when the transfusion service has been able to identify it, or by advising the blood collection establishment when the transfusion service has determined that the species cannot be identified.

(d) In the event that a contaminating organism is identified under paragraph (b) or (c) of this section, the collection establishment's responsible physician, as defined in § 630.3(i) of this chapter, must determine whether the contaminating organism is likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor, in accordance with a standard operating procedure developed under § 606.100(b)(22). This determination may not be further delegated.

■ 9. In § 606.160, revise paragraphs (b)(1)(ix) through (xi), and (e) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(ix) The donor's postal address provided at the time of donation where the donor may be contacted within 8 weeks after donation.

(x) Records of notification of donors deferred or determined not to be eligible for donation, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 of this chapter.

(xi) Records of notification of the referring physician of a deferred autologous donor, including appropriate followup if the initial attempt at notification fails, performed under § 630.40 of this chapter.

* * * * *

(e) *Records of deferred donors.* (1) Establishments must maintain at each location a record of all donors found to be ineligible or deferred at that location so that blood and blood components from an ineligible donor are not collected and/or released while the donor is ineligible or deferred; and

(2) Establishments must maintain at all locations operating under the same license or under common management a cumulative record of donors deferred from donation under § 610.41 of this chapter because their donation tested reactive under § 610.40(a)(1) of this chapter for evidence of infection due to HIV, HBV, or HCV. In addition, establishments other than Source Plasma establishments must include in this cumulative record donors deferred from donation under § 610.41 of this chapter because their donation tested reactive under § 610.40(a)(2) of this chapter for evidence of infection due to HTLV or Chagas disease.

(3) The cumulative record described in paragraph (e)(2) of this section must be updated at least monthly to add

donors newly deferred under § 610.41 of this chapter due to reactive tests for evidence of infection due to HIV, HBV, or HCV, and, if applicable, HTLV or Chagas disease.

(4) Establishments must revise the cumulative record described in paragraph (e)(2) of this section to remove donors who have been requalified under § 610.41(b) of this chapter.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 10. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 11. Revise the heading for subpart E to read as follows:

Subpart E—Testing Requirements for Relevant Transfusion-Transmitted Infections

■ 12. Add § 610.39 to subpart E to read as follows:

§ 610.39 Definitions.

The definitions set out in § 630.3 of this chapter apply to this subpart.

■ 13. Amend § 610.40 as follows:
■ a. Revise paragraph (a);
■ b. Revise paragraph (b);
■ c. Revise paragraph (c) heading;
■ d. Remove paragraph (c)(2) and redesignate paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3);
■ e. In redesignated paragraph (c)(2)(i), remove ''communicable disease agents listed in paragraphs (a)(5) and (a)(6) of this section'' and add in its place ''relevant transfusion-transmitted infections listed in § 630.3(h)(iv) of this chapter'';
■ f. In paragraph (d), remove ''communicable disease agents'' and add in its place ''relevant transfusion-transmitted infections''; and remove ''or by a serological test for syphilis under paragraph (i) of this section'';
■ g. Revise paragraph (e);
■ h. In paragraph (f), remove ''Health Care Financing Administration'' and add in its place ''Centers for Medicare and Medicaid Services'';
■ i. In paragraph (g) introductory text, remove ''communicable disease agents'' in both places it appears and add in each place ''relevant transfusion-transmitted infections''; and remove ''paragraphs (a) and (i)'' and add in its place ''paragraph (a)'';
■ j. In paragraph (h)(1), remove ''a communicable disease agent(s) designated in paragraphs (a) and (i)'' in both places it appears and add in each place ''relevant transfusion-transmitted infection(s) designated in paragraph (a)'';
■ k. In paragraphs (h)(2)(ii) introductory text, (h)(2)(ii)(C), and (h)(2)(iv) introductory text, remove ''communicable disease agent(s)'' wherever it appears and add in its place ''relevant transfusion-transmitted infection(s)'';
■ *l.* In paragraph (h)(2)(iv)(A), remove ''suitable'' and add in its place ''eligible'';
■ m. In paragraph (h)(2)(vi), remove ''paragraph (i)'' and add in its place ''paragraph (a)''; and remove ''consistent with § 640.5 of this chapter,'';
■ n. In paragraph (h)(2)(vii), remove ''§ 610.40(i)'' and add in its place ''§ 640.65(a)(2)(ii) and (b)(1)(i)''; and remove ''§ 640.65(b)(2)'' and add in its place ''§ 640.65(b)(2)(i) through (b)(2)(iv)''; and
■ *o.* Remove paragraph (i).

The revisions read as follows:

§ 610.40 Test requirements.

(a) *Human blood and blood components.* Except as specified in paragraphs (c) and (d) of this section, you, an establishment that collects blood and blood components for transfusion or for use in manufacturing a product, including donations intended as a component of, or used to manufacture, a medical device, must comply with the following requirements:

(1) Test each donation for evidence of infection due to the relevant transfusion-transmitted infections described in § 630.3(h)(1)(i) through (iii) of this chapter (HIV, HBV, and HCV).

(2) Test each donation for evidence of infection due to the relevant transfusion-transmitted infections described in § 630.3(h)(1)(iv) through (vii) of this chapter (HTLV, syphilis, West Nile virus, and Chagas disease). The following exceptions apply:

(i) To identify evidence of infection with syphilis in donors of Source Plasma, you must test donors for evidence of such infection in accordance with § 640.65(b) of this chapter, and not under this section.

(ii) You are not required to test donations of Source Plasma for evidence of infection due to the relevant transfusion-transmitted infections described in § 630.3(h)(1)(iv), (vi), and (vii) of this chapter (HTLV, West Nile virus, and Chagas disease).

(iii) For each of the relevant transfusion-transmitted infections described in § 630.3(h)(1)(iv) through (vii) of this chapter (HTLV, syphilis, West Nile virus, and Chagas disease):

(A) If, based on evidence related to the risk of transmission of that relevant transfusion-transmitted infection, testing each donation is not necessary to reduce adequately and appropriately the risk of transmission of such infection by blood or a blood component, you may adopt an adequate and appropriate alternative testing procedure that has been found acceptable for this purpose by FDA.

(B) If, based on evidence related to the risk of transmission of that relevant transfusion-transmitted infection, testing previously required for that infection is no longer necessary to reduce adequately and appropriately the risk of transmission of such infection by blood or a blood component, you may stop such testing in accordance with procedures found acceptable for this purpose by FDA.

(3) For each of the relevant transfusion-transmitted infections described in § 630.3(h)(1)(viii) through (x) of this chapter (CJD, vCJD, malaria) and § 630.3(h)(2) of this chapter (other transfusion-transmitted infections):

(i) You must test for evidence of infection when the following conditions are met:

(A) A test(s) for the relevant transfusion-transmitted infection is licensed, approved or cleared by FDA for use as a donor screening test and is available for such use; and

(B) Testing for the relevant transfusion-transmitted infection is necessary to reduce adequately and appropriately the risk of transmission of the relevant transfusion-transmitted infection by blood, or blood component, or blood derivative product manufactured from the collected blood or blood component.

(ii) You must perform this testing on each donation, unless one of the following exceptions applies:

(A) Testing of each donation is not necessary to reduce adequately and appropriately the risk of transmission of such infection by blood, blood component, or blood derivative product manufactured from the collected blood or blood component. When evidence related to the risk of transmission of such infection supports this determination, you may adopt an adequate and appropriate alternative testing procedure that has been found acceptable for this purpose by FDA.

(B) Testing of each donation is not necessary to reduce adequately and appropriately the risk of transmission of such infection by blood, blood component, or blood derivative product manufactured from the collected blood or blood component. When evidence related to the risk of transmission of

such infection supports this determination, you may stop such testing in accordance with procedures found acceptable for this purpose by FDA.

(4) Evidence related to the risk of transmission of a relevant transfusion-transmitted infection that would support a determination that testing is not necessary, or that testing of each donation is not necessary, to reduce adequately and appropriately the risk of transmission of such infection by blood or blood component, as described in paragraphs (a)(2)(iii)(A) and (B) of this section, or by blood, blood component, or blood derivative, as described in paragraphs (a)(3)(ii)(A) and (B) of this section, includes epidemiological or other scientific evidence. It may include evidence related to the seasonality or geographic limitation of risk of transmission of such infection by blood or blood component, or other information related to when and how a donation is at risk of transmitting a relevant transfusion-transmitted infection. It may also include evidence related to the effectiveness of manufacturing steps (for example, the use of pathogen reduction technology) that reduce the risk of transmission of the relevant transfusion-transmitted infection by blood, blood components, or blood derivatives, as applicable.

(b) *Testing using one or more licensed, approved, or cleared screening tests.* To perform testing for evidence of infection due to relevant transfusion-transmitted infections as required in paragraph (a) of this section, you must use screening tests that FDA has licensed, approved, or cleared for such use, in accordance with the manufacturer's instructions. You must perform one or more such tests as necessary to reduce adequately and appropriately the risk of transmission of relevant transfusion-transmitted infections.

(c) *Exceptions to testing for dedicated donations, medical devices, and samples.* * * *

* * * * *

(e) *Further testing.* You must further test each donation, including autologous donations, found to be reactive by a donor screening test performed under paragraphs (a) and (b) of this section using a licensed, approved, or cleared supplemental test, when available. If no such supplemental test is available, you must perform one or more licensed, approved, or cleared tests as adequate and appropriate to provide additional information concerning the reactive donor's infection status. Except:

(1) For autologous donations:

(i) You must further test under this section, at a minimum, the first reactive donation in each 30 calendar day period; or

(ii) If you have a record for that donor of a positive result on further testing performed under this section, you do not have to further test an autologous donation.

(2) You are not required to perform further testing of a donation found to be reactive by a treponemal donor screening test for syphilis.

* * * * *

■ 14. Amend § 610.41 as follows:

■ a. In paragraph (a) introductory text, remove ''communicable disease agent(s) listed in § 610.40(a) or reactive for a serological test for syphilis under § 610.40(i)'' and add in its place ''relevant transfusion-transmitted infection(s) under § 610.40(a)'';

■ b. Revise paragraph (a)(1);

■ c. In paragraph (a)(2), remove ''communicable disease agent(s) listed in'' and add in its place ''relevant transfusion-transmitted infection(s) under'';

■ d. In paragraphs (a)(3) and (4), remove ''suitable'' and add in its place ''eligible'';

■ e. In paragraph (a)(5), remove ''communicable disease agent(s) described under § 610.40(a) or reactive with a serological test for syphilis under § 610.40(i)'' and add in its place ''relevant transfusion-transmitted infections(s) under § 610.40(a)''; and

■ f. In paragraph (b), remove ''suitable'' and add in its place ''eligible''.

The revisions read as follows:

§ 610.41 Donor deferral.

(a) * * *

(1) You are not required to defer a donor who tests reactive for anti-HBc or anti-HTLV, types I and II, on only one occasion. However, you must defer the donor if further testing for HBV or HTLV has been performed under § 610.40(e) and the donor is found to be positive, or if a second, licensed, cleared, or approved screening test for HBV or HTLV has been performed on the same donation under § 610.40(a) and is reactive, or if the donor tests reactive for anti-HBc or anti-HTLV, types I and II, on more than one occasion;

* * * * *

§ 610.42 [Amended]

■ 15. In § 610.42(a), remove ''or reactive for syphilis under § 610.40(i)''; and remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s)''.

§ 610.44 [Amended]

■ 16. In paragraph (a)(1) remove ''communicable disease agents listed in'' and add in its place ''relevant transfusion-transmitted infections under''; and in paragraph (a)(2) remove ''communicable disease agent'' and add in its place ''relevant transfusion-transmitted infection''.

§ 610.46 [Amended]

■ 17. Amend § 610.46 as follows:

■ a. In paragraph (a)(2), remove ''a supplemental (additional, more specific) test'' and add in its place ''further testing'';

■ b. In paragraph (a)(3), remove ''supplemental (additional, more specific) test results'' and add in its place ''results of further testing''; and remove ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing under paragraph (a)(2) of this section is not available'';

■ c. In paragraph (a)(4), remove ''supplemental (additional, more specific) test'' and add in its place ''further testing''; and remove ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''; and

■ d. In paragraph (b)(2), remove ''supplemental (additional, more specific) test'' and add in its place ''further testing''; and remove ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''; and

■ e. In paragraph (b)(3), remove in the first sentence ''the supplemental (additional, more specific) test'' and add in its place ''further testing''; remove in the first sentence ''there is no available supplemental test that is approved for such use by FDA,'' and add in its place ''further testing is not available''; remove in the last sentence ''supplemental (additional, more specific) test results'' and add in its place ''results of further testing''; and remove in the last sentence ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''.

§ 610.47 [Amended]

■ 18. Amend 610.47 as follows:

■ a. In paragraph (a)(2), remove ''a supplemental (additional, more specific) test'' and add in its place ''further testing'';

■ b. In paragraph (a)(3), remove in the first sentence ''supplemental (additional, more specific) test results''

and add in its place ''results of further testing''; and remove in the first sentence ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available'';

■ c. In paragraph (a)(4), remove ''supplemental (additional, more specific) test'' and add in its place ''further testing''; and remove ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''; and

■ d. In paragraph (b)(2), remove ''supplemental (additional, more specific) test'' and add in its place ''further testing''; and remove ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''; and

■ e. In paragraph (b)(3), remove in the first sentence ''supplemental (additional, more specific) test'' and add in its place ''further testing''; remove in the first sentence ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''; remove in the last sentence ''supplemental (additional, more specific) test results'' and add in its place ''results of further testing''; and remove in the last sentence ''there is no available supplemental test that is approved for such use by FDA'' and add in its place ''further testing is not available''.

PART 630—REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR FOR FURTHER MANUFACTURING USE

■ 19. The authority citation for part 630 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 264.

■ 20. Revise the heading for part 630 to read as set forth above.

■ 21. Add subpart C with the heading to read as follows:

Subpart C—Donor Notification

■ 22. Redesignate § 630.6 as § 630.40, and further redesignate newly designated § 630.40 to subpart C.

■ 23. Amend newly designated § 630.40 as follows:

■ a. Revise the section heading;

■ b. In paragraph (a), revise the first sentence; and remove the word ''supplemental'' from the second and third sentences and add in its place ''further'';

■ c. In paragraphs (b) introductory text and (b)(1), remove ''suitable'' and add in its place ''eligible'';

■ d. In paragraph (b)(3), remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s)''; and remove ''supplemental (*i.e.,* additional, more specific) tests'' and add in its place ''further testing'';

■ e. In paragraph (c), remove ''suitable'' and add in its place ''eligible'';

■ f. In paragraph (d)(1) introductory text, remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s) or whose platelets indicate evidence of a bacterial infection that is endogenous to the bloodstream of the donor'';

■ g. In paragraph (d)(1)(i), remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s)''; and

■ h. In paragraph (d)(1)(iii), remove ''communicable disease agent(s)'' and add in its place ''relevant transfusion-transmitted infection(s)''; and remove ''supplemental (*i.e.,* additional, more specific) tests'' and add in its place ''further testing'';

The revisions read as follows:

§ 630.40 Requirements for notifying deferred donors.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a relevant transfusion-transmitted infection(s) as required by § 610.41(a) of this chapter; any donor who has been deferred as required under § 630.30(b)(3) because their donated platelets have been determined under § 606.145(d) of this chapter to be contaminated with an organism that is identified as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor; and any donor who has been determined not to be eligible as a donor based on eligibility criteria under §§ 630.10 and 630.15. * * *

* * * * *

■ 24. Add subparts A and B to part 630 to read as follows:

Subpart A—General Provisions

Sec.
630.1 Purpose and scope.
630.3 Definitions.

Subpart B—Donor Eligibility Requirements

Sec.
630.5 Medical supervision.
630.10 General donor eligibility requirements.
630.15 Donor eligibility requirements specific to Whole Blood, Red Blood Cells and Plasma collected by apheresis.
630.20 Exceptions for certain ineligible donors.
630.25 Exceptions from certain donor eligibility requirements for infrequent plasma donors.
630.30 Donation suitability requirements.
630.35 Requalification of previously deferred donors.

Subpart A—General Provisions

§ 630.1 Purpose and scope.

(a) *What is the purpose of subparts A, B, and C of this part*? The purpose of these subparts, together with §§ 610.40 and 610.41 of this chapter, is to provide certain minimum criteria for each donation of blood and blood components, for:

(1) Determining the eligibility of a donor of blood and blood components;

(2) Determining the suitability of the donation of blood and blood components; and

(3) Notifying a donor who is deferred from donation.

(b) *Who must comply with subparts A, B, and C of this part*? Blood establishments that manufacture blood and blood components, as defined in § 630.3(a) and (b), must comply with subparts A, B, and C of this part.

§ 630.3 Definitions.

As used in this part and in part 610, subpart E, and part 640 of this chapter:

(a) *Blood* means a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human.

(b) *Blood component* means a product containing a part of blood separated by physical or mechanical means.

(c) *Donor* means a person who: (1) Donates blood or blood components for transfusion or for further manufacturing use; or

(2) Presents as a potential candidate for such donation.

(d) *Eligibility of a donor* means the determination that the donor is qualified to donate blood and blood components.

(e) *Infrequent plasma donor* means a donor who has:

(1) Not donated plasma by plasmapheresis or a co-collection of plasma with another blood component in the preceding 4 weeks; and

(2) Not donated more than 12.0 liters of plasma (14.4 liters of plasma for donors weighing more than 175 pounds) in the past year.

(f) *Intimate contact with risk for a relevant transfusion-transmitted infection* means having engaged in an

activity that could result in the transfer of potentially infectious body fluids from one person to another.

(g) *Physician substitute* means a trained and qualified person(s) who is:

(1) A graduate of an education program for health care workers that includes clinical training;

(2) Currently licensed or certified as a health care worker in the jurisdiction where the collection establishment is located;

(3) Currently certified in cardiopulmonary resuscitation; and

(4) Trained and authorized under State law, and/or local law when applicable, to perform the specified functions under the direction of the responsible physician.

(h) *Relevant transfusion-transmitted infection* means:

(1) Any of the following transfusion-transmitted infections:

(i) Human immunodeficiency virus, types 1 and 2 (referred to, collectively, as HIV);

(ii) Hepatitis B virus (referred to as HBV);

(iii) Hepatitis C virus (referred to as HCV);

(iv) Human T-lymphotropic virus, types I and II (referred to, collectively, as HTLV);

(v) *Treponema pallidum* (referred to as syphilis);

(vi) West Nile virus;

(vii) *Trypanosoma cruzi* (referred to as Chagas disease);

(viii) Creutzfeldt-Jakob disease (referred to as CJD);

(ix) Variant Creutzfeldt-Jakob disease (referred to as vCJD); and

(x) *Plasmodium* species (referred to as malaria).

(2) A transfusion-transmitted infection not listed in paragraph (h)(1) of this section when the following conditions are met:

(i) Appropriate screening measures for the transfusion-transmitted infection have been developed and/or an appropriate screening test has been licensed, approved, or cleared for such use by FDA and is available; and

(ii) The disease or disease agent:

(A) May have sufficient incidence and/or prevalence to affect the potential donor population; or

(B) May have been released accidentally or intentionally in a manner that could place potential donors at risk of infection.

(i) *Responsible physician* means an individual who is:

(1) Licensed to practice medicine in the jurisdiction where the collection establishment is located;

(2) Adequately trained and qualified to direct and control personnel and relevant procedures concerning the determination of donor eligibility; collection of blood and blood components; the immunization of a donor; and the return of red blood cells or other blood components to the donor during collection of blood component(s) by apheresis; and

(3) Designated by the collection establishment to perform the activities described in paragraph (i)(2) of this section.

(j) *Suitability of the donation* means a determination of whether the donation is acceptable for transfusion or for further manufacturing use.

(k) *Trained person* means an individual, including a physician substitute, who is authorized under State law, and/or local law when applicable, and adequately instructed and qualified to perform the specified functions under the direction of the responsible physician.

(*l*) *Transfusion-transmitted infection* means a disease or disease agent:

(1) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to a body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure; and

(2) For which there may be a risk of transmission by blood or blood components, or by a blood derivative product manufactured from blood or blood components, because the disease or disease agent is potentially transmissible by that blood, blood component, or blood derivative product.

Subpart B—Donor Eligibility Requirements

§ 630.5 Medical supervision.

(a) *Who must determine the eligibility of a donor*? The responsible physician must determine the eligibility of a donor of blood or blood components in accordance with this subchapter.

(b) *Which activities related to the collection of blood and blood components, other than Source Plasma and plasma collected by plasmapheresis, may the responsible physician delegate*?

(1) The responsible physician may delegate the following activities to a physician substitute or other trained person:

(i) Determining the eligibility of a donor and documenting assessments related to that determination, except the responsible physician must not delegate:

(A) The examination and determination of the donor's health required in § 630.10(f)(2) for donors with blood pressure measurements outside specified limits, or for certain more frequent donations under § 630.15(a)(1)(ii);

(B) The determination of the health of the donor required in §§ 630.10(f)(4), 630.20(a), and 640.21(e)(4) of this chapter. The responsible physician may make this determination by telephonic or other offsite consultation; or

(C) The determination of the health of the donor and the determination that the blood or blood component collected would present no undue medical risk to the transfusion recipient, as required in § 630.20(c). The responsible physician may make these determinations by telephonic or other offsite consultation.

(ii) Collecting blood or blood components;

(iii) Returning red blood cells to the donor during apheresis;

(iv) Obtaining the informed consent of a plateletpheresis donor as described in § 640.21(g) of this chapter; or

(v) Other activities provided that the Director, Center for Biologics Evaluation and Research, determines that delegating the activities would present no undue medical risk to the donor or to the transfusion recipient, and authorizes the delegation of such activities.

(2) The responsible physician need not be present at the collection site when activities delegated under paragraph (b)(1) of this section are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is adequately trained and experienced in the performance of these activities and is also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures.

(c) *Which activities related to the collection of Source Plasma and plasma collected by plasmapheresis may the responsible physician delegate*?

(1) *Donor eligibility and blood component collection activities.* (i) The responsible physician may delegate to a physician substitute or other trained person any of the activities described in paragraph (c)(1)(i)(A) of this section, provided that the responsible physician or a physician substitute is on the premises at the collection site:

(A) The activities listed in paragraphs (b)(1)(i) through (iii) and (b)(1)(v) of this section, with respect to Source Plasma and plasma collected by plasmapheresis. However, the responsible physician must not delegate:

(*1*) The examination and determination of the donor's health required in § 630.10(f)(2) for donors with blood pressure measurements outside specified limits, or in § 630.15(b)(7) for certain donors who have experienced red blood cell loss;

(*2*) The determination of the health of the donor required in §§ 630.10(f)(4) and 630.20(a) and (b). The responsible physician may make this determination by telephonic or other offsite consultation;

(*3*) The determination of the health of the donor and the determination that the blood component would present no undue medical risk to the transfusion recipient, as required in § 630.20(c). The responsible physician may make this determination by telephonic or other offsite consultation.

(*4*) The determination related to a donor's false-positive reaction to a serologic test for syphilis in accordance with § 640.65(b)(2)(iii) of this chapter; and

(*5*) The determination to permit plasmapheresis of a donor with a reactive serological test for syphilis in accordance with § 640.65(b)(2)(iv) of this chapter.

(B) The collection of Source Plasma in an approved collection program from a donor who is otherwise determined to be ineligible.

(C) The collection of a blood sample in accordance with § 640.65(b)(1)(i) of this chapter.

(ii) The responsible physician, who may or may not be present when these activities are performed, may delegate to a physician substitute the following activities:

(A) Approval and signature for a plasmapheresis procedure as provided in § 640.65(b)(1)(ii) of this chapter; and

(B) Review and signature for accumulated laboratory data, the calculated values of each component, and the collection records in accordance with § 640.65(b)(2)(i) of this chapter. However, the responsible physician must not delegate the decision to reinstate the deferred donor in accordance with that provision.

(2) *Donor immunization.* The responsible physician must not delegate activities performed in accordance with § 640.66 of this chapter, except that:

(i) The responsible physician may delegate to a physician substitute or other trained person the administration of an immunization other than red blood cells to a donor in an approved collection program, provided that the responsible physician or a physician substitute is on the premises at the collection site when the immunization is administered.

(ii) The responsible physician may delegate to a physician substitute the administration of red blood cells to a donor in an approved collection program, provided that the responsible physician has approved the procedure and is on the premises at the collection site when the red blood cells are administered.

(3) *Medical history, physical examination, informed consent, and examination before immunization.* Provided that such activities are performed under the supervision of the responsible physician, the responsible physician may delegate to a physician substitute the activities described in § 630.15(b)(1), (2), and (5). The responsible physician is not required to be present at the collection site when the physician substitute performs these activities under supervision.

(4) *Infrequent plasma donors.* (i) For infrequent plasma donors other than those described in paragraph (c)(4)(ii) of this section, the responsible physician may delegate to a trained person the activities listed in paragraphs (b)(1)(i) through (iii) and (b)(1)(v) of this section and the informed consent requirements described in § 630.15(b)(2). The responsible physician or a physician substitute need not be present at the collection site when any of these activities are performed, provided that the responsible physician has delegated oversight of these activities to a trained person who is not only adequately trained and experienced in the performance of these activities but also adequately trained and experienced in the recognition of and response to the known adverse responses associated with blood collection procedures. However, the responsible physician must not delegate:

(A) The examination and determination of the donor's health required in § 630.10(f)(2) for donors with blood pressure measurements outside specified limits, or in § 630.15(b)(7) for certain donors who have experienced red blood cell loss; or

(B) The determination of the health of the donor required in § 630.10(f)(4).

(ii) For infrequent plasma donors who are otherwise ineligible or are participating in an approved immunization program, the responsible physician may delegate only in accordance with paragraphs (c)(1) through (3) of this section.

(d) *Must rapid emergency medical services be available*? Establishments that collect blood or blood components must establish, maintain, and follow standard operating procedures for obtaining rapid emergency medical services for donors when medically necessary. In addition, establishments must assure that an individual (responsible physician, physician substitute, or trained person) who is currently certified in cardiopulmonary resuscitation is located on the premises whenever collections of blood or blood components are performed.

§ 630.10 General donor eligibility requirements.

(a) *What factors determine the eligibility of a donor*? You, an establishment that collects blood or blood components, must not collect blood or blood components before determining that the donor is eligible to donate or before determining that an exception to this provision applies. To be eligible, the donor must be in good health and free from transfusion-transmitted infections as can be determined by the processes in this subchapter. A donor is not eligible if the donor is not in good health or if you identify any factor(s) that may cause the donation to adversely affect:

(1) The health of the donor; or

(2) The safety, purity, or potency of the blood or blood component.

(b) *What educational material must you provide to the donor before determining eligibility*? You must provide educational material concerning relevant transfusion-transmitted infections to donors before donation when donor education about that relevant transfusion-transmitted infection, such as HIV, is necessary to assure the safety, purity, and potency of blood and blood components. The educational material must include an explanation of the readily identifiable risk factors closely associated with exposure to the relevant transfusion-transmitted infection. You must present educational material in an appropriate form, such as oral, written or multimedia, and in a manner designed to be understood by the donor. The educational material must instruct the donor not to donate blood and blood components when a risk factor is present. When providing educational material to donors under this section, you may include in those materials the information required to be provided to donors under paragraph (g)(2)(ii)(E) of this section.

(c) *When must you determine the eligibility of a donor*? You must determine donor eligibility on the day of donation, and before collection. Except:

(1) When a donor is donating blood components that cannot be stored for more than 24 hours, you may determine the donor's eligibility and collect a sample for testing required under § 610.40 of this chapter, no earlier than

2 calendar days before the day of donation, provided that your standard operating procedures address these activities.

(2) In the event that, upon review, you find that a donor's responses to the donor questions before collection were incomplete, within 24 hours of the time of collection, you may clarify a donor's response or obtain omitted information required under paragraph (e) of this section, provided that your standard operating procedures address these activities.

(d) *How must you determine the eligibility of a donor*? You must determine the donor's eligibility before collection of blood or blood components, by the following procedures:

(1) You must consult the records of deferred donors maintained under § 606.160(e)(1) and (2) of this chapter. Exception: If pre-collection review of the record described in § 606.160(e)(2) of this chapter is not feasible because you cannot consult the cumulative record at the collection site, you must consult the cumulative record prior to release of any blood or blood component prepared from the collection.

(2) Assure that the interval since the donor's last donation is appropriate;

(3) Assess the donor's medical history; and

(4) Perform a physical assessment of the donor.

(e) *How do you assess the donor's medical history*? Before collection you must conduct a medical history interview as described in this section to determine if the donor is in good health; to identify risk factors closely associated with exposure to, or clinical evidence of a relevant transfusion-transmitted infection; and to determine if there are other conditions that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components or any product manufactured from the blood or blood components. Your assessment must include each of the following factors:

(1) Factors that make the donor ineligible to donate because of an increased risk for, or evidence of, a relevant transfusion-transmitted infection. A donor is ineligible to donate when information provided by the donor or other reliable evidence indicates possible exposure to a relevant transfusion-transmitted infection if that risk of exposure is still applicable at the time of donation. Information and evidence indicating possible exposure to a relevant transfusion-transmitted infection include:

(i) Behaviors associated with a relevant transfusion-transmitted infection;

(ii) Receipt of blood or blood components or other medical treatments and procedures associated with possible exposure to a relevant transfusion-transmitted infection;

(iii) Signs and/or symptoms of a relevant transfusion-transmitted infection;

(iv) Institutionalization for 72 hours or more consecutively in the past 12 months in a correctional institution;

(v) Intimate contact with risk for a relevant transfusion-transmitted infection; and

(vi) Nonsterile percutaneous inoculation.

(2) Other factors that make the donor ineligible to donate. A donor is ineligible to donate when donating could adversely affect the health of the donor, or when the safety, purity, or potency of the blood or blood component could be affected adversely. Your assessment of the donor must include each of the following factors:

(i) Symptoms of a recent or current illness;

(ii) Certain medical treatments or medications;

(iii) Travel to, or residence in, an area endemic for a transfusion-transmitted infection, when such screening is necessary to assure the safety, purity, and potency of blood and blood components due to the risks presented by donor travel and the risk of transmission of that transfusion-transmitted infection by such donors;

(iv) Exposure or possible exposure to an accidentally or intentionally released disease or disease agent relating to a transfusion-transmitted infection, if you know or suspect that such a release has occurred;

(v) Pregnancy at the time of, or within 6 weeks prior to, donation;

(vi) Whether, in the opinion of the interviewer, the donor appears to be under the influence of any drug, alcohol or for any reason does not appear to be providing reliable answers to medical history questions, or if the donor says that the purpose of donating is to obtain test results for a relevant transfusion-transmitted infection; and

(vii) The donor is a xenotransplantation product recipient.

(f) *How do you perform a physical assessment of the donor*? You must determine on the day of donation, and before collection that the donor is in good health based on the following, at a minimum:

(1) *Temperature.* The donor's oral body temperature must not exceed 37.5 °C (99.5 °F), or the equivalent if measured at another body site;

(2) *Blood pressure.* The donor's systolic blood pressure must not measure above 180 mm of mercury, or below 90 mm of mercury, and the diastolic blood pressure must not measure above 100 mm of mercury or below 50 mms of mercury. A donor with measurements outside these limits may be permitted to donate only when the responsible physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating.

(3) *Hemoglobin or hematocrit determination.* You must determine the donor's hemoglobin level or hematocrit value by using a sample of blood obtained by fingerstick, venipuncture, or by a method that provides equivalent results. Blood obtained from the earlobe is not acceptable.

(i) Allogeneic donors must have a hemoglobin level or hematocrit value that is adequate to assure donor safety and product potency. The following minimum standards apply.

(A) Female allogeneic donors must have a hemoglobin level that is equal to or greater than 12.5 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 38 percent. Recognizing that lower levels are also within normal limits for female donors, you may collect blood from female allogeneic donors who have a hemoglobin level between 12.0 and 12.5 grams per deciliter of blood, or a hematocrit value between 36 and 38 percent, provided that you have taken additional steps to assure that this alternative standard is adequate to ensure that the health of the donor will not be adversely affected due to the donation, in accordance with a procedure that has been found acceptable for this purpose by FDA.

(B) Male allogeneic donors must have a hemoglobin level that is equal to or greater than 13.0 grams of hemoglobin per deciliter of blood, or a hematocrit value that is equal to or greater than 39 percent.

(ii) An autologous donor must have a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood, or a hematocrit value no less than 33 percent.

(4) *Pulse.* The donor's pulse must be regular and between 50 and 100 beats per minute. A donor with an irregular pulse or measurements outside these limits may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(5) *Weight.* The donor must weigh a minimum of 50 kilograms (110 pounds).

(6) *Skin examination.* (i) The donor's phlebotomy site must be free of infection, inflammation, and lesions; and

(ii) The donor's arms and forearms must be free of punctures and scars indicative of injected drugs of abuse.

(g) *Are there additional requirements for determining the eligibility of the donor*? You must obtain the following from the donor on the day of donation:

(1) *Proof of identity and postal address.* You must obtain proof of identity of the donor and a postal address where the donor may be contacted for 8 weeks after donation; and

(2) *Donor's acknowledgement.* (i) Prior to each donation, you must provide information to the donor addressing the elements specified in paragraphs (g)(2)(ii)(A) through (E) of this section and obtain the donor's acknowledgement that the donor has reviewed the information. You must establish procedures in accordance with § 606.100 of this chapter to assure that the donor has reviewed this material, and provide for a signature or other documented acknowledgement.

(ii) The donor acknowledgement must not include any exculpatory language through which the donor is made to waive or appear to waive any of the donor's legal rights. It must, at a minimum clearly address the following:

(A) The donor has reviewed the educational material provided under paragraph (b) of this section regarding relevant transfusion-transmitted infections;

(B) The donor agrees not to donate if the donation could result in a potential risk to recipients as described in the educational material;

(C) A sample of the donor's blood will be tested for specified relevant transfusion-transmitted infections;

(D) If the donation is determined to be not suitable under § 630.30(a) or if the donor is deferred from donation under § 610.41 of this chapter, the donor's record will identify the donor as ineligible to donate and the donor will be notified under § 630.40 of the basis for the deferral and the period of deferral;

(E) The donor has been provided and reviewed information regarding the risks and hazards of the specific donation procedure; and

(F) The donor has the opportunity to ask questions and withdraw from the donation procedure.

(h) *What must you do when a donor is not eligible*? You must not collect blood or blood components from a donor found to be ineligible prior to collection based on criteria in §§ 630.10 or 630.15, or deferred under § 610.41 of this chapter or § 630.30(b)(2), unless this subchapter provides an exception. You must defer donors found to be ineligible and you must notify the donor of their deferral under § 630.40.

§ 630.15 Donor eligibility requirements specific to Whole Blood, Red Blood Cells and Plasma collected by apheresis.

(a) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Whole Blood or Red Blood Cells by apheresis*?

(1) *Donation frequency must be consistent with protecting the health of the donor.*

(i) For a collection resulting in a single unit of Whole Blood or Red Blood Cells collected by apheresis, donation frequency must be no more than once in 8 weeks, and for apheresis collections resulting in two units of Red Blood Cells, the donor must not donate more than once in 16 weeks.

(ii) The limitations in paragraph (a)(1)(i) of this section apply unless the responsible physician examines the donor at the time of donation and one of the following conditions exists:

(A) The donation is for autologous use as prescribed by the donor's physician and the responsible physician determines and documents that the donation may proceed; or

(B) The donation is a dedicated donation based on the intended recipient's documented exceptional medical need and the responsible physician determines and documents that the health of the donor would not be adversely affected by donating.

(2) *Therapeutic phlebotomy.* When a donor who is determined to be eligible under § 630.10 undergoes a therapeutic phlebotomy under a prescription to promote the donor's health, you may collect from the donor more frequently than once in 8 weeks for collections resulting in a single unit of Whole Blood or Red Blood Cells, or once in 16 weeks for apheresis collections resulting in two units of Red Blood Cells, provided that the container label conspicuously states the disease or condition of the donor that necessitated phlebotomy. However, no labeling for the disease or condition is required under this section if:

(i) The donor meets all eligibility criteria;

(ii) The donor undergoes a therapeutic phlebotomy as prescribed by a licensed health care provider treating the donor for:

(A) Hereditary hemochromatosis; or

(B) Another disease or condition, when the health of a donor with that disease or condition will not be adversely affected by donating, and the donor's disease or condition will not adversely affect the safety, purity, and potency of the blood and blood components, or any products manufactured from them, and the collection is in accordance with a procedure that has been found acceptable for this purpose by FDA; and

(iii) You perform without charge therapeutic phlebotomies for all individuals with that disease or condition.

(b) *What additional donor eligibility requirements apply when you, an establishment that collects blood or blood components, collect Source Plasma or plasma by plasmapheresis*?

(1) *Medical history and physical examination.* Except as provided in § 630.25:

(i) The responsible physician must conduct an appropriate medical history and physical examination of the donor on the day of the first donation or no more than 1 week before the first donation and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must examine the donor for medical conditions that would place the donor at risk from plasmapheresis. If the donor is determined to be at risk, you must defer the donor from donating.

(iii) The responsible physician must conduct a new medical history and physical examination of a donor who does not return for 6 months.

(2) *What requirements apply to obtaining informed consent*?

(i) The responsible physician must obtain the informed consent of a plasma donor on the first day of donation or no more than 1 week before the first donation, and at subsequent intervals of no longer than 1 year.

(ii) The responsible physician must obtain the informed consent of a plasma donor who does not return within 6 months of the last donation.

(iii) The responsible physician must explain the risks and hazards of the procedure to the donor. The explanation must include the risks of a hemolytic transfusion reaction if the donor is given the cells of another donor and the risks involved if the donor is immunized. The explanation must be made in such a manner that the donor may give their consent and has a clear opportunity to refuse the procedure.

(iv) If a donor is enrolled in a new program, such as an immunization or special collection program, the responsible physician must again obtain

an informed consent specific for that program.

(3) *Weight.* You must weigh a donor at each donation.

(4) *Total protein level.* You must determine the donor's total plasma protein level before each plasmapheresis procedure. The donor must have a total plasma protein level of no less than 6.0 grams per deciliter and no more than 9.0 grams per deciliter in a plasma sample or a serum sample.

(5) *Examination before immunization.* (i) No more than 1 week before the first immunization injection for the production of high-titer antibody plasma, the responsible physician must conduct an appropriate medical history and physical examination, as described in paragraph (b)(1) of this section, in addition to assessing the general donor eligibility requirements under § 630.10. It is not necessary to repeat the medical history and physical examination requirement in paragraph (b)(1) of this section, if the immunized donor's plasma is collected within 3 weeks of the first immunization injection.

(ii) You are not required to repeat the medical history and physical examination required under paragraph (b)(1) of this section for a donor currently participating in a plasmapheresis collection program and determined to be eligible under § 630.10 unless the medical history and physical examination are due under paragraph (b)(1)(i) or (b)(1)(iii) of this section.

(6) *Deferral of donors due to red blood cell loss.* (i) You must defer a donor from donating plasma by plasmapheresis for 8 weeks if the donor has donated a unit of Whole Blood, or a single unit of Red Blood Cells by apheresis. However, you may collect plasma by plasmapheresis after a donation of Whole Blood or a single unit of Red Blood Cells by apheresis after at least 2 calendar days have passed, provided that the extracorporeal volume of the apheresis device is less than 100 milliliters.

(ii) You must defer a donor from donating plasma by plasmapheresis for a period of 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure;

(iii) You must defer a donor for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

(7) *Exceptions to deferral due to red blood cell loss.* You are not required to defer a Source Plasma donor from donating plasma by plasmapheresis due to red blood cell loss if the following conditions are met:

(i) The responsible physician examines the donor at the time of the current donation and determines and documents that the donor is in good health and the donor's health permits the plasmapheresis;

(ii) The donor's plasma possesses a property, such as an antibody, antigen, or protein deficiency that is transitory, of a highly unusual or infrequent specificity, or of an unusually high titer;

(iii) The special characteristics of the donor's plasma and the need for plasmapheresis of the donor under § 630.20(b) are documented at your establishment; and

(iv) The extracorporeal volume of the apheresis device is less than 100 milliliters.

(8) *Malaria.* Freedom from risk of malaria is not required for a donor of Source Plasma.

(9) You must comply with other requirements for collection of plasma in part 640 of this chapter and this part including restrictions on frequency of collection as specified in §§ 640.32 and 640.65 of this chapter.

§ 630.20 Exceptions for certain ineligible donors.

After assessing donor eligibility under §§ 630.10 and 630.15, an establishment may collect blood and blood components from a donor who is determined to be not eligible to donate under any provision of § 630.10(e) and (f) or § 630.15(a) if one of the following sets of conditions are met:

(a) The donation is for autologous use only as prescribed by the donor's physician, the donor has a hemoglobin level no less than 11.0 grams of hemoglobin per deciliter of blood or a hematocrit value no less than 33 percent, and the responsible physician determines and documents that the donor's health permits the collection procedure; or

(b) The donation is collected under a Source Plasma collection program which has received prior written approval from the Director, Center for Biologics Evaluation and Research, to collect plasma for further manufacturing use into in vitro products for which there are no alternative sources, the donor meets the criteria in § 630.10(f)(1) through (6), and the responsible physician determines and documents for each donation that the donor's health permits the collection procedure, and the collection takes place under the medical oversight specified in the approved plasmapheresis program.

(c) The donation is restricted for use solely by a specific transfusion recipient based on documented exceptional medical need, and the responsible physician determines and documents that the donor's health permits the collection procedure, and that the donation presents no undue medical risk to the transfusion recipient.

§ 630.25 Exceptions from certain donor eligibility requirements for infrequent plasma donors.

For an infrequent plasma donor who is not participating in an immunization program, establishments are not required to:

(a) Perform a medical history and physical examination of the donor under § 630.15(b)(1);

(b) Perform a test for total protein under § 630.15(b)(4);

(c) Determine the total plasma or serum protein and immunoglobulin composition under § 640.65(b)(1)(i) of this chapter; or

(d) Review the data and records as required in § 640.65(b)(2)(i) of this chapter.

§ 630.30 Donation suitability requirements.

(a) *When is a donation suitable*? A donation is suitable when:

(1) The donor is not currently deferred from donation as determined by review of the records of deferred donors required under § 606.160(e) of this chapter;

(2) The results in accordance with §§ 630.10 through 630.25 indicate that the donor is in good health and procedures were followed to ensure that the donation would not adversely affect the health of the donor;

(3) The results in accordance with § 630.10(e) indicate that the donor is free from risk factors for, or evidence of, relevant transfusion-transmitted infections and other factors that make the donor ineligible to donate;

(4) The donor's blood is tested in accordance with § 610.40 of this chapter, and is negative or nonreactive, unless an exception applies under § 610.40(h) of this chapter; and

(5) The donation meets other requirements in this subchapter.

(b) *What must you do when the donation is not suitable*? (1) You must not release the donation for transfusion or further manufacturing use unless it is an autologous donation, or an exception is provided in this chapter.

(2) You must defer the donor when a donation is determined to be unsuitable based on the criteria in paragraphs (a)(1) through (4) of this section.

(3) You must defer the donor of bacterially contaminated platelets when the contaminating organism is identified in accordance with § 606.145(d) of this chapter as likely to be associated with a bacterial infection that is endogenous to the bloodstream of the donor.

(4) You must notify the deferred donor in accordance with the notification requirements in § 630.40.

§ 630.35 Requalification of previously deferred donors.

Establishments may determine a deferred donor to be eligible as a donor of blood and blood components if, at the time of the current collection, the donor meets the eligibility criteria in this part, except for the record of the previous deferral, and you determine that the criteria that were the basis for the previous deferral are no longer applicable. Criteria for the previous deferral are no longer applicable if the following conditions are met:

(a) The previous deferral was for a defined period of time and that time period has passed, or the deferral was otherwise temporary, such as a deferral based on eligibility criteria described in §§ 630.10(f)(1) through (5) or 630.15(b)(4); or

(b) For a donor deferred for reasons other than under § 610.41(a) of this chapter, you determine that the donor has met criteria for requalification by a method or process found acceptable for such purpose by FDA.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

■ 25. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.3 [Removed]

■ 26. Remove § 640.3.

§ 640.4 [Amended]

■ 27. In § 640.4, remove and reserve paragraph (a); and in paragraph (e), remove ''§ 640.3'' and add in its place ''§ 630.10 of this chapter''.

§ 640.5 [Amended]

■ 28. Amend § 640.5 as follows:

■ a. In the introductory text, remove ''at the time of collecting the unit of blood'';

■ b. Remove and reserve paragraph (a); and

■ c. In heading and text of paragraph (f), remove ''communicable disease agents'' wherever it appears and add in its place ''relevant transfusion-transmitted infections''.

■ 29. Revise § 640.12 to read as follows:

§ 640.12 Eligibility of donor.

Establishments must determine the eligibility of donors of the source blood for Red Blood Cells in accordance with §§ 630.10 and 630.15 of this chapter.

§ 640.14 [Amended]

■ 30. In 640.14, remove ''§ 640.5(a), (b),'' and add in its place ''§ 640.5(b)''.

■ 31. Revise § 640.21 to read as follows:

§ 640.21 Eligibility of donors.

(a) Establishments must determine the eligibility of donors of platelets derived from Whole Blood and donors of platelets collected by plateletpheresis in accordance with §§ 630.10 and 630.15 of this chapter, except as provided in this section.

(b) A plateletpheresis donor must not serve as the source of platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function.

(c) A Whole Blood donor must not serve as the source of platelets for transfusion if the donor has recently ingested a drug that adversely affects platelet function unless the unit is labeled to identify the ingested drug that adversely affects platelet function.

(d) If you are collecting platelets by plateletpheresis, you must assess and monitor the donor's platelet count.

(1) You must take adequate and appropriate steps to assure that the donor's platelet count is at least 150,000 platelets per microliter (/μL) before plateletpheresis begins. Exception: If you do not have records of a donor's platelet count from prior donations and you are not able to assess the donor's platelet count either prior to or immediately following the initiation of the collection procedure, you may collect platelets by plateletpheresis, but you must not collect 9.0×10^{11} or more platelets from that donor.

(2) You must defer from platelet donation a donor whose pre-donation platelet count is less than 150,000 platelets/μL until a subsequent pre-donation platelet count indicates that the donor's platelet count is at least 150,000 platelets/μL; and

(3) You must take appropriate steps to assure that the donor's intended post-donation platelet count will be no less than 100,000 platelets/μL.

(e) *Frequency of plateletpheresis collection.* (1) The donor may donate no more than a total of 24 plateletpheresis collections during a 12-month rolling period.

(2) When you collect fewer than 6×10^{11} platelets, you must wait at least 2 calendar days before any subsequent plateletpheresis collection. You must not attempt to collect more than 2 collections within a 7 calendar day period.

(3) When you collect 6×10^{11} or more platelets, you must wait at least 7 calendar days before any subsequent plateletpheresis collection.

(4) *Exception.* For a period not to exceed 30 calendar days, a donor may serve as a dedicated plateletpheresis donor for a single recipient, in accordance with § 610.40(c)(1) of this chapter, as often as is medically necessary, provided that the donor is in good health, as determined and documented by the responsible physician, and the donor's platelet count is at least 150,000 platelets/μL, measured at the conclusion of the previous donation or before initiating plateletpheresis for the current donation.

(f) *Deferral of plateletpheresis donors due to red blood cell loss.* (1) You must defer a donor from donating platelets by plateletpheresis or a co-collection of platelets and plasma by apheresis for 8 weeks if the donor has donated a unit of Whole Blood, or a single unit of Red Blood Cells by apheresis unless at least 2 calendar days have passed and the extracorporeal volume of the apheresis device is less than 100 milliliters.

(2) You must defer a donor from donating platelets for a period of 16 weeks if the donor donates two units of Red Blood Cells during a single apheresis procedure.

(3) You must defer a donor for 8 weeks or more if the cumulative red blood cell loss in any 8 week period could adversely affect donor health.

(g) The responsible physician must obtain the informed consent of a plateletpheresis donor on the first day of donation, and at subsequent intervals no longer than 1 year.

(1) The responsible physician must explain the risks and hazards of the procedure to the donor; and

(2) The explanation must be made in such a manner that the donor may give consent, and has a clear opportunity to refuse the procedure.

■ 32. Revise § 640.22(c) to read as follows:

§ 640.22 Collection of source material.

* * * * *

(c) If plateletpheresis is used, the procedure for collection must be as prescribed in §§ 640.21, 640.64 (except paragraph (c)), and 640.65, or as described in an approved biologics license application (BLA) or an approved supplement to a BLA.

* * * * *

§ 640.23 [Amended]

■ 33. In § 640.23(a), remove ''§ 640.5(a), (b),'' and add in its place ''§ 640.5(b)''.

§ 640.27 [Removed]

■ 34. Remove § 640.27.

■ 35. Revise § 640.31 to read as follows:

§ 640.31 Eligibility of donors.

(a) Whole Blood donors must meet the criteria for donor eligibility prescribed in §§ 630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§ 630.10 and 630.15 of this chapter.

§ 640.32 [Amended]

■ 36. In § 640.32(b), remove ''§§ 640.62, 640.64'' and add in its place ''§ 640.64''.

§ 640.33 [Amended]

■ 37. In § 640.33(a), remove ''§ 640.5(a), (b),'' and add in its place ''§ 640.5(b)''.

■ 38. Revise § 640.51 to read as follows:

§ 640.51 Eligibility of donors.

(a) Whole blood donors must meet the criteria for eligibility prescribed in §§ 630.10 and 630.15 of this chapter.

(b) Collection establishments must determine the eligibility of plasmapheresis donors in accordance with §§ 630.10 and 630.15 of this chapter.

§ 640.52 [Amended]

■ 39. In § 640.52(b), remove ''§§ 640.62, 640.64'' and add in its place ''§ 640.64''.

§ 640.53 [Amended]

■ 40. In § 640.53(a), remove ''§ 640.5(a), (b),'' and add in its place ''§ 640.5(b)''.

§ 640.61 [Removed]

■ 41. Remove § 640.61.

§ 640.62 [Removed]

■ 42. Remove § 640.62.

§ 640.63 [Removed]

■ 43. Remove § 640.63.

§ 640.64 [Amended]

■ 44. In § 640.64, remove and reserve paragraph (a).

■ 45. Amend § 640.65 as follows:

■ a. In paragraph (b)(1)(i), revise the first sentence;

■ b. In paragraph (b)(1)(ii), remove ''physician on the premises'' and add its place ''responsible physician'';

■ c. Revise paragraph (b)(2)(i); and

■ d. In paragraphs (b)(2)(iii) and (iv) remove ''physician on the premises'' and add in its place ''responsible physician''.

The revisions read as follows:

§ 640.65 Plasmapheresis.

* * * * *

(b) * * *

(1)(i) Except as provided under § 630.25 of this chapter, the responsible physician must draw a sample of blood from each donor on the day of the initial physical examination or plasmapheresis, whichever comes first, and at least every 4 months thereafter. * * *

* * * * *

(2)(i) Except as provided under § 630.25 of this chapter, the responsible physician must review the accumulated laboratory data, including any tracings of the plasma or serum protein electrophoresis pattern, the calculated values of the protein composition of each component, and the collection records within 14 calendar days after the sample is drawn to determine whether or not the donor should be deferred from further donation. If a determination is not made within 14 calendar days, the donor must be deferred pending such a determination. The responsible physician must sign the review. If the protein composition is not within normal limits established by the testing laboratory, or if the total protein level is less than 6.0 grams per deciliter or more than 9.0 grams per deciliter in a plasma sample or serum sample, the donor must be deferred from donation until the protein composition returns to acceptable levels. Reinstatement of the donor into the plasmapheresis program when the donor's protein composition values have returned to an acceptable level must first be approved by the responsible physician.

* * * * *

■ 46. In § 640.66, revise the first sentence and remove the second sentence. The revisions read as follows:

§ 640.66 Immunization of donors.

If specific immunization of a donor is to be performed, the selection, scheduling and administration of the antigen, and the evaluation of each donor's clinical response, shall be by the responsible physician. * * *

§ 640.67 [Amended]

■ 47. In § 640.67, remove ''communicable disease agents'' and add in its place ''relevant transfusion-transmitted infections''.

■ 48. In § 640.69, add paragraphs (e) and (f) to read as follows:

§ 640.69 General requirements.

* * * * *

(e) *Restrictions on distribution.* Establishments must ensure that Source Plasma donated by paid donors not be used for further manufacturing into injectable products until the donor has a record of being found eligible to donate in accordance with § 630.10 of this chapter and a record of negative test results on all tests required under § 610.40(a) of this chapter on two occasions in the past 6 months.

(f) *Hold.* Source Plasma donated by paid donors determined to be suitable for further manufacturing into injectable products must be held in quarantine for a minimum of 60 calendar days before it is released for further manufacturing. If, after placing a donation in quarantine under this section, the donor is subsequently deferred under § 610.41 of this chapter, or you subsequently determine a donor to be ineligible under § 630.10 of this chapter due to risk factors closely associated with exposure to, or clinical evidence of, infection due to a relevant transfusion-transmitted infection, you must not distribute quarantined donations from that donor for further manufacturing use to make an injectable product.

§ 640.71 [Amended]

■ 49. Amend § 640.71 as follows:

■ a. In paragraph (a) introductory text, remove ''the following tests'' and add in its place ''testing performed in accordance with § 610.40 of this chapter and § 640.65(b)'';

■ b. Remove paragraphs (a)(1) through (4); and

■ c. In paragraph (b)(1), remove ''licensed physician'' and add in its place ''responsible physician''.

■ 50. In § 640.72, revise paragraphs (a)(2) through (4) to read as follows:

§ 640.72 Records.

(a) * * *

(2)(i) For each donor, establishments must maintain records including a separate and complete record of initial and periodic examinations, tests, laboratory data, and interviews, etc., as required in §§ 630.10 and 630.15 of this chapter and §§ 640.65, 640.66, and 640.67, except as provided in paragraph (a)(2)(ii) of this section.

(ii) Negative results for testing for evidence of infection due to relevant transfusion-transmitted infections required in § 610.40 of this chapter, and the volume or weight of plasma withdrawn from a donor need not be recorded on the individual donor record if such information is maintained on the premises of the plasmapheresis center where the donor's plasma has been collected.

(3) The original or a clear copy or other durable record which may be electronic of the donor's consent for participation in the plasmapheresis program or for immunization.

(4) Records of the medical history and physical examination of the donor conducted in accordance with § 630.15(b)(1) of this chapter and, where applicable, § 630.15(b)(5) of this chapter must document the eligibility of the donor as a plasmapheresis donor and,

when applicable, as an immunized donor.

* * * * *

■ 51. Revise § 640.120 to read as follows:

§ 640.120 Alternative procedures.

(a) The Director, Center for Biologics Evaluation and Research, may issue an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products. The Director may issue such an exception or alternative in response to:

(1) A written request from an establishment. Licensed establishments must submit such requests in accordance with § 601.12 of this chapter;

(2) An oral request from an establishment, if there are difficult circumstances and submission of a written request is not feasible. Establishments must follow up such oral request by submitting written requests under paragraph (a)(1) of this section within 5 working days.

(b) To respond to a public health need, the Director may issue a notice of exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products, if a variance under this section is necessary to assure that blood, blood components, or blood products will be available in a specified location or locations to address an urgent and immediate need for blood, blood components, or blood products or to provide for appropriate donor screening and testing.

(c) If the Director issues such an exception or alternative orally, the Director will follow up by issuing a written notice of the exception or alternative. Periodically, FDA will provide a list of approved exceptions and alternative procedures on the FDA Center for Biologics Evaluation and Research Web site.

■ 52. Add subpart M, consisting of §§ 640.125 and 640.130, to part 640 to read as follows:

Subpart M—Definitions and Medical Supervision

Sec.
640.125 Definitions.
640.130 Medical supervision.

§ 640.125 Definitions.

The definitions set out in § 630.3 of this chapter apply to the use of those defined terms in this part.

§ 640.130 Medical supervision.

The requirements for medical supervision established in § 630.5 of this chapter supplement the regulations in this part.

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

■ 53. The authority citation for 21 CFR part 660 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 54. Revise § 660.31 to read as follows:

§ 660.31 Eligibility of donor.

Donors of peripheral blood for Reagent Red Blood Cells must meet all the criteria for donor eligibility under §§ 630.10 and 630.15 of this chapter.

PART 820—QUALITY SYSTEM REGULATION

■ 55. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

§ 820.1 [Amended]

■ 56. In § 820.1(a)(1), remove ''Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter'' and add in its place ''Manufacturers of blood and blood components used for transfusion or for further manufacturing are not subject to this part, but are subject to subchapter F of this chapter''.

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12228 Filed 5–21–15; 8:45 am]

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Part IV

Department of Transportation

Federal Highway Administration

23 CFR Part 172

Procurement, Management, and Administration of Engineering and Design Related Services; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 172

[FHWA Docket No. FHWA–2012–0043]

RIN 2125–AF44

Procurement, Management, and Administration of Engineering and Design Related Services

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This rule updates the regulations governing the procurement, management, and administration of engineering and design related services directly related to a highway construction project and reimbursed with Federal-aid highway program (FAHP) funding. In issuing the final rule, FHWA revises the regulations to conform to changes in legislation and other applicable regulations [including the DOT's recent adoption of the revised ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,'' and removal of outdated references] and addresses certain findings and recommendations for the oversight of consultant services contained in national review and audit reports.

DATES: This final rule is effective June 22, 2015.

FOR FURTHER INFORMATION CONTACT: For technical information, please contact: Mr. Robert Mooney, FHWA Office of Program Administration, (202) 366–2221, or via email at *robert.mooney@dot.gov*. For legal information, please contact: Mr. Steven Rochlis, FHWA Office of the Chief Counsel, (202) 366–1395, or via email at *steve.rochlis@dot.gov*. Office hours for FHWA are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov*. The Web site is available 24 hours each day, 365 days each year. Please follow the instructions. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *http://www.archives.gov/federal-register/,* or the Government Publishing Office's Web page at: *http://www.gpo.gov/fdsys*.

Background

This rulemaking modifies existing regulations for the administration of engineering and design related service contracts to ensure consistency and conformance to changes in authorizing legislation codified in 23 United States Code (U.S.C.) 112(b)(2) and changes in other applicable Federal regulations. These revisions also address certain findings contained in a 2008 U.S. Government Accountability Office (GAO) review report (*http://www.gao.gov/products/GAO-08-198*) regarding increased reliance on consulting firms by State transportation agencies (STAs) and a 2009 DOT Office of Inspector General (OIG) audit report (*http://www.oig.dot.gov/library-item/30274*) regarding oversight of engineering consulting firms' indirect costs claimed on Federal-aid projects or activities related to construction.

The primary authority for the procurement, management, and administration of engineering and design related services directly related to a highway construction project and reimbursed with FAHP funding is codified in 23 U.S.C. 112(b)(2). On November 30, 2005, the Transportation, Treasury, Housing and Urban Development, the Judiciary, the District of Columbia, and Independent Agencies Appropriations Act, 2006 (Pub. L. 109–115, 119 Stat. 2396, HR 3058), commonly referred to as the ''2006 Appropriations Act,'' was signed into law. Section 174 of this Act amended 23 U.S.C. 112(b)(2) by removing the provisions that permitted States to use ''alternative'' or ''equivalent'' State qualifications-based selection procedures and other procedures for acceptance and application of consultant indirect cost rates that were enacted into State law prior to June 9, 1998.

Effective on the date of enactment of the ''2006 Appropriations Act,'' States and local public agencies could no longer use alternative or equivalent procedures. States and local public agencies are required to procure engineering and design related services in accordance with the qualifications-based selection procedures prescribed in the Brooks Act (40 U.S.C. 1101 *et seq.*) and to accept and apply consultant indirect cost rates established by a cognizant Federal or State agency in accordance with the Federal Acquisition Regulation (FAR) cost principles (48 CFR part 31) as required by 23 U.S.C. 112(b)(2). To comply with the amendments to 23 U.S.C. 112(b)(2), this rulemaking removes all references to alternative or equivalent procedures.

In addition, the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council published a final rule in the **Federal Register** of August 30, 2010, (75 FR 53129), and effective on October 1, 2010, raising the Federal simplified acquisition threshold established in 48 CFR 2.101 of the FAR cost principles from $100,000 to $150,000 to account for inflation using the Consumer Price Index as required in statute. This rulemaking revises the small purchase procurement method to reflect this increase in the Federal threshold.

This rulemaking also addresses certain findings and recommendations contained in the aforementioned GAO review and OIG audit reports, clarifies existing requirements to enhance consistency and compliance with Federal laws and regulations, and addresses evolutions in industry practices regarding the procurement, management, and administration of consultant services.

Summary Discussion of Comments Received in Response to the NPRM

On September 4, 2012, FHWA published an NPRM in the **Federal Register** at 77 FR 53802 soliciting public comments on its proposal to update the existing regulations. The following presents an overview of the comments received to the NPRM. Comments were submitted by STAs, local government agencies, industry organizations, and individuals. The docket contained comments from 31 different parties, including 18 STAs, 1 regional association of local government agencies, 8 industry organizations, and 4 individuals.

The majority of the comments received related to clarification or interpretation of various provisions within the proposed regulatory text. Many commenters supported the proposed rule and its alignment with current policies, guidance, and industry best practices. Several STA commenters asserted that the provisions proposed within the NPRM would impose burdens on STAs, requiring additional staff and resources. However, the majority of these specific comments related to existing requirements imposed by statute and other applicable regulations which were clarified within the text of this part for consistency and to assure compliance with all applicable requirements for the procurement, management, and administration of engineering and design related consultant services.

The FHWA appreciates the feedback the commenters provided and has carefully reviewed and analyzed all the

comments that were submitted and made revisions to the NPRM to incorporate suggestions where necessary. For example, some of the more significant revisions made in the Final Rule include:

- Adding, removing, or revising several definitions or phrases such as the terms ''subconsultant,'' ''fixed fee,'' ''management support role,'' and others;
- Revising § 172.7(a)(1)(iv)(C) regarding discussion requirements following submission and evaluation of proposals to require STA's to specify within a Request for Proposals (RFP) what type of additional discussions, if any, will take place;
- Adding clarifying language in § 172.9(a)(3)(iv)(B)(*1*) to indicate that the process of issuing a task order under an indefinite delivery/indefinite quantity (IDIQ) contract, may include, but does not require a second, formal RFP, and;
- Revising the term ''performance report'' to ''performance evaluation'' in § 172.9(d)(2) to allow States discretion as to the structure of the evaluation.

A discussion of the substantive comments received is provided in the following section.

Comments Directed at Specific Sections of the Proposed Revisions to 23 CFR Part 172

The California DOT suggested changing the title of the part to ''Procurement, Management, and Administration of Architectural, Engineering and Related Services'' for consistency with the terminology of the Brooks Act (40 U.S.C. 1101 *et seq.*).

While the Brooks Act establishes the qualifications-based selection procurement procedures, the title proposed was selected to correlate to the terminology contained within 23 U.S.C. 112(b)(2), an authorizing statute for this part. No change was made to the regulation.

§ 172.3—Definitions

The Virginia DOT and California DOT proposed that definitions of ''grantee,'' ''subgrantee'' and ''other direct grantee'' be added.

After these comments were received, the Office of Management and Budget revised and published 2 CFR part 200, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. That regulation, adopted by DOT by issuance of 2 CFR part 1201, effective December 26, 2014 [1], no longer uses the terms ''grantee,'' ''subgrantee,'' or ''other direct grantee.'' New terms to describe Federal assistance include: ''recipients'' (2 CFR 200.86) and ''subrecipients'' (2 CFR 200.93). Given the terms discussed above are defined in 2 CFR part 200, FHWA has decided not to redefine the terms. The term ''direct grantee'' was modified to ''recipient'' to conform to these changes.

The California DOT proposed that a definition of ''subconsultant'' be added to the regulation.

The FHWA agrees with the comment and the regulation was modified accordingly.

The Oregon DOT proposed that a definition of ''assurance'' be added as this is a specific audit term. Oregon DOT recommends reference to the American Institute of Certified Public Accountants (AICPA) standards where ''assurance'' is defined.

The context in which the ''assurance'' term is used in the regulation is one of providing assurance of compliance with the cost principles, similar to that used in 2 CFR 200.300(b) requiring non-Federal recipients of Federal financial assistance to be responsible for compliance with Federal requirements; and not, in the AICPA standards context. No change was made to the regulation.

The Oregon DOT proposed that a definition of ''acceptance'' be added, as it could be interpreted as either ''approved'' or ''audited,'' when used in the context of ''acceptance of indirect cost rates.''

Within the context of ''acceptance of indirect cost rates,'' contracting agencies must *accept* cognizant agency *approved* rates established in accordance with the FAR cost principles (48 CFR part 31). The FHWA considered the recommendation but believes that the term ''acceptance'' could not be interpreted as ''approved'' or ''audited'' in this context. No change was made to the regulation.

The Professional Engineers in California Government (PECG) proposed that a definition of ''fair and reasonable'' be added which would include an analysis of the cost using internal contracting agency staff to determine whether it is more cost effective to perform the services in-house or to contract the services out to consultants.

Section 302(a) of Title 23, U.S.C. permits the State to use private engineering firms to the extent necessary or desirable, provided the contracting agency is suitably equipped and organized to discharge to the satisfaction of the Secretary, the duties required by Title 23. No change was made to the regulation.

A comment from Collins Engineers, Inc. recommended that the definition of ''engineering and design related services'' be expanded to include bridge inspection, rating, and evaluation services.

''Engineering and design related services'' contracts are described in 23 U.S.C. 112(b)(2)(A) and ''bridge inspection, rating, and evaluation services'' are not specifically addressed. The Brooks Act further defines architectural and engineering related services as professional services of an architectural or engineering nature, as defined by State law, if applicable, that are required to be performed, approved, or logically/justifiably performed by a person licensed, registered, or certified as an engineer or architect to provide the services (as specified in 40 U.S.C. 1102(2)). As such, bridge inspection, rating, and evaluation services may be considered engineering services under State law and regulation, and dependent upon the specific details of the scope of work being provided and its nexus with construction, these engineering services would be subject to these requirements. No change was made to the regulation.

The South Dakota DOT recommended that activities such as ''research, planning, and feasibility studies'' be explicitly excluded from the definition of ''engineering and design related services.''

''Engineering and design related services'' contracts are described in 23 U.S.C. 112(b)(2)(A) and include ''feasibility studies.'' However, each contract subject to and being procured under 23 U.S.C. 112(b)(2) must have a construction nexus (related in some way to highway construction) to be subject to these requirements. The proposed definition was expanded to include other services included within the definition of engineering under State law as specified within the Brooks Act. As such, service contracts for research or planning cannot be excluded as these contracts may require engineering expertise under State law and regulation. For those contracts to be subject to 23 U.S.C. 112(b)(2), however, they must be related to highway construction as specified in 23 U.S.C. 112(b)(2)(A), which cross-references section 112(a) of Title 23. No change was made to the regulation.

The Connecticut DOT requested that additional detail as to what is included in ''construction management'' be provided.

''Engineering and design related services'' '' contracts are described in 23 U.S.C. 112(b)(2)(A) and includes ''construction management.'' Construction management is a common

[1] *https://www.federalregister.gov/articles/2014/12/19/2014-28697/federal-awarding-agency-regulatory-implementation-of-office-of-management-and-budgets-uniform.*

term within the industry. However, it is difficult to quantify the extent of services included within construction management by every STA. The proposed definition of engineering and design related services was expanded to include other services included within the definition of engineering under State law as specified within the Brooks Act. As such, State law will determine whether construction related services would be considered engineering and design related for the purposes of applying part 172 requirements. No change was made to the regulation.

The California DOT suggested expanding the second part of the proposed definition of engineering and design related from ''Professional services of an architectural or engineering nature . . .'' to ''Professional services of an architectural or engineering nature including support services as defined by State law . . .''

The proposed definition is consistent with the Brooks Act. State law already determines what is included in the ''related services'' term. No change was made to the regulation.

The Indiana DOT believes the definition for ''cognizant agency'' imposes a requirement on the STA to determine the location of a consultant's accounting and financial records.

The definition of ''cognizant agency'' is consistent with the American Association of State Highway and Transportation Officials (AASHTO) Uniform Audit & Accounting Guide [2] and state of the practice. Consultants are responsible for disclosing and properly representing their financial information. No change was made to the regulation.

Gannett Fleming, Inc. proposed revisions to recognize consultants working under contract to Federal agencies as a cognizant Federal agency, ranking above a State agency in a hierarchy.

The NPRM definition is consistent with the AASHTO Uniform Audit & Accounting Guide and state of the practice. The referenced Federal statutory provisions apply to direct Federal contracting and are not incorporated for application to the Federal Aid Highway Program. No change was made to the regulation.

The American Council of Engineering Companies (ACEC) commented on the definition of the ''federal cost principles,'' indicating that the term Federal Acquisition Regulation is a singular term and the ''s'' should be removed.

The FHWA agrees with the comment and the regulation was modified accordingly.

To ensure consistency with terminology used throughout the regulation and AASHTO publications, the Indiana DOT recommended changing the word ''overhead,'' found in the definition for ''fixed fee,'' to ''indirect cost.''

The FHWA agrees with the comment and the regulation was modified accordingly.

To provide a more accurate definition for ''fixed fee,'' the ACEC recommends replacing ''not allocable to overhead'' with ''not allowable or otherwise included in overhead.''

The FHWA agrees with the comment and a change was made in the regulation; however, the word ''overhead'' was replaced with ''indirect cost'' to be consistent with terminology used throughout the regulation and AASHTO publications.

The Massachusetts DOT stated that their department pays ''net fees'' on task order contracts whereby fees are paid on a net basis based on the amount of salary expended for each assignment, although a maximum fee is budgeted similar to ''fixed fee'' as defined. Massachusetts DOT is concerned that the proposed definition of ''fixed fee'' would prohibit use of the ''net fee'' approach on task order contracts.

The use of ''net fee'' is similar to a cost plus percentage of cost payment method which is prohibited from use under 23 CFR 172.9(b)(2) (previously 23 CFR 172.5(c)) on engineering and design related services funded with FAHP funding. No change was made to the regulation.

The American Society of Civil Engineers (ASCE) requested clarification of the engineer's management role.

The range of management services provided by a consultant will vary based on the organizational structure and capacity of the contracting agency. While the definition in § 172.3 is more general, 23 CFR 172.7(b)(5) provides additional parameters and examples of management roles. No change was made to the regulation.

§ 172.5—Program Management and Oversight

§ 172.5(a)—STA Responsibilities

The North Dakota DOT asserts that oversight of subgrantee (subrecipient) consultant services programs will be cumbersome for the DOT and require significant additional staff time and resources.

The STA (or other recipient) responsibility for subrecipient oversight is an existing requirement specified in 23 U.S.C. 106(g)(4) and 23 CFR 172.9(a), and 2 CFR 200.331. No change was made in the regulation.

The PECG recommended adding a requirement for grantees (recipients) and subgrantees (subrecipients) to perform a cost comparison analysis, in which the cost of using a private engineering consultant is compared with the cost of using engineers employed by a public agency, to determine if using a private engineering firm is in the public interest and an efficient use of public funds.

Section 302(a) of Title 23, U.S.C. permits a suitably equipped and organized STA to use consultants to the extent necessary or desirable. No change was made in the regulation.

The ACEC strongly opposed the recommendations made by PECG and others related to the placement of restrictions on the flexibility of STAs to ''contract out'' for engineering and design services.

Section 302(a) of Title 23, U.S.C. permits a suitably equipped and organized STA to use consultants to the extent necessary or desirable. No change was made in the regulation.

The Virginia DOT and AASHTO requested clarification on expectations for the compliance with ''develop and sustain organizational capacity.'' They assert that the responsibilities listed in § 172.5(a)(1)–(4) are new requirements, burdensome, and contrary to FHWA's intent noted in the Background section.

The existing 23 U.S.C. 302(a) requires STA's to have adequate powers and be suitably equipped and organized to receive FAHP funds. In meeting the provisions of 23 U.S.C. 302(a), a STA may engage the services of private engineering firms. Subparagraphs (a)(1)–(4) help clarify the responsibilities of the STA in demonstrating its ability to procure, manage, and administer those services. No change was made in the regulation.

§ 172.5(a)(2)

The Indiana DOT, Virginia DOT, and AASHTO assert that staffing and resource estimates for consultant services are labor intensive and difficult

[2] Per *https://bookstore.transportation.org/item_details.aspx?ID=2048,* ''This concept was developed to assign primary responsibility for an audit to a single entity (the ''cognizant agency'') to avoid the duplication of audit work performed in accordance with Government Auditing Standards to obtain reasonable assurance that claimed costs are accordance with the FAR Subpart 31.2 cost principles. Such audit work may be performed by home-State auditors, a Federal audit agency, a CPA firm, or a non-home State auditor designated by the home-State auditor.''

for contracting agencies. Additionally, Virginia DOT requests clarification on ''staffing and resource estimates'' and asserts it is too restrictive and would impact subgrantees (subrecipients).

The staffing and resource estimate is for STA oversight of consultant services needed as well as for any services to be provided by the STA. The estimated STA costs (staffing and resources) combined with estimated consultant costs would then be used to support the project authorization submitted to FHWA. These resource estimates also ensure the STA is suitably equipped and organized to discharge the duties required of the STA under Title 23, including its use of engineering consultants [23 U.S.C. 302(a)]. The provision was reworded to clearly indicate the STA is responsible for establishing a procedure for estimating the costs of ''. . . agency staffing and resources for management and oversight in support of project authorization requests . . .''

The South Dakota DOT requested clarification whether the submittal is for each project or is it a procedure applied by the agency to all projects. South Dakota DOT recommends that this provision should only apply when engineering services are anticipated to exceed $150,000.

As this provision is located under the ''Program management and oversight'' section, the procedure is intended to be an agency procedure for estimation of consultant costs and agency oversight in support of individual project authorizations. The procedures developed by STAs for estimation may vary based on estimated size of engineering services contracts needed. No change was made to the regulation.

§ 172.5(a)(4)

The Tennessee DOT recommended indicating that STAs may accept work performed by subgrantees (subrecipients) via certification acceptance.

''Certification acceptance,'' formerly authorized under 23 U.S.C. 117, permitted the Secretary to discharge the responsibilities under Title 23 by accepting a certification of the STA, applicable to projects not on the Interstate System, that the STA would accomplish consistent with the policy, objectives, and standards of Title 23. This provision was struck by section 1601(a) of Public Law 105–178 (112 Stat. 255). An STA may use a variety of methods in providing oversight of a Local Public Agency (LPA), including use of certifications from the LPA. Regardless of the method used, the STA is not relieved of oversight responsibility and subrecipient monitoring and management in accordance with 23 U.S.C. 106, and 2 CFR 200.331. No change was made to the regulation.

The California DOT recommended adding (or other direct grantee) following STA for consistency.

The FHWA agrees with the recommendation of consistency and the regulation was modified to read (or other recipient). This reflects the recent change in nomenclature adopted by 2 CFR part 200.

§ 172.5(b) Subrecipient Responsibilities

The Indiana DOT asserted that requiring LPAs to develop detailed hourly estimates places a severe undue burden on LPAs.

The development of an independent agency estimate to use as a basis for negotiation with the selected consultant is a fundamental element of Qualification Based Selection (QBS) in accordance with the Brooks Act. No change was made in the regulation.

§ 172.5(b)(1)

The Virginia DOT interpreted the requirements of § 172.5(b)(1) to require a resolution by subgrantees (subrecipients) to adopt the STA's policy and recommends this be a ''may'' condition.

The provision requires subrecipients to adopt the STA's policy or to develop its own for review and approval by the STA. The subrecipient must do one or the other and the awarding STA may require use of the STA's policy. As the regulation does not limit the STA to require subrecipients to adopt the STA's policy, no change was made in the regulation.

The California DOT recommends using the word ''administering'' instead of ''awarding.''

The word ''awarding'' is consistent with 2 CFR part 200 terminology. No change was made in the regulation.

§ 172.5(c) Written Policies and Procedures

The New York State DOT expressed a concern with FHWA requiring approval of minor changes as the New York State DOT often issues Consultant Instructions containing guidance on various and sometimes minute aspects of its consultant program without prior FHWA approval.

The FHWA approval of written policies and procedures (often in the form of a Consultant Manual) is an existing requirement under § 172.9(a) and will continue under proposed § 172.5(c). The FHWA approved written policies and procedures should define minor changes/clarifications that may be adopted without additional FHWA review. No change was made in the regulation.

The Wyoming DOT asserted the addition of items to be addressed within written procedures such as conflicts of interest, penalty assessment, and dispute resolution are overly burdensome and would be more appropriate as guidance.

These are fundamental contract administration functions incorporated to address compliance concerns and internal controls, and address recommendations from national audits/reviews. The regulations do not address how to implement these procedures and thus allow STAs flexibility in addressing these elements within their written policies and procedures. No change was made in the regulation.

The PECG recommended that FHWA should approve subgrantee (subrecipient) written policies and procedures instead of the STA.

Subrecipient oversight is a primary responsibility of the STA in accordance with 23 U.S.C. 106(g)(4). No change was made in the regulation.

The Oregon DOT requested clarification regarding how and when ''approval by FHWA'' would occur.

The FHWA approval must occur whenever changes to the consultant manual are necessary or desired (or in accordance with the STA and FHWA stewardship and oversight agreement) and the approval will come from the FHWA Division Office. This is an existing requirement under § 172.9(a). No change was made in the regulation.

The Virginia DOT, Idaho Transportation Department, and AASHTO asserted that the requirement for STA review and approval of subgrantee (subrecipient) written policies and procedures will be an extreme burden for Virginia DOT and the LPAs.

Subrecipient oversight is a responsibility of the STA in accordance with 23 U.S.C. 106(g)(4) and STA review and approval of subrecipient written policies and procedures is an existing requirement under § 172.9(a). No change was made in the regulation.

The California DOT suggested noting that subgrantees (subrecipients) may adopt the STA procedures and do not necessarily have to prepare their own procedures.

In accordance with the requirements in § 172.5(b)(1), a subrecipient may only prepare written procedures when not prescribed by the awarding STA. No change was made in the regulation.

§ 172.5(c)(2)

The California DOT suggested that the ''Soliciting proposals from prospective consultants'' phrase be revised to ''Soliciting proposals/qualifications from prospective consultants.''

The FHWA agrees, as the procedures should address evaluation of prequalification information, statements of qualifications, and proposals. The regulation was modified accordingly.

§ 172.5(c)(5)

The California DOT suggested that the ''Evaluating proposals and the ranking/selection of a consultant'' phrase be revised to ''Evaluating proposals/qualifications and the ranking/selection of a consultant.''

The FHWA agrees, as the procedures should address evaluation of prequalification information, statements of qualifications, and proposals. The regulation was modified accordingly.

§ 172.5(c)(6) [Re-Designated § 172.5(c)(7)]

The California DOT suggested that the ''Preparing an independent agency estimate for use in negotiation with the selected consultant'' phrase be revised to ''Preparing an independent agency cost estimate for use in negotiation with the highest ranked consultant.''

The independent agency estimate is more than a cost estimate and includes a breakdown of tasks, hours, etc. The existing regulation and the Brooks Act use the term ''selected.'' The term ''selected'' is used over ''higher ranked'' since negotiations could be terminated with the highest ranked consultant and negotiations initiated with the next highest ranked consultant. No change was made in the regulation.

§ 172.5(c)(7) [Re-Designated § 172.5(c)(8)]

The California DOT suggested that subparagraph (c)(7) [re-designated subparagraph (c)(8)] should have a higher precedence and should be moved to follow subparagraph (c)(1).

After review and consideration, FHWA deemed no change was necessary. No change was made in the regulation.

§ 172.5(c)(8) [Re-Designated § 172.5(c)(9)]

The California DOT suggested that the ''Negotiating a contract with the selected consultant'' phrase be revised to ''Negotiating a contract with the highest ranked consultant.''

The existing regulation and the Brooks Act use the term ''selected.'' The term ''selected'' is used over ''highest ranked'' since negotiations could be terminated with the highest ranked consultant and negotiations initiated with the next highest ranked. No change was made in the regulation.

§ 172.5(c)(9) [Re-Designated § 172.5(c)(10)]

The Montana and Virginia DOTs, and AASHTO expressed concern with the language ''assuring consultant compliance'' since the definition of assure is ''to make certain.'' The Montana DOT asserted that the meaning ''assuring'' makes it too burdensome. Montana DOT and AASHTO recommended allowing the STAs to use a risk-based approach with periodic reviews of the consultant for compliance.

The provision states ''. . . assuring consultant compliance with the Federal cost principles in accordance with § 172.11.'' The expectation for providing this ''assurance'' is provided in § 172.11 which includes a risk-based approach. Additionally, the determination of cost allowance in accordance with the Federal cost principles is an existing requirement of the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (2 CFR 200.401(a)). No change was made in the regulation.

§ 172.5(c)(10) [Re-Designated § 172.5(c)(11)]

The Montana DOT expressed a concern with the language ''assuring consultant compliance'' since the definition of assure is ''to make certain.'' Montana DOT asserted that ''assuring'' is too burdensome. Montana DOT recommended allowing STAs to use a risk-based approach with periodic reviews of the consultant for compliance.

Determination of cost allowance in accordance with the Federal cost principles in part 31 of the FAR cost principles is an existing requirement of 23 U.S.C. 112(b)(2)(B). A risk-based approach to provide reasonable assurance of consultant compliance with Federal cost principles is allowed in § 172.11. No change was made in the regulation.

The Indiana DOT asserted that assuring consultant costs billed are allowable in accordance with the Federal cost principles is a new requirement which will require additional training for project managers.

Determination of cost allowance in accordance with the Federal cost principles in part 31 of the FAR cost principles is an existing requirement of 23 U.S.C. 112(b)(2)(B). No change was made in the regulation.

§ 172.5(c)(12) [Re-Designated § 172.5(c)(13)]

The Colorado DOT supports the consideration of performance evaluations in the evaluation and selection phase, but asked what happens if a few consultants being considered do not have available performance evaluation results.

Many STAs include ''past performance'' as an evaluation criteria which considers the consultant's previous work on similar projects and may also include any available performance evaluation data. If a consultant has not performed work for the STA previously, references from other clients of the consultant should be considered. No change was made in the regulation.

§ 172.5(c)(15) [Re-Designated § 172.5(c)(16)] and 172.9(c)(12) [Re-Designated § 172.5(c)(13)]

The ACEC requested FHWA to include a provision under ''policies and procedures'' and under ''contract provisions'' which prohibits ''unreasonable indemnification and liability provisions imposed by contracting agencies.''

This would introduce a new provision not included within the NPRM and would be difficult to define/enforce ''unreasonable'' indemnification and liability provisions. The proposed provisions clearly state that liability is based upon errors and omissions in the work furnished under the consultant's contract (*e.g.,* negligence). No change was made in the regulation.

§ 172.5(c)(16) [Re-Designated § 172.5(c)(17)]

The Nebraska Department of Roads (DOR) asked whether the failure to meet the project schedule is considered a violation or breach of contract.

The answer depends on the specific terms of the contract and the materiality of the delay in relation to the project consistent with State law. No change was made in the regulation.

§ 172.5(c)(17) [Re-Designated § 172.5(c)(18)]

The California DOT suggested adding language to *§ 172.5(c)(17) [re-designated § 172.5(c)(18)]* so it would read: ''Resolving disputes in the procurement, management, and administration of engineering and design related consultant services *in accordance with the contract.''*

The FHWA asserts a dispute could occur at any time in the procurement process regardless of whether a contract had yet been established. The intention of the section is to establish a dispute

resolution process that could be invoked regardless of contract status. No change was made in the regulation.

§ 172.5(e)

The North Dakota DOT, Virginia DOT, Wyoming DOT, and AASHTO expressed concerns about this section. The North Dakota DOT requested that the time frame to update written procedures be extended to 18 months and that it include compliance with the final rule provisions and not simply just update of written procedures. Virginia DOT requested a time period of 18 to 24 months to ensure changes are made to policies and procedures of the STA and LPAs. Wyoming DOT expressed concern with reviewing and approving LPA policies and procedures within the 12 months proposed. The AASHTO noted that some STAs may need changes in legislation to meet the requirements of the rule.

The updated regulations provide clarifications of existing requirements and as such, a 12-month period is adequate for an update of the written procedures. An extension may be granted to a contracting agency by FHWA where unique or extenuating circumstances exist. No change was made in the regulation.

§ 172.7—Procurement Methods and Procedures

The South Dakota DOT recommended that activities funded by State Planning and Research or Metropolitan Planning funds be excluded from the requirement of this section.

The application of 23 CFR 172.7 depends on whether the engineering and design related services as defined in 23 CFR 172.3 are connected to highway construction and is not dependent on the category of FAHP funding being used to fund the services. No change was made in the regulation.

The Virginia DOT and AASHTO asserted that this section is detailed beyond the intent of the Brooks Act and should be re-issued as guidance.

The proposed rule provides clarification and promotes uniformity of procurement requirements based upon the Brooks Act and other applicable regulations to ensure a compliant and transparent procurement process. No change was made in the regulation.

§ 172.7(a) Procurement Methods

The Massachusetts DOT believes the procurement methods under this regulation should apply consistently to all Federal-aid architectural and engineering procurements, not just those related to construction projects. The Massachusetts DOT recommended striking ''and directly related to a highway construction project subject to the provision of'' and replacing it with ''under'' to allow these regulations to apply to all engineering related procurements whether leading to a construction project or not (*e.g.,* bridge inspection, bridge load rating, etc.).

The application of these requirements is based on the authority provided within 23 U.S.C. 112(b)(2)(A) and requires the engineering services in question to be related to a highway construction project. The Brooks Act defines architectural and engineering related services as professional services of an architectural or engineering nature, as defined by State law, if applicable, that are required to be performed, approved, or logically/justifiably performed by a person licensed, registered, or certified as an engineer or architect to provide the services (as specified in 40 U.S.C. 1102(2)). As such, bridge inspection, rating, and evaluation services may be considered engineering services under State law and regulation, and dependent upon the specific details of the scope of work being provided, and its nexus with construction, these engineering services would be subject to these requirements. Accordingly, STAs must apply 23 CFR part 172 to all Title 23 eligible engineering and design related services procurements that have a construction nexus. For those architectural or engineering contracts unrelated to construction, States must follow their procurement procedures for those contracts consistent with 2 CFR 200.317. No change was made in the regulation.

§ 172.7(a)(1)(i)

Tennessee DOT disagrees with the use of the Request for Qualifications (RFQ) and Request for Proposals (RFP) terminology. Tennessee DOT requests ''Letters of Interest'' and shortlisted firms are asked to provide ''Contract Specific Qualifications'' (using the Federal SF 330).

The FHWA believes that the NPRM terminology is consistent with the AASHTO Guide for Consultant Contracting,[3] which has widespread acceptance and use by the States. No change was made in the regulation.

The Texas DOT uses a multitiered approach to selecting the most qualified provider which includes a prequalification process, evaluation of statements of qualifications or letters of interest, and then conducting interviews of the highest qualified providers (3 or more). The requirements for an RFP impose an additional requirement upon the STA and provider beyond the requirements stated in 40 U.S.C. 1103. Texas DOT requests the use of proposals remain optional.

The Brooks Act requires an evaluation of qualified firms for each proposed procurement or project. An RFP specific to the project, task, or service is required for evaluation of a consultant's specific technical approach and qualifications. No change was made in the regulation.

The California DOT asserted that the rule will increase costs to both the consultant industry and public agencies by requiring an RFQ followed by an RFP. California DOT typically issues an RFQ followed by an interview of shortlisted firms to evaluate the technical approach of the firms.

Oral technical proposals may be permitted in response to an RFP under a multiphase process following an RFQ; however, for the purpose of transparency, the requirements for an RFP would remain as stated in the proposed regulation. No change was made in the regulation.

The Montana DOT, ACEC-Montana, and Wyoming DOT expressed some concerns with this section. The Montana DOT and ACEC-Montana opposed the provision that an RFP specific to a project is required. Both organizations asserted that this requirement will increase time and consultant costs and will eliminate the ability to procure consultants using only a prequalification process for routine services or time sensitive projects. The ACEC-Montana recommended allowing the use of a comprehensive prequalification process such as that of Montana's DOT for procurement of consultants to provide a specific and narrow range of services. The Wyoming DOT asserted that RFPs are not appropriate for all engineering and design related services, and that requiring a RFP will eliminate current streamlined processes, increasing cost and time.

The FHWA contends that a prequalification process alone does not satisfy qualifications based selection requirements. The Brooks Act provides that for each proposed procurement or project, the agency shall evaluate qualifications and conduct discussions with at least three consultants to consider concepts and compare alternative methods for furnishing services. Simplified acquisition procedures for work that fall within the simplified acquisition threshold provide a more streamlined process for those procurements meeting the simplified

[3] This item is available for purchase through AASHTO at: *https://bookstore.transportation.org/item_details.aspx?ID=1196.*

acquisition threshold. For procurements that fall outside the simplified acquisition threshold, the RFP facilitates this discussion of concepts, alternatives, and methods specific to each project. No change was made in the regulation.

The ACEC requested clarification on whether an RFP is required for task orders under an IDIQ contract. The ACEC asserted that issuance of a ''full-blown'' RFP for every task order under an IDIQ would be burdensome. The ACEC recommends deleting ''task, or service'' from the provision or to provide some other clarification. Additionally, AASHTO and California DOT asserted that an RFP is not a feasible process in evaluating consultants for on-call contracts which are not project specific.

''Project, task, or service'' is language in existing regulation and is necessary as an RFP may not relate to a specific project, but may be to provide a service or perform a task on multiple projects which may be unknown at the time of RFP issuance. The IDIQ is a type of contract and award of task orders to selected engineering consulting firms is focused on contract administration after the selection of the most qualified consultant firm(s). In instances where multiple consultants are selected and awarded IDIQ contracts under a single RFP, the procedures in § 172.9(a)(3)(iv) would be followed. To clarify expectations, the following language was added to § 172.9(a)(3)(iv)(B)(1), ''which may include, but does not require a formal RFP in accordance with § 172.7(a)(1)(ii).''

The Tennessee DOT, Massachusetts DOT, South Dakota DOT, Wyoming DOT, and AASHTO commented on prequalification periods. The Tennessee DOT recommended that a 24 or 26 month prequalification process be permitted rather than an annual basis. Massachusetts DOT currently employs a biannual prequalification process and recommended allowing prequalification at ''regular intervals not to exceed 2 years.'' South Dakota DOT recommended evaluation of consultant qualification on a 2-year basis. Wyoming DOT currently utilizes a 2 year cycle and finds it sufficient.

The STAs (or other recipients) may opt to use a prequalification process to assess minimum qualifications of consultants to perform services under general work categories. The Brooks Act requires the STA to encourage firms to submit annual statements of qualifications and performance data. The regulation was revised to better align with the requirements of the Brooks Act because 23 U.S.C. 112(b)(2)(A) requires that engineering service contracts subject to 23 U.S.C. 112(a) be awarded in the same manner as the Brooks Act.

The California DOT requested clarification on what constitutes proper notice to consultants and asked if posting on a Web site was adequate.

Specific examples of public notice are more appropriate for guidance versus regulation. As noted within the regulation, any method which provides both in-State and out-of-State consultants an equal and fair opportunity to be considered is adequate. No change was made in the regulation.

§ 172.7(a)(1)(ii)(A)

The South Dakota DOT and Connecticut DOT made recommendations pertaining to competitive negotiations. The South Dakota DOT recommended that providing a general description of the work and requiring the consultant to provide a more detailed description and scope of work be allowed, as it is helpful in selecting the consultant based on their understanding of the work needed. The Connecticut DOT recommended eliminating the language ''clear, accurate, and detailed description of the.'' The Connecticut DOT asserted that a comprehensive understanding of the details are sometimes unknown early in a project's development and may create an administrative burden to make modifications later.

The information provided for the scope of work should address the items specified within the provision at a minimum, but the level of detail is subject to the level of project planning, range of services desired, etc. The Brooks Act requires that ''all requirements'' be advertised such that interested and qualified consultants all have an equal opportunity to compete. No change was made in the regulation.

The Tennessee DOT indicated that the level of detail proposed for an RFP is not obtained until negotiations under Tennessee DOT's current multiphase process.

The RFP contents proposed are consistent with AASHTO Guide for Consultant Contracting (March 2008) and industry practice. The Brooks Act requires ''all requirements'' be advertised and the basic contents proposed are necessary to determine the most qualified consultant to provide the necessary services. The FHWA acknowledges that for some projects/services, the level of detail suggested in the provision may not be available. To clarify expectations, the regulation was changed by adding the phrase ''To the extent practicable'' to the beginning of the second sentence of § 172.7(a)(1)(ii)(A).

§ 172.7(a)(1)(ii)(B) and (iv)(C)–(E)

The Indiana DOT, South Dakota DOT, California DOT, Nebraska DOR, and AASHTO had comments related to the competitive negotiation requirement to identify at least three of the most qualified firms responding to a solicitation. The Indiana DOT asserted that the requirement for a minimum of three consultants in the discussion process and final ranking is new. Indiana DOT, as well as AASHTO, also recommended that agencies should have flexibility to evaluate two sources if advertised and competition is found to be limited. The South Dakota DOT recommended language requiring three responses be removed, provided that a procedure to verify a good faith effort to solicit responses is in place. The California DOT requested clarification and the Nebraska DOR asked what options are available if less than three firms submit proposals.

To clarify expectations, the regulation was changed to address instances where only two qualified consultants respond to the solicitation, which, as described in § 172.7(a)(1)(iv)(D), would permit the contracting agency to proceed provided competition was not arbitrarily limited. In addition, in unique circumstances, a contracting agency may pursue procurement following the noncompetitive method when competition is inadequate and it is not feasible or practical to re-compete under a new solicitation.

§ 172.7(a)(1)(ii)(C)

The Tennessee DOT and Connecticut DOT provided comments in relation to evaluation factors and their relative weight. Tennessee DOT disagrees that evaluation factors with relative weight of importance be provided in an RFP. Tennessee DOT indicates that providing weights implies a rigid formula and eliminates STA discretion to select between firms with similar qualifications. Connecticut DOT recommends removing the requirement to identify the weight of importance as it is unclear of the benefit to the selection process.

The FHWA believes that providing relative weights for evaluation factors is consistent with Federal procurement practices under the Brooks Act, provides consultants a better understanding of what to focus their proposal on, and is essential for transparency of the selection process. No change was made in the regulation.

§ 172.7(a)(1)(ii)(D)

The New York State DOT and the Connecticut DOT expressed concern in relation to contract types and method(s) of payment. Connecticut DOT recommends removal of (D) as the decision on contract type and payment method is often determined in negotiations with the selected firm and questions if specifying up front would preclude the STA from changing the type later if necessary. New York State DOT expressed a similar concern.

The contract type and payment method are a function of how well the scope of work is defined, the type and complexity of the work, the period of performance, etc. These items should generally be known in advance, when the need for consultant services is identified. Where appropriate, deviations from the advertised contract type and payment method may be warranted, such as for subcontracts, contract modifications, etc. To clarify expectations, the regulation was revised to read: ''Specify the contract type and method(s) of payment anticipated to contract for the solicited services in accordance with § 172.9.''

§ 172.7(a)(1)(ii)(E)

The Connecticut DOT-Local Roads requested clarification on what special provisions or contract requirements are required.

This provision requires inclusion of any ''special'' provisions or contract requirements associated with the solicited services that are not included within the standard contract template/documents used by the contracting agency. This would include provisions unique to the services being solicited or contracted. No change was made in the regulation.

§ 172.7(a)(1)(ii)(F) and 172.7(a)(1)(v)(C)

The ACEC and Connecticut DOT-Local Roads expressed concern in relation to consultant cost information. The ACEC requested that the submittal of concealed cost proposals not be permitted, as the accuracy of the scope of work and cost proposal at the RFP stage is limited. The Connecticut DOT-Local Roads recommended not permitting submittal of consultant cost information until later in the selection process to guard against improper use of that information.

Many contracting agencies currently require concealed cost proposals. This practice was recognized within the regulations provided that the specified controls are included. The FHWA agrees that the scope of work and accuracy of the cost proposal at the RFP stage is limited on some projects, but submittal of cost proposals with the RFP may prove more efficient on more routine and straightforward projects/services. As such, the flexibility should be provided to STAs. No change was made in the regulation.

§ 172.7(a)(1)(ii)(G)

Connecticut DOT recommends removal of the language ''key dates.'' Connecticut DOT asserts that aside from the submittal deadline for responses to the RFP, the selection timeline may vary depending on the number of responses received and other procurement steps. The Virginia DOT suggested removing the provision.

To provide transparency in the procurement process, a schedule of estimated dates for interviews and selection of the most qualified consultant shall be provided to interested consultants. A 14-calendar day minimum advertisement period is required to ensure fair and open competition. Based on the comments received, the regulation was revised to require an ''estimated schedule'' rather than a ''schedule of key dates''.

The AASHTO agreed that a consultant should be provided sufficient time to prepare a proposal, but recommended against mandating a 14-day requirement.

The 14-day period is provided as the minimum length of time for advertisement of an RFP. No change was made in the regulation.

§ 172.7(a)(1)(iii)(B)

The South Dakota DOT recommended that price/cost of engineering services be permitted as an evaluation criteria.

Consideration of price or cost in the evaluation and selection of engineering consultant services is prohibited in (23 U.S.C. 112(b)(2)(A) and 40 U.S.C. 1103). No change was made in the regulation.

§ 172.7(a)(1)(iii)(C)

The Nebraska DOR requested clarification on ''local preference'' and whether it simply means that the consultant must have an in-state professional engineering (PE) license.

Requirements at 2 CFR 200.319(b) prohibits the use of in-state or local geographic preferences in the evaluation of bids or proposals except where Federal statute mandates or encourages the use of such preferences [4]. However, a State may require that the consultant have the necessary PE license per State law or regulation. No change was made in the regulation.

The South Dakota DOT, Connecticut DOT, and Connecticut DOT-Local Roads expressed a need for clarification between § 172.7(a)(1)(iii)(C) and (D) feeling that the provisions in (a)(1)(iii)(C) and (a)(1)(iii)(D) contradict one another.

The provisions in (a)(1)(iii)(C) and (a)(1)(iii)(D) are intended to address separate elements; subparagraph (a)(1)(iii)(C) addresses the prohibition of ''local preference'' while subparagraph (a)(1)(iii)(D) makes allowance for evaluation criteria that is related to services performance, which may include an agency's desire for a ''local office presence'' or use of Disadvantage Business Enterprise (DBE) subconsultants. No change was made in the regulation.

§ 172.7(a)(1)(iii)(D)

The Tennessee DOT and Massachusetts DOT recommended that the ''non-qualifications'' based criteria not be permitted since such criteria are inconsistent with the Brooks Act.

A local office presence criterion is used by many States and while not specifically qualifications oriented, a local office presence criterion recognizes that providing a local office presence may provide value to the quality and efficiency of a project. The use of DBE participation as an evaluation criterion is practiced by many STAs and harmonizes Brooks Act requirements with DBE regulations as specified in 49 CFR part 26. By addressing and providing a limitation on the use of these criteria, the integrity of a QBS process is maintained. No change was made in the regulation.

§ 172.7(a)(1)(iii)(D)(1)

The Tennessee DOT asserted that a local presence criterion may add value at times and that it should be merged with (a)(1)(iii)(C) regarding the prohibition on in-State and local preference.

The provisions in (a)(1)(iii)(C) and (a)(1)(iii)(D) are intended to address separate elements; (a)(1)(iii)(C) addresses the prohibition of ''local preference'' while (a)(1)(iii)(D) makes allowance for other evaluation criteria that have historically been used on a limited basis to promote efficient project delivery and other FAHP goals. No change was made in the regulation.

The North Dakota DOT asserted that the proposed revision is too restrictive and believes that location is a valid criterion that adds value to the quality and efficiency of a project, under certain circumstances.

[4] For example, 23 U.S.C. 140(d) authorizes the preferential employment of Indians living on or near a reservation on projects and contracts on Indian reservations roads under the Federal-aid Highway Program.

Evaluation criteria such as knowledge of a locality and familiarity of the general geographic area are qualifications that a consultant may need to demonstrate to compete for a project and may be included along with technical criteria. A consultant could demonstrate knowledge of a locality and project site without having a physical local office and thus the need for a limitation on evaluation of a ''local presence'' as local presence is unrelated to the technical expertise of the firm. No change was made in the regulation.

§ 172.7(a)(1)(iii)(D)(2)

The Connecticut DOT-Local Roads questioned the benefit gained by awarding points in the evaluation process for use of DBEs when meeting a DBE goal is a requirement of the project contract.

The allowance of an evaluation criterion for participation of qualified and certified DBEs is to harmonize Federal requirements for qualifications based selection and for consideration of DBEs in the procurement of engineering and design related services. No change was made in the regulation.

§ 172.7(a)(1)(iv)

The ACEC recommended that a provision be inserted to provide an opportunity for non-selected firms to review evaluation, ranking and selection information with the agency, if requested (*e.g.,* debriefing).

The FHWA encourages agencies to provide for debriefings to maintain transparency in the procurement process; however, this does not relate to statutory requirements. No change was made in the regulation.

§ 172.7(a)(1)(iv)(A)

The Texas DOT recommended that ''public solicitation'' be replaced with ''RFP.''

While the ''solicitation'' is effectively the RFP as defined within § 172.7(a)(1)(i), solicitation is used generally throughout the proposed part 172. Reference to solicitation is key to reinforce the requirements for public advertisement and consideration of both in-State and out-of-State consultants. No change was made in the regulation.

§ 172.7(a)(1)(iv)(C)

The ACEC, Alaska DOT, Nebraska DOR, South Dakota DOT, and Texas DOT expressed similar opinions in reference to § 172.7(a)(1)(iv)(C). The ACEC recommended that ''shall'' conduct interviews or other types of discussions be changed to ''may'' so as to not conflict with the final sentence of the provision which allows for no discussions if proposal information is sufficient. The ACEC recognized that discussions are not necessary in some situations. The Alaska DOT and South Dakota DOT made the same recommendations, while the Nebraska DOR and Texas DOT requested some clarification.

The FHWA agrees the wording was confusing and the regulation was revised to require the STA to establish criteria and a written policy, [as specified in § 172.5(c)(6)] under which additional discussions would be take place following RFP submission and evaluation. The RFP shall state what type of discussions, if any, will take place following submission and evaluation of proposals.

The Connecticut DOT-Local Roads asserted that not requiring discussions following proposal submission will remove structure from the selection process and make it difficult to document decision criteria.

Historically, many contracting agencies relied on the information contained within consultant proposals and did not conduct subsequent discussions/interviews. This is an acceptable practice based upon State procedures under a risk-based framework and consistent with the comments received on this NPRM provided the proposals contain sufficient information for evaluation of technical approach and qualifications. The contracting agency must maintain documentation to support the evaluation and selection of a consultant based on the advertised evaluation criteria. No change was made in the regulation.

§ 172.7(a)(1)(iv)(C) Through (E)

The New York State DOT indicated that it does not always conduct additional discussions and that when shortlisting firms for additional discussions, and the rankings are not provided.

Section 172.7(a)(1)(iv)(C), modified to require the STA to establish a written policy under which additional discussion are needed, will not mandate additional discussion of proposals that contain sufficient information for evaluation of technical approach and qualifications. Section 172.7(a)(1)(iv)(E) does not require initial rankings to be provided when short-listing firms, only the final rankings must be provided. No change was made to § 172.7(a)(1)(iv)(E) of the regulation.

§ 172.7(a)(1)(iv)(D)

The South Dakota DOT recommended language requiring ''three responses'' be removed provided a procedure to verify a good faith effort to solicit responses is in place. The South Dakota DOT recommended adding the following language, ''When an RFP does not result in three responses, the agency may proceed with the evaluation of the responses obtained.''

To clarify expectations, the regulation was changed to address instances where only two qualified consultants respond to the solicitation, which, as described in § 172.7(a)(1)(iv)(D), would permit the contracting agency to proceed provided competition was not arbitrarily limited. In addition, in unique circumstances, a contracting agency may pursue procurement following the noncompetitive method when competition is inadequate and it is not feasible or practical to re-compete under a new solicitation.

§ 172.7(a)(1)(iv)(E)

The Tennessee DOT, South Dakota DOT, Connecticut DOT-Local Roads, Montana DOT, Nebraska DOR, and Wyoming DOT expressed similar opinions. Tennessee DOT recommended deleting § 172.7(a)(1)(iv)(E), since it objects to providing notification of the ''final ranking'' of the three most highly qualified. The South Dakota DOT also recommended removing the requirement for notification of ranking because all participating consultants are notified of the consultant selected and are provided a brief explanation of why they were not selected. The Connecticut DOT-Local Roads questioned the benefit of providing the final ranking information to responding consultants. The Montana DOT asserted that compliance with this provision will require additional staff time to prepare notifications to each respondent. The Nebraska DOR recommended that the term ''ranking'' be replaced with the term ''selection.'' The Wyoming DOT asserted that the proposed section changes the notification procedures by adding additional unnecessary requirements.

The Brooks Act requires the evaluation of at least three of the most highly qualified firms based upon established and published criteria. The contracting agency must enter into negotiations with the highest ranked firm and negotiate a contract for compensation that is fair and reasonable to the Federal Government. If the contracting agency is unable to negotiate a satisfactory contract with the highest ranked firm, the contracting agency must undertake negotiations with the next highest ranked firm, continuing the process until a contract agreement for fair and reasonable compensation is reached. Section 172.7(a)(1)(iv)(E)

promotes transparency in the selection process and notification can be as simple as posting the final ranking on a Web site. No change was made in the regulation.

§ 172.7(a)(1)(v)

The Idaho Transportation Department and AASHTO suggest ensuring reasonable wage rates for specific labor classifications, in addition to employee classifications, labor hours by classification, fixed fees and other direct costs contribute to the overall reasonableness of the agreement.

The FHWA agrees. Section 172.7(a)(1)(v)(B) references § 172.11 for establishment of the direct salary rates, which includes an assessment of reasonableness in accordance with the Federal cost principles. For clarification, proposed § 172.7(a)(1)(v)(B), under the re-designated § 172.7(a)(1)(v)(C) was revised to indicate that the use of the independent estimate and determination of cost allowance in accordance with § 172.11 shall ensure the consultant services are obtained at a fair and reasonable cost.

The Oregon DOT recommended a section regarding ''order of negotiation'' [40 U.S.C. 1104(b)] from the Brooks Act be included so it is not misinterpreted that this section does not apply.

Although the ''order of negotiation'' section [40 U.S.C. 1104(b)] of the Brooks Act applies as specified in § 172.7(a)(1), for clarification purposes, specific language was added to § 172.7(a)(1)(v) as new paragraph § 172.7(a)(1)(v)(A).

§ 172.7(a)(1)(v)(A)

The North Dakota DOT, Indiana DOT, Wyoming DOT, AASHTO, and the Illinois Association of County Engineers (IACE) expressed concerns with the requirement to develop a detailed independent cost estimate. The North Dakota DOT asserted that the independent estimate is a new requirement that would require additional STA resources (time and staff). The Indiana DOT asserted that STAs and LPAs do not all have the ability to prepare detailed labor estimates (independent estimate) as the basis for negotiation with a consultant and that detailed labor estimates may not be the best way to estimate the cost of consultant services in all instances. The Wyoming DOT asserted that other procedures are equally appropriate and effective for obtaining independent estimates, and that the proposed method is too prescriptive. The AASHTO asserted that smaller contracting agencies, especially local agencies, may not have the expertise to prepare a detailed independent estimate with a breakdown of labor hours, direct and indirect costs, fixed fees, etc. In this situation, contracting agencies should be allowed to use typical percentages of construction costs to prepare their independent estimate for purposes of negotiation. The IACE asserted that development of independent cost estimates with an appropriate breakdown of the labor hours and classifications could add considerable staff time for STAs and LPAs, as most of the current IACE members rely on previous experience with projects of similar scope, magnitude, and construction cost to determine an estimate or anticipated range of consultant costs prior to negotiation. The IACE recommends that the description of independent agency estimate be broadened to include less rigorous estimating methods and guidelines.

The regulation is consistent with 2 CFR 200.323, which requires recipients to perform a cost or price analysis in connection with every procurement action in excess of the simplified acquisition threshold (as defined in 48 CFR 2.101) and with the Brooks Act (40 U.S.C. 1104) which requires the agency head to consider the scope, complexity, professional nature, and estimated value of the services to be rendered. The method and degree of analysis is dependent on the facts surrounding the particular procurement situation, but as a starting point, contracting agencies must make independent estimates before receiving bids or proposals. The proposed provision notes ''an appropriate breakdown'' of the various cost elements which provides flexibility in the degree of analysis subject to the scope and complexity of the services. No change was made to the regulation.

§ 172.7(a)(1)(v)(C) [Re-Designated § 172.7(a)(1)(v)(D)]

The Alaska DOT recommended changing ''consultants with which negotiations are not initiated'' to ''unsuccessful consultants'' as price proposals are not returned until negotiations are concluded and the cost proposal of the 2nd ranked firm will be needed should negotiations fail with the highest ranked firm.

The FHWA agrees the revision to ''unsuccessful consultants'' streamlines the provision while the first sentence of subparagraph (a)(1)(v)(C) [re-designated subparagraph (a)(1)(v)(D)] provides the requirement to only open the proposal of a consultant when entering negotiations and to only consider that consultant's proposal. The regulation was modified accordingly.

The Alaska DOT and New York State DOT provided comments on concealed cost proposals. The Alaska DOT recommended changing ''should be returned'' to ''may be returned if requested by the consultant'' as this places a burden on STAs to return the documents to consultants in lieu of destroying along with unsuccessful proposals. The New York State DOT asserted that returning cost proposals is not necessary. Cost proposals are often electronic and would simply be discarded, or if hard copies are provided, the hard copies would be shredded unopened.

The FHWA agrees to the revision [re-designated § 172.7(a)(1)(v)(D)] changing ''should'' to a ''may'' condition where the contracting agency establishes written policies and procedures [in accordance with § 172.5(c)] for disposal of unopened cost proposals. The regulation was modified accordingly.

The California DOT recommended replacing the word ''concealed'' with ''sealed.''

Many contracting agencies currently require concealed cost proposals though not all proposals are in hard copy form. The FHWA considered the recommendation and determined that using the term ''sealed'' would imply erroneously that a hard copy sealed envelope would be required. No change was made to the regulation.

§ 172.7(a)(2)

The Connecticut DOT-Local Roads asserted that the subject provisions are in conflict since (a)(2) indicates a lower State threshold must be used and (b)(1)(ii) indicates that Federal requirements prevail when a conflict with State or local requirements exist.

The provisions do not conflict. A State small purchase threshold that is lower than the Federal threshold would not violate Federal requirements, as the Federal requirement would still be satisfied. However, a State threshold above the Federal threshold would not be permitted as this would violate Federal requirements. No change was made to the regulation.

The Indiana DOT did not support the requirement for discussion/review of a minimum of three sources (consultants) when using small purchase procedures. Existing regulations indicate ''adequate number of qualified sources.''

Section 172.7(a)(2)(ii) established that a minimum of three consultants be reviewed to promote adequate competition. The regulation was revised to include requirements to address circumstances where there are less than three respondents.

The Wyoming DOT asserted that requiring STAs to use a lessor STA threshold for small purchase procedures is too restrictive.

Both 23 CFR 1.9 and 2 CFR 200.317 require compliance with State laws where not inconsistent with applicable Federal law and regulation. As such, a lessor State threshold for use of small purchase procedures is more restrictive than Federal requirements and thus must be complied with. No change was made to the regulation.

The Alaska DOT recommended allowing procurements less than $10,000 to be accomplished without competition and not require three quotes as with small purchase procurement procedures.

The small purchase procedures permitted mirror direct Federal acquisition requirements which do not provide a similar threshold where competition is not necessary. No change was made to the regulation.

§ 172.7(a)(2)(ii)

The Oregon DOT requested clarification on what is meant by ''review of at least three qualified sources.'' South Dakota DOT recommended language requiring ''three responses'' be removed and replaced with a provision for agencies to provide a procedure to verify a good faith effort to solicit responses. South Dakota DOT recommends adding the following language, ''When an RFP does not result in three responses, the agency may proceed with the evaluation of the responses obtained.''

The level of review (request for proposals, discussions, etc.) shall be in accordance with State procedures, but a minimum of three consultants must be considered. Although small purchases are a permitted exception to compliance with the Brooks Act, review of three sources is a simplified means to promote competition among qualified firms. Section 172.7(a)(2)(ii), was revised to address instances where less than three consultants respond to the solicitation.

§ 172.7(a)(2)(iv)

The Nebraska DOR and AASHTO requested clarification as to whether only the amount above the simplified acquisition threshold is ineligible or the entire contract is ineligible. The AASHTO asserted that ''The full amount of any contract modification or amendment that would cause the total contract amount to exceed the established simplified acquisition threshold would be ineligible for Federal-aid funding'' is penalty enough and that FHWA needed to establish circumstances that warranted the extreme action of withdrawal of all Federal funding from the contract.

As specified within the proposed regulation, the full amount of any contract modification or amendment which causes a contract to exceed the threshold would be ineligible. The FHWA has the discretion to withdraw all Federal-aid funding from the contract if it determines that the small purchase procurement was used to circumvent competitive negotiation procurement procedures. No change was made to the regulation.

The Connecticut DOT asserted that this provision may be difficult to monitor and administer.

This provision is intended to prevent abuse of the use of small purchase procedures to circumvent qualifications based selection procurement requirements. A simple check or audit of contracts procured under small purchase procedures to verify the appropriate threshold was not exceeded is all that would be necessary to verify compliance. No change was made to the regulation.

§ 172.7(a)(3)

The AASHTO requests clarification as to whether FHWA is approving each contract or approving a STA's noncompetitive procedures. The AASHTO recommends approval of procedures.

The specific scenarios for use of noncompetitive procedures should be addressed within the STA's written procedures. While FHWA approval on a contract basis is indicated within § 172.7(a)(3)(ii), a STA's procedures allow programmatic approval under specified circumstances. No change was made to the regulation.

The California DOT requested clarification as to whether this applies if less than three qualified consultants submit proposals in response to a RFQ.

Yes, noncompetitive procedures would apply under § 172.7(a)(3)(iii)(C). Revisions to the regulation, § 172.7(a)(iv)(D), address instances where less than three consultants respond to the solicitation. No change was made to the regulation.

§ 172.7(a)(3)(iii)

The San Diego Association of Governments (SANDAG) requested that proposed language be modified to clarify that approval from FHWA is one method for authorizing a sole source, but not the only method.

Use of noncompetitive procedures requires FHWA approval as specified within the existing and proposed regulations. An agency's written procedures approved by the FHWA Division Office may define situations whereby FHWA approval is granted on a programmatic basis. No change was made to the regulation.

§ 172.7(b)(1)(i)

The Nebraska DOR finds the phrase, ''. . . procedures which are not addressed by or in conflict with applicable Federal laws . . .'' confusing when compared to § 172.7(b)(1)(ii) which states ''When State and local procurement laws, regulations, policies, or procedures are in conflict with applicable Federal laws and regulations . . .''

For clarity, § 172.7(b)(1)(i) was revised to read, ''. . . procedures which are not addressed by or are not in conflict with applicable Federal laws and regulations . . .''

§ 172.7(b)(2)(i)

The AASHTO recommends revising ''shall'' to ''may'' as DBE requirements are met through construction contracts.

Participation by DBE firms in FAHP projects is a requirement of 49 CFR 26. A contracting agency might meet most of its approved DBE participation goals through construction contracts; however, in accordance with the STA's DBE program approved by FHWA, consultant work accomplished by consultants/subconsultants that are on the STA's approved DBE list could count toward satisfying DBE goals. No change was made to the regulation.

The California DOT requested additional clarification regarding the utilization of DBE goals or evaluation criteria for DBE participation.

The proposed rule is consistent with existing FHWA policy and guidance. A contracting agency might meet most of its approved DBE participation goals through construction contracts; however, in accordance with the STA's DBE program approved by FHWA, consultant work accomplished by consultants/subconsultants that are on the STA's approved DBE list could count toward DBE goal accomplishment. No change was made to the regulation.

The Virginia DOT and AASHTO asserted that this provision is in conflict with the Federal DBE Small Business Enterprise Program, and interpreted this provision as requiring STAs to have set-asides for Small Business.

The proposed rule is consistent with existing FHWA policy and guidance, and it is not in conflict with 49 CFR 26.43, which explicitly prohibits set-asides or quotas for DBEs. No change was made to the regulation.

§ 172.7(b)(3)

The AASHTO recommended allowing consultant self-certification for no suspension or debarment actions rather than requiring STAs to verify eligibility on a contract by contract basis. The Wyoming DOT also suggested self-certification by consultants and subconsultants.

The requirements for verification of suspension and debarment actions and consultant eligibility status are specified within 2 CFR part 180. Use of a contract-based self-certification is currently permitted. No change was made to the regulation.

§ 172.7(b)(4)

The Wyoming DOT asserted that this section is unclear and potentially far reaching.

The proposed provision addresses basic Conflict of Interest (COI) scenarios and is an existing requirement of the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (2 CFR 200.112). No change was made to the regulation.

The California DOT recommended including COI provisions for various types of services (design and construction engineering, design and environmental services, etc.).

The regulations provide the basis for STAs to develop more specific COI policies based on the specific risks and range of controls a STA may have. No change was made to the regulation.

§ 172.7(b)(5)(i)

The PECG recommended that STAs be precluded from awarding management contracts as it is inappropriate for a consultant to perform an inherently governmental function.

Use of consultants in a program management role is permitted under existing requirements in 23 U.S.C. 112(b)(2)(A). Section 302(a) of Title 23, U.S.C. allows the use of consultants to the extent necessary or desirable provided the contracting agency is suitably equipped and organized. Use of consultants in a management role warrants additional conflicts of interest controls as prescribed to mitigate concerns with performance of inherently governmental functions. No change was made to the regulation.

§ 172.7(b)(5)(ii)

The California DOT recommended that project management services to manage scope, cost, and schedule of a project be excluded.

In order to show that the STA has adequate powers and is suitably equipped and organized to discharge the duties required by this title, § 172.9(d)(1) requires a public agency employee to perform these functions and serve in responsible charge of the project. No change was made to the regulation.

§ 172.7(b)(5)(iii)

Guy Engineering Services, Inc. interpreted the provision to prohibit a consultant from providing construction management services for projects for which the consultant provided design services.

A ''management support role,'' as defined in § 172.3 and as intended in § 172.5(b), relates to a program or project administration type role on behalf of the contracting agency where a consultant may manage or oversee the work of other consultants or contractors. The scenario described by the commenter does not involve a consultant overseeing its own work. No change was made to the regulation.

The ACEC and the American Road and Transportation Builders Association recommended the removal of the last sentence, ''A consultant serving in a management role shall be precluded from providing services on projects, activities, or contracts under its oversight.'' The ACEC is concerned the sentence is broad and will limit various technical services that firms in program management roles routinely provide to their clients.

The FHWA agrees that the sentence could be interpreted and applied in a manner more restrictive than intended. The regulation was modified to read that consultants ''may'' be precluded from providing additional services due to potential conflicts of interest.

The Alaska DOT expressed a concern that this provision would preclude a consultant from providing construction management services for projects in which they provided design services. Alaska recommends the provision be amended to specifically allow consultants to provide construction management services for projects in which they provided design services.

Consistent with current FHWA policy and guidance, necessary controls must be in place for oversight and prevention of conflicts of interest to permit a consultant to provide services in the design and construction phase of the same project. As such, a specific blanket approval via regulation would not be appropriate. Additionally, the proposed provision notes that the consultant in a management support role would be precluded from providing services on projects under its oversight. No change was made to the regulation.

The PECG agrees with the provision to preclude a consultant serving in a management role from also providing services on projects, activities, or contracts under its oversight.

The PECG's position was noted. No change was made to the regulation.

§ 172.9(a)(2)

The California DOT and AASHTO requested clarification on whether negotiation includes both scope and costs on a phase by phase basis under a multiphase contract.

Negotiation always includes detailed elements of the scope of work and associated costs. However, the type of services and work negotiated must be included within the overall scope of services of the original solicitation from which a qualifications-based selection was made. The regulation was modified to include clarification language.

§ 172.9(a)(3)(i)

The Indiana DOT, New York State DOT, California DOT, SANDAG, Massachusetts DOT, Virginia DOT, South Dakota DOT, Texas DOT, and AASHTO expressed concerns with the maximum 5 years limitation specified in the regulation. The Indiana DOT recommended that exceptions to the on-call contract timeframe be provided where a consultant may have largely completed a project design and it would be unreasonable to contract with another firm to complete the design. The New York State DOT noted that 5 years may not be sufficient where it is desired to retain the consultant to provide ongoing construction support services. The California DOT asserted that it is sometimes required to have a contract last longer than 5 years due to the complexity of the projects and its length of construction, and that this section should include language to allow exceptions. The SANDAG requested that FHWA consider recommending the 5 year contract term, but allow contract terms in excess of 5 years when justified by grantee (recipient) documentation. Massachusetts DOT recommended removal of the 5 year limitation on contracts. Virginia DOT questioned the need for a 5 year limitation for on-call contracts. South Dakota DOT and Texas DOT recommended removal of the 5 year limitation on contracts.

The 5 year maximum contract length only applies to IDIQ contracts. The IDIQ contracts are intended for smaller projects or for performance of routine or specialized services on a number of projects. As such, only services which fall within the advertised scope, funding, and schedule limitations of the established IDIQ contract may be awarded to the consultant. Should the

scope or complexity of a project warrant a more flexible schedule, a project specific solicitation should be utilized over a task order under an IDIQ contract. No change was made to the regulation.

§ 172.9(a)(3)(ii)

The South Dakota DOT asserted this provision is misplaced and should be moved to project specific contracts rather than IDIQ contracts.

The thresholds provided for IDIQ contracts are essential to ensuring that an unlimited amount of work over an unlimited period of time is not awarded to a single consultant. While project specific contracts will also generally define a maximum total contract dollar amount, these contracts are subject to contract modification as appropriate which may increase the amount. No change was made to the regulation.

§ 172.9(a)(3)(iv)

The California DOT requested clarification on the process for awarding multiple consultants on-call contracts under a single solicitation.

If the STA wishes to award contracts to three consultants, then the top three ranked firms may be awarded contracts under a single solicitation when advertised accordingly. Additional information may be provided in implementing guidance, but is not appropriate for inclusion within the regulatory language. No change was made to the regulation.

§ 172.9(a)(3)(iv)(A)

The Tennessee DOT recommended deleting the provision to specify the number of consultants that may be selected under the IDIQ solicitation as providing this information is unnecessary and provides little useful information to interested firms. The Massachusetts DOT and South Dakota DOT also recommended similar revisions.

The provision is to indicate the number of consultants/contracts that ''may'' be awarded through the specific IDIQ solicitation. When advertising, an STA should know how many contracts it may need based on an estimated workload of needed services. This allows interested consultants to know how many contracts ''may'' be awarded and provides transparency to the process. Additionally, since ''may'' is used, this does not lock the STA into awarding the number of contracts shown on the solicitation and contract provision, if an adequate number of qualified consultants do not submit a proposal. No change was made to the regulation.

§ 172.9(a)(3)(iv)(B)

The Tennessee DOT, Massachusetts DOT, Texas DOT, Montana DOT, Connecticut DOT, Wyoming DOT, and AASHTO expressed concerns about the additional QBS process specified in this provision. The Tennessee DOT recommended deleting this section based on their concern that requiring an additional QBS process to award task orders among multiple firms is contrary to the purpose of an IDIQ contract to accelerate the selection process of small or short duration type projects. Massachusetts DOT recommended deleting this section based on their opinion that requiring an additional QBS process or regional method to award task orders among multiple firms is contrary to the purpose of an IDIQ contract to accelerate the selection process and it limits the flexibility of the STA. Texas made similar recommendations and offered that a third option for award of task orders on a rotational basis be provided. Montana DOT and Connecticut DOT expressed concerns with additional time and cost associated with a secondary qualification based process. The Connecticut DOT recommended revising the provision to simply state ''the contracting agency shall ensure it has an equitable method to distribute the work between the selected qualified consultants and it shall be approved by FHWA in advance.'' Wyoming DOT expressed similar concerns of additional time and resources. The AASHTO expressed a concern with the requirements of the provision and asked that if a ''full'' competitive negotiation procedure was not what was meant by the secondary ''qualifications-based selection,'' that the provision be revised for clarification or that the requirement for a secondary qualifications-based selection be removed.

If multiple consultants are awarded IDIQ contracts under a QBS procedure, a methodology which considers consultant qualifications must be used to award individual task orders among the firms. A Department of Homeland Security Office of Inspector General audit has criticized practices of Federal agencies awarding task orders on a rotational basis (equitable funding distribution) as a potential violation of the Brooks Act.[5] A fair and transparent methodology is necessary. The ''second'' QBS process to award task orders may be abbreviated and not require additional submittals by firms under contract. The regulation was modified to include clarification language.

The South Dakota DOT recommended that the contracting agency be permitted to award task orders on the basis of qualifications and price/cost. The South Dakota DOT proposed the following language, ''Task or work orders shall not be competed and awarded among the selected, and qualified consultants on the *sole* basis of costs . . .''

If multiple consultants are awarded IDIQ contracts under a QBS procedure, a methodology which considers consultant qualifications must be used to award individual task orders among the firms. A Department of Homeland Security Office of Inspector General audit has criticized practices of Federal agencies awarding task orders on a rotational basis (equitable funding distribution) as a potential violation of the Brooks Act.[5] A fair and transparent methodology is necessary and competing on the basis of costs is not permitted. No change was made to the regulation.

§ 172.9(a)(3)(iv)(B)(1)

The Ohio DOT recommended that an additional QBS procedure to award task orders under an IDIQ contract should apply only to specific tasks which exceed the simplified acquisition threshold.

The provision only applies to task orders on IDIQ contracts procured under competitive negotiation. Adding a caveat to only apply to task orders over $150,000 is mixing competitive negotiation and simplified acquisition procurement procedures. The regulation was modified to include clarification language concerning the QBS procedure.

The ACEC recommended clarifying that a ''full-blown'' RFP is not required to compete every task order under an IDIQ with multiple consultants under contract.

The ''second'' QBS process to award task orders may be abbreviated and not require additional submittals by firms under contract. The regulation was modified to include clarification language.

§ 172.9(a)(3)(iv)(B)(2)

The Texas DOT requested clarification on assigning work if consultants are selected to provide work in a particular region.

Under a regional basis, a single consultant would be selected to provide the desired services on an on-call basis within a designated region. Any specified services within that region could then be assigned via task order to

[5] *http://www.oig.dhs.gov/assets/Mgmt/OIG_11–02_Oct10.pdf.*

the selected consultant. No change was made to the regulation.

§ 172.9(b)(1)

The Connecticut DOT questioned why payment method must be included in the original solicitation.

The payment method is a function of how well the scope of work is defined, the type and complexity of the work, the period of performance, etc. This should generally be known up front when the need for consultant services is identified. Where appropriate, deviations from the advertised payment method may be warranted, such as for subcontracts, contract modifications, etc. It is noted within the provision that different payment methods may be warranted for different elements of the work. No change was made to the regulation.

§ 172.9(b)(5)

The California DOT recommended providing additional information regarding the specific rates of compensation payment method and any limitations to auditing the indirect cost rate or in providing oversight on contracts where the indirect cost rate is fixed for the term of a multiyear contract.

The specific rates of compensation payment method does not impose any special requirements related to indirect cost rate different from other payment methods other than the indirect cost is included within a loaded hourly rate. No change was made to the regulation.

§ 172.9(b)(6) and (c)(10)

The ACEC strongly supported the § 172.9(b)(6) and (c)(10) provisions regarding retainage and prompt pay.

The ACEC's position was noted. No change was made to the regulation.

§ 172.9(c)

Wyoming DOT questioned the value of the proposed section of contract requirements and recommends lengthening the compliance period to allow STAs time to consult with State Attorney General's office to determine appropriate contract language.

Many of the contract provisions noted reference a requirement contained within other applicable regulations. Other general provisions reflect similar requirements contained within the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (2 CFR 200.326/appendix II of 2 CFR part 200). No change was made in the regulation.

The Virginia DOT and AASHTO asserted that not all provisions seem applicable to subcontracts; specifically the provisions for Title VI assurance, DBE assurance, error and omissions, and conflicts of interest.

The extension of the assurances for Title VI and DBE to subcontracts is a requirement of the referenced order or regulation. The errors and omissions and conflicts of interest provisions must be incorporated into subcontracts as well, since these issues reach beyond the consultant and subconsultant. No change was made to the regulation.

The New York State DOT asserted that many of the provisions are too lengthy to include in each individual contract and the regulations should allow incorporation by reference.

The FHWA agrees that some contract provisions may permit incorporation by reference. However, other provisions specified in other applicable statutes and regulations require physical incorporation of the language into each contract. The regulation was modified to allow incorporation by reference where applicable.

§ 172.9(c)(6)

The ACEC requested clarification on to whom the records retention requirements apply and what is meant by ''all other pending matters are closed.''

The provision is consistent with 2 CFR 200.333 and was incorporated to 23 CFR 172 to avoid any misinterpretations of its application to consultant contracts under the FAHP. As a consultant contract provision, it applies to consultants under contract with a contracting agency. ''All other pending matters'' could include claims, lawsuits, etc. No change was made to the regulation.

§ 172.9(d)(1)

The PECG expressed concerns that the provisions permit a public employee to serve in responsible charge of multiple projects and that contracting agencies may use multiple employees to fulfill monitoring responsibilities. The PECG recommended requiring STAs to employ sufficient staff to carry out a highway program in a manner that maximizes public safety and promotes efficient use of public funds.

Clarification is provided that responsible charge is not intended to correspond to its usage in State laws regarding PE licensure. The provision is intended to articulate the minimum requirements for contract administration and oversight. No change was made to the regulation.

The Virginia DOT and AASHTO asserted that this provision appears to be a job description instead of a regulation and should be removed.

The provision sets the requirements for oversight of consultants under contract to provide engineering and design related services funded with FAHP funds. The monitoring requirements specified within the regulation are fundamental to administration of the FAHP as specified in 23 U.S.C. 302(a). Providing a full-time agency employee in responsible charge is also addressed within 23 CFR 635.105(b). No change was made to the regulation.

The PECG expressed concerns that ''responsible charge'' is a recognized term within the profession of engineering. The ACEC expressed concerns with the use of the term ''responsible charge'' for public agency employee functions since the term has legal connotations within the engineering profession.

The ''responsible charge'' term is used in 23 CFR 635.105 for construction project oversight and has been a common term within the Federal-aid highway program for years. It is intended to be applied only in the context defined within the regulation. It may or may not correspond to its usage in State laws regulating licensure of professional engineers. Language to clarify the intentions of the ''responsible charge'' term was added to the regulation.

The North Dakota DOT, Montana DOT, Wyoming DOT, and AASHTO expressed concerns that the monitoring requirements would require additional staff. The Montana DOT expressed a particular concern with the responsible charge individual having to ensure that consultant costs billed are allowable in accordance with the Federal cost principles and consistent with the contract terms as well as the acceptability and progress of the consultant's work. The AASHTO expressed the concern that the requirement to provide a ''Full-Time'' employee to monitor and administer the contracts can be extremely burdensome on LPAs and pointed out that many use ''Part-Time'' employees to oversee contracts.

The monitoring requirements specified within the regulation are fundamental to administration of the FAHP as specified in 23 U.S.C. 302(a). The provision allows for a full-time public employee to serve in responsible charge of multiple projects, and contracting agencies may use multiple public employees to fulfill monitoring responsibilities. Providing a full-time agency employee in responsible charge is also addressed within 23 CFR 635.105(b). No change was made to the regulation.

§ 172.9(d)(1)(i)

The PECG asserted that construction inspection is an inherently governmental function that must be performed by public agency employees.

Section 302(a) of Title 23 U.S.C. permits the use of consultants to the extent necessary or desirable provided the contracting agency is suitably equipped and organized. Use of consultants in management support roles, including construction management is permitted under existing regulations. No change was made to the regulation.

§ 172.9(d)(2)

The Tennessee DOT recommends deleting reference to ''report'' and to simply note a performance evaluation to allow the STA discretion as to the structure of the evaluation.

The FHWA agrees with the recommendation and the regulation was modified accordingly.

The Alaska DOT interprets the existing § 172.9(a)(5) for the conduct of consultant performance evaluations as optional per STA developed written procedures and requests that the proposed regulations not make consultant performance evaluations mandatory. Wyoming DOT also asserts that conducting performance evaluations is a new requirement.

The requirement to establish a written procedure to monitor a consultant's work and to prepare a consultant's performance evaluation at project completion is an existing regulatory requirement found in § 172.9(a)(5) and is a component of a sound oversight program required by 23 U.S.C. 106(g). The proposed regulations do not impose a new requirement. However, the regulation was revised to require a ''performance evaluation'' rather than an ''evaluation report'' to maintain the STA's discretion as to the structure of the evaluation.

The Nebraska DOR requested clarification and asserted that there is a current ''low threshold contract value of $30,000'' whereby contracts under that threshold do not require a performance evaluation.

The FAR cost principles set contracting procedures when the Federal Government acts as the contracting agency. Section 42.1502(f) of the FAR cost principles states that ''past performance evaluations shall be prepared for each architect-engineer services contract of $30,000 or more . . .'' In the case of the FAHP, the STA is recognized as the contracting agency. The FHWA regulations and policy do not currently provide a ''contract threshold'' for the requirement to conduct performance evaluations. Section 172.5(c) allows the STA to create performance evaluation materials, forms, and procedures that are commensurate with the scope, complexity and size of a contract. No change was made to the regulation.

§ 172.9(e)

The California DOT recommended adding a provision which states that a contract cannot be amended after the term of the contract has ended/expired.

This is a fundamental contract law issue for the States and not necessary for inclusion within the regulation. No change was made to the regulation.

§ 172.9(e)(4)

The IACE and the Wyoming DOT expressed concerns with the proposed regulation limiting the type of services and work allowed to be added to a contract. The IACE recommended that the provision be clarified to allow contractual supplements or additional necessary work items so long as they are germane to the contract and receive an appropriate level of review/approval by the public agency. The Wyoming DOT recommended eliminating this requirement to provide flexibility to STAs for unforeseen circumstances.

The addition of work not included in the advertised scope of services and evaluation criteria would be contrary to the intent of the competitive negotiation/qualifications based selection (Brooks Act) process to publicly announce all requirements and ensure qualified firms are provided a fair opportunity to compete and be considered to provide the prescribed services as specified in 23 U.S.C. 112(b)(2)(A) and 23 CFR 172.5(a)(1). No change was made to the regulation.

§ 172.9(f)

The AASHTO requests clarification of the intent of this section.

Section 172.9(f) is redundant and addressed in 23 CFR 140(e). The regulation was revised to delete this section in its entirety.

§ 172.11

The ASCE asserted that the proposed section attempts to establish the allowable costs that are reimbursable by FHWA to the STA for architectural and/or engineering nature services that are not directly connected to a project's actual construction and thus may conflict with the allocability requirements of 48 CFR 31.2.

The rule establishes that allowable costs shall be determined in accordance with the Federal cost principles in 48 CFR part 31. For consultants serving in a management support role which benefits more than a single Federal-aid project, the allocability of the consultant costs must be distributed consistent with the cost principles applicable to the contracting agency. The STAs with indirect cost allocation plans will be able to seek reimbursement of these indirect costs when properly allocated to all benefiting cost objectives. No change was made to the regulation.

The California DOT recommended referencing the 2012 AASHTO Audit Guide within the regulation.

The AASHTO Audit Guide is a guidance document based on statutory and regulatory requirements. Incorporation of the AASHTO Audit Guide within the regulation is not necessary and may create unintended consequences relating to guidance material contained within the Guide. No change was made to the regulation.

The SANDAG requested clarification that it may continue to perform post award audits in lieu of pre-award audits.

Section 172.11(b)(1)(iii)(C) permits contracting agencies to establish a provisional indirect cost rate for the specific contract and adjusting contract costs based upon an audited final audit at the completion of the contract. No change was made to the regulation.

§ 172.11(b)(1)

The Texas DOT asserted that this section requires an STA to accept indirect cost rates generated by a private entity and not actually reviewed or approved by any cognizant State or Federal agency in violation of Federal statute.

The proposed revision complies with Federal statute and requires the STA (or other grantee) to perform an evaluation to establish or accept an indirect cost rate to provide assurance of compliance with the Federal cost principles. No change was made to the regulation.

The New York State DOT stated that it believes negotiation of indirect cost rates should be permitted.

Section 112(b)(2) of Title 23, U.S.C. requires acceptance of consultant indirect cost rates established in accordance with the Federal cost principles for the applicable 1-year accounting period of the consultant. No change was made to the regulation.

Gannett Fleming, Inc. proposed incorporation of procedures found in 48 CFR 42.7 into 23 CFR 172.11 because consultants can also act in a Federal role on FAHP funded projects. Gannett Fleming also asserted that the proposed options for establishment of a consultant indirect cost rate when a

cognizant audit is not available conflicts with the single cognizant agency concept discussed in 48 CFR 72.703.

The recommended Federal statutory provisions apply to direct Federal contracting and have not been incorporated for application to the FAHP. No change was made to the regulation.

§ 172.11(b)(1)(i)

The Wyoming DOT stated that it does not believe an annual update of indirect cost rates is necessary, especially in instances where a consultant is not being considered for a new contract.

Section 112(b)(2)(C) of Title 23, U.S.C. requires establishment of consultant indirect cost rates in accordance with the Federal cost principles for the applicable 1-year accounting period of the consultant. As such, establishment on an annual basis is required. However, if it is mutually agreed to utilize the established indirect cost rate for the duration of a contract and a consultant is not being considered for work in subsequent years, the establishment of a new rate in subsequent years would not be necessary. No change was made to the regulation.

§ 172.11(b)(1)(ii)

The California DOT requested the regulation address circumstances where an established indirect cost rate is above an independent analysis of what is fair and reasonable and when negotiations can then proceed with the second highest ranked firm.

Reasonableness of the indirect cost rate is determined during the audit or other evaluation of the indirect cost rate. Under 23 U.S.C. 112(b)(2)(C), a rate developed in accordance with the Federal cost principles is not subject to negotiation. No change was made to the regulation.

The AASHTO asserted that requiring subconsultants to have an audited indirect cost rate puts an additional burden on both the subconsultant and the STA.

An audit is not required, but the contracting agency must perform an evaluation of a subconsultant's indirect cost rate when that cost rate has not been established by a cognizant agency. The evaluation provides assurance of consultant compliance with the Federal cost principles under part 31 of the FAR cost principles as required by 23 U.S.C. 112(b)(2)(B). No change was made to the regulation.

§ 172.11(b)(1)(iii)

The Ohio DOT recommended providing an exemption on establishing a FAR cost principles compliant indirect cost rate for firms providing non-engineering related support services or for small firms (*e.g.,* less than 20 employees).

Under 23 U.S.C. 112(b)(2)(B), use of the FAR cost principles for determination of allowable costs of ''for-profit'' entities is required. A cost analysis of individual elements of costs is still necessary for non-engineering services when price competition is lacking and the firm submits the cost breakdown of proposed services. No change was made to the regulation.

The North Dakota DOT and Montana DOT expressed concerns with the indirect cost rate requirements extending to subconsultants. The North Dakota DOT asserted that including subconsultants within the indirect cost rate requirements would require additional STA resources (time and staff) to evaluate subconsultant rates. The Montana DOT has established a minimum contract amount for requiring subconsultant audited rates. Montana DOT asserts that reviewing all subconsultant rates would require additional staff and may be difficult for small firms to pay for an audit.

While cognizant audit requirements were not previously prescribed for subconsultants, subconsultant costs must still comply with the Federal cost principles and reasonable assurance of compliance must be provided via some level of evaluation. The level of evaluation may be subject to a STAs risk based analysis in accordance with 23 CFR 172.11(c)(2). Additionally, subconsultants can perform a significant percentage of the work on a contract and may have a cognizant approved or otherwise accepted indirect cost rate. As such, it would not be prudent to limit or otherwise not apply the accepted rate based solely on the role as a subconsultant. No change was made to the regulation.

§ 172.11(b)(1)(iii)(A)

The Montana DOT recommended that generally accepted auditing standards other than generally accepted government auditing standards (GAGAS) be permitted for use in conducting audits of consultants. Montana DOT asserted that some STAs internal audit staff conduct audits of consultants and follow International Professional Practices Fieldwork Standards of Internal Auditing Standards.

Per accepted practice in the AASHTO Uniform Audit and Accounting Guide, AASHTO and ACEC agree that for an audit to be cognizant, it must be performed to test compliance with the Federal cost principle in accordance with GAGAS (Yellow Book). Additionally, 23 CFR 140.803 requires that project related audits must be performed in accordance with GAGAS for the agency audit related costs to be reimbursable under the FAHP. An audit performed by an STA not following GAGAS may still provide reasonable assurance of consultant compliance with the Federal cost principles in accordance with an STAs risk-based oversight process as specified in § 172.11(b)(1)(iii)(D) and (c)(2), but the audit could not be considered as cognizant and the associated agency audit costs would not be eligible for Federal reimbursement. No change was made to the regulation.

§ 172.11(b)(1)(iii)(B)

The ACEC requested that paragraph (b)(1)(iii)(B) be moved to precede paragraph (b)(1)(iii)(A) to provide some deference to FAR cost principles compliant CPA audits to encourage firms to obtain CPA audits and to discourage agencies from performing additional and unnecessary work. If paragraph (b)(1)(iii)(A) is then listed second, provide the following introductory clause, ''If another audit has not already been performed . . .''

Section 172.11(b)(1)(iii)(A)–(D) are not a hierarchy; they do not have to be taken in order. Subpart A through subpart D are options for the STA to consider when evaluating an indirect cost rate that has not been established by a cognizant agency. Using any single or combination of options would satisfy the provision. No change was made to the regulation.

§ 172.11(b)(1)(iii)(C)

The AASHTO asserted that this paragraph is too restrictive and recommended removal.

Use of a provisional indirect cost rate with adjusted final audit is an option for STA use. The STA is able to follow other evaluations in accordance with paragraph (b)(1)(iii)(D). No change was made to the regulation.

The California DOT suggested adding a clarification that the contract can be executed and work may commence with adjustment of the indirect cost rates at a later date as necessary.

Subject to a successful negotiation and acceptance of an indirect cost rate (including a provisional rate) any contract may be executed. No change was made to the regulation.

The California DOT requested clarification of the definition of ''final'' indirect cost rate and questioned whether the rate be ''reviewed'' rather than ''audited.''

The regulation states an audited final rate, but adding ''at the completion of the contract'' will clarify that this means an audit of the incurred indirect cost at the completion of the contract. The regulation was modified accordingly.

§ 172.11(b)(1)(iv)

The ACEC requested that the provision for acceptance of an indirect cost rate offered ''voluntarily'' by a consultant be deleted, as ACEC believes the existing provision is used by STAs and LPAs to pressure firms to negotiate lower overhead rates.

This is a provision in existing regulations that was substantiated in the 2002 Final Rule. The 2002 Final Rule noted there are many reasons an indirect cost rate of a firm may be unusually high for a short period of time and that a firm should be permitted to offer a lower rate. No change was made to the regulation.

§ 172.11(b)(1)(v)

The AASHTO asserted that requiring use of the actual indirect cost rate in negotiations and contract estimations makes the independent estimate less independent and assumes the rate is reasonable.

This is an existing statutory and regulatory requirement. Reasonableness of the indirect cost rate is determined by the evaluation of the rate in accordance with the Federal cost principles. No change was made to the regulation.

The ACEC requests clarification as to whether a rate ''accepted'' by an agency requires acceptance by all other agencies whether a cognizant audit or letter of concurrence is provided or not. The ACEC supports the interpretation that once accepted by an agency, the rate must also be accepted by other agencies.

The provision in question requires agencies to apply the rate free of an administrative or de facto ceiling. Subparagraphs (b)(1)(ii)–(iv) establish the process for acceptance of a consultant's indirect cost rate. Only rates established by a cognizant agency must be accepted for use and application by other agencies. No change was made to the regulation.

§ 172.11(b)(1)(vii)

The Oregon DOT asserted that STAs do not have staff to support disputes on cognizant rates and request clarification as to what level within the STA should a dispute resolution process be located.

The ''disputed rates'' section is an existing section to permit agencies the ability to not accept a cognizant rate if in dispute among the parties involved in performing the indirect cost rate audit. Procedures under § 172.5(c) require an agency to provide a general dispute resolution process for resolving disputes among the STA and consultants within the procurement, management, and administration process. There is no requirement for a full-time independent employee to handle disputes, and STAs are free to develop a process that fits with their organizational structure, as appropriate. No change was made to the regulation.

§ 172.11(b)(2)(ii)

The Virginia DOT, Idaho Transportation Department, and AASHTO requested clarification and details of what is acceptable and expected to establish salary benchmarks.

The reasonableness provisions of the FAR cost principles (as specified in 48 CFR 31.201–3 and 31.205–6(b)(2)) establish the expectations. No change was made to the regulation.

The Wyoming DOT asserted that while this would allow STAs the ability to negotiate direct salary rates based on an assessment of reasonableness, the process is likely too cumbersome for agency programs.

The STAs may limit or benchmark consulting firm direct salaries and wages if an assessment of reasonableness is performed in accordance with FAR cost principles (as specified in 48 CFR 31.201–3 and 31.205–6(b)(2)). If an assessment of reasonableness has not been performed, contracting agencies must use and apply the consulting firm's actual direct salary rates when negotiating or administering contracts or contract amendments. No change was made to the regulation.

§ 172.11(b)(2)(iii)

The Montana DOT and AASHTO opposed this provision and asserted that STAs would lose the ability to evaluate the reasonableness of the total cost of the proposed work since a consultant's actual indirect cost rate and actual direct salary rates would be utilized for estimation and negotiation.

In accordance with § 172.11(b)(2)(i)–(ii), the STA is to evaluate the reasonableness of the consultant's proposed direct salary rates in accordance with the reasonableness provisions of the FAR cost principles. In the absence of a reasonableness assessment to benchmark or limit rates, a consultant's actual rates must be used. Limitations or benchmarks on direct salary rates which do not consider the factors prescribed in the FAR cost principles are contrary to qualifications based selection procedures as specified in 23 U.S.C. 112(b)(2)(A) and 40 U.S.C. 1104(a), which require fair and reasonable compensation considering the scope, complexity, professional nature, and value of the services to be rendered. Additionally, if limitations or benchmarks on direct salary rates are too low, their use is likely to limit the number of consulting firms and the qualifications of the firms which submit proposals to perform work on projects. Furthermore, as a consulting firm's indirect cost rate is applied to direct labor costs, any direct labor limitations or benchmarks not supported by the FAR cost principles have the effect of creating an administrative or de facto ceiling on the indirect cost rate, contrary to FAHP requirements [as specified in 23 U.S.C. 112(b)(2)(D)]. No change was made to the regulation.

§ 172.11(b)(3)

The California DOT recommends specifying a range for fixed fee and incorporating the following Federal statutory provisions: 10 U.S.C. 2306(d) and 41 U.S.C. 254(b).

The recommended Federal statutory provisions apply to direct Federal contracting and have not been incorporated for application to the FAHP. No change was made to the regulation.

§ 172.11(b)(3)(ii)

The SANDAG requests clarification as to whether a grantee (recipient) may establish a fixed fee at the contract level in addition to the project or task order level.

A fixed fee may be established at the contract level. The regulation was modified to include clarification language.

§ 172.11(c)(2)

The Virginia DOT, Idaho Transportation Department, Wyoming DOT, and AASHTO expressed concerns with the requirements of this section. Virginia DOT asserted that the provisions for risk-based analysis are too prescriptive and burdensome. Idaho Transportation Department recommended using the phrase ''To the extent applicable, a risk-based oversight process shall . . . '' rather than ''A risk-based oversight process shall . . .'' which would require all of the listed items be included in a risk-based approach. Wyoming DOT asserted that requiring specific factors removes flexibility for STAs. The AASHTO asserted that the term ''shall'' is very prescriptive and does not allow the contracting agency any flexibility in developing the risk-based analysis.

Each of the factors proposed address a different area of risk and are consistent

with the AASHTO Uniform Audit & Accounting Guide and state of the practice. A STA's use of a risk-based oversight process is optional, but shall address the factors specified at a minimum. No change was made to the regulation.

§ 172.11(c)(2)(i)

The Indiana DOT, Idaho Transportation Department, and AASHTO expressed concerns about this section. Indiana DOT recommended that risk assessment factors (A)–(K) are listed for consideration and not be required for every consultant, every year. Idaho Transportation Department and AASHTO asserted that conducting an ''annual'' risk assessment of all consultants (and subconsultants) is burdensome and not reasonable.

Each of the factors proposed address a different area of risk and are consistent with the AASHTO Uniform Audit & Accounting Guide and state of the practice. An STA's use of a risk-based oversight process is optional, but shall address the factors specified at a minimum. Indirect costs are established for consultants on an annual basis and thus an annual assessment of risk is warranted. Only the consultants doing business with the STA (contracting) would need to have a risk assessment performed. No change was made to the regulation.

The Idaho Transportation Department and AASHTO asserted that the risk-based analysis process would not produce favorable responses for small and/or new firms and thus not allow the STAs to gain any efficiency.

Consultant contract volume is one of the identified factors for consideration. Small and/or new firms typically have a smaller volume of contracts and are generally lower dollar contracts. Additionally, the risk-based process will allow the STA to reduce time spent on larger, more established consultants with which the STA has familiarity in order to focus on other firms of higher risk. No change was made to the regulation.

§ 172.11(c)(2)(i)(B)

The AASHTO and Idaho Transportation Department asserted that a specific STA will not be concerned with the volume of work a consultant has in another State.

This factor is consistent with the AASHTO Uniform Audit & Accounting Guide. To reduce the duplication of effort in reviewing a consultant's compliance with the Federal cost principles, STAs should be aware of a consultant's workload in other States and can accept the review or evaluation performed by the other STAs. No change was made to the regulation.

§ 172.11(c)(2)(ii)(C)

The Oregon DOT requests clarification and examples of ''desk reviews'' or ''other analytical procedures.''

The level of analysis and evaluation performed by STAs under a ''desk review'' varies and has not been defined within the AASHTO Uniform Audit & Accounting Guide. As such, ''(C) Desk reviews;'' was removed from the provision. The evaluation and analysis performed by STAs under the label of ''desk review'' could be captured under ''Other analytical procedures.'' Additional information for ''other analytical procedures'' will be provided with implementing guidance, but an STA may define these procedures within its written policies and procedures for FHWA review and approval. The regulation was modified accordingly.

§ 172.11(c)(2)(ii)(F) [Re-Designated § 172.11(c)(2)(ii)(E)]

The Indiana DOT requested clarification on whether the ''Training on the Federal cost principles'' is directed to STA staff or consultant staff.

To provide reasonable assurance of consultant compliance with the Federal cost principles, a risk mitigation strategy could be to provide additional training to consultants and CPAs. The regulation was modified accordingly.

§ 172.11(c)(3)

The Wyoming DOT supported the addition of the Consultant Cost Certification requirement.

The Wyoming DOT's position is noted. No change was made to the regulation.

The Connecticut DOT is concerned that indirect cost rate certification is required with each response to an RFP or with each negotiation. The Connecticut DOT recommended that STAs be given the option of requiring consultant certification of final indirect costs either during the proposal preparation phase or once yearly through an audit.

The ''proposal'' referred to in the certification language is referring to the consultant's indirect cost rate proposal which is assumed to be provided to the STA once yearly as a part of an audit process and not necessarily with each response to a RFP or with each negotiation. No change was made to the regulation.

The Virginia DOT, Idaho Transportation Department, and AASHTO recommended that STAs be provided the flexibility to incorporate items important to that State within the Contractor Cost Certification.

In an effort to promote consistency and STA acceptance of audits conducted or reviewed by other STAs, it is essential a standard contractor cost certification be utilized. The STAs are free to require an additional STA specific certification to address areas of concern to the STA. No change was made to the regulation.

§ 172.11(c)(3)(i)

Gannett Fleming, Inc. asserted that the requirement is redundant for consultants that are Federal contractors. Gannett Fleming, Inc. proposed that the provision note inclusion of the cost certification with the indirect cost rate proposal submitted to the consultant's cognizant agency and reference 48 CFR 42.703–2, 10 U.S.C. 2324(h), and 41 U.S.C. 256(a).

The recommended Federal statutory provisions apply to direct Federal contracting and have not been incorporated for application to the FAHP. Additionally, a consultant cost certification is warranted even when a consultant's indirect cost rate proposal is not being audited or reviewed for cognizant approval or acceptance. No change was made to the regulation.

The ACEC requested that the certification be required on an annual basis rather than submit a certification for every project submission.

The FHWA agrees that only one certification submittal is necessary at the time the consultant's indirect cost rate proposal for its applicable 1-year accounting period is submitted for acceptance. Subparagraph (i) indicates that the certification requirement applies to all indirect cost rate proposals submitted for acceptance. Assuming the rate is submitted on an annual basis to the STA for acceptance, only one certification for that rate is necessary. No change was made to the regulation.

§ 172.11(c)(3)(i) and (ii)

The ACEC requested that an additional provision be added to clarify that a firm can only certify their own rate and is not responsible for or required to certify the rate of another firm (subconsultant).

The FHWA agrees with the comment. The regulation was modified to include clarification language.

§ 172.11(c)(4)

The Indiana DOT requested clarification on requirements for sanctions and penalties to include within written policies and contract documents.

The extent of sanctions and penalties are a matter of State laws, regulations, policies, and procedures. Although false claims, false statement, and suspension and debarment actions may be imposed at the Federal level, FHWA is not a party to the contract with the consultant and as such, any contract sanctions and penalties, except for those prosecutions brought under the False Claims Act are a matter for the STA. These provisions address incorporation of any sanctions and penalties within policies and contract documents, as appropriate. No change was made to the regulation.

The Wyoming DOT asserted that these requirements are very specific and entail additional work with limited benefit to the contracting agency.

Sanctions and penalties are fundamental contract administration functions and address recommendations from national audits/reviews. These regulations do not prescribe how sanctions and penalties are assessed and thus allow STAs flexibility in addressing these elements within their written policies and procedures. No change was made to the regulation.

One individual interpreted § 172.11(c)(4)(i) as a requirement for STAs to pursue sanctions and penalties against consultants who knowingly charge unallowable costs and asserts this would be a hardship on STA resources. The language ''as may be appropriate'' is of concern and needs clarification.

''As may be appropriate'' is a determination of the contracting agency and the range of sanction or penalties are a function of State law, regulation, policies, and procedures. The actions pursued by a contracting agency will be defined in agency written procedures as noted in §§ 172.11(c)(4), 172.5(c), and 172.9(c). No change was made to the regulation.

General Comments

The ACEC requested that current FHWA question and answer guidance regarding field indirect cost rates be incorporated into the regulation update.

Provisions regarding FHWA guidance on field indirect cost rates were not included within the NPRM, as the guidance is based on the Federal cost principles. The FHWA's guidance and interpretation of the Federal cost principles as it relates to home and field based indirect cost rates is still valid, but was not included as the Federal cost principles are subject to change. No change was made to the regulation.

The Nebraska DOR asked if ''testing services'' are considered engineering and design related services.

The FHWA question and answer guidance addresses this, but the answer depends on the specifics of the services in question and definition of engineering services in State law and regulation and their relationship to highway construction. No change was made to the regulation.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

The FHWA determined that this rule does not constitute a significant regulatory action within the meaning of Executive Order 12866 or within the meaning of DOT regulatory policies and procedures. The amendments clarify and revise requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. Additionally, this action complies with the principles of Executive Order 13563. The changes to part 172 provide additional clarification, guidance, and flexibility to stakeholders implementing these regulations. This rule is not anticipated to adversely affect, in any material way, any sector of the economy. In addition, these changes will not create a serious inconsistency with any other agency's action or materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. After evaluating the costs and benefits of these amendments, FHWA anticipates that the economic impact of this rule will be minimal; therefore, a full regulatory evaluation is not necessary.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Public Law 96–354, 5 U.S.C. 601–612), FHWA evaluated the effects of this rule on small entities, such as local governments and businesses. The FHWA determined that this action would not have a significant economic impact on a substantial number of small entities. The amendments clarify and revise requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. After evaluating the cost of these proposed amendments, as required by changes in authorizing legislation, other applicable regulations, and industry practices, FHWA has determined the projected impact upon small entities which utilize FAHP funding for consultant engineering and design related services would be negligible. Therefore, FHWA certifies that the rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Public Law 104–4, March 22, 1995, 109 Stat. 48). Furthermore, in compliance with the Unfunded Mandates Reform Act of 1995, FHWA evaluated this rule to assess the effects on State, local, and tribal governments and the private sector. This rule does not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $143.1 million or more in any one year (2 U.S.C. 1532). Additionally, the definition of ''Federal Mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The FAHP permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

This rule was analyzed in accordance with the principles and criteria contained in Executive Order 13132, dated August 4, 1999, and it was determined that this rule does not have a substantial direct effect or sufficient federalism implications on States that would limit the policymaking discretion of the States. Nothing in this rule directly preempts any State law or regulation or affects the States' ability to discharge traditional State governmental functions.

Paperwork Reduction Act

Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. This rule does not contain a collection of information requirement for the purpose of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

National Environmental Policy Act

The FHWA analyzed this rule for the purpose of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and determined that this action would not have any effect on the quality of the human and natural environment. This rule establishes the requirements for the

procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project.

Executive Order 13175 (Tribal Consultation)

The FHWA analyzed this rule under Executive Order 13175, dated November 6, 2000, and believes that this proposed action would not have substantial direct effects on one or more Indian tribes, would not impose substantial direct compliance costs on Indian tribal governments, and would not preempt tribal law. This rule establishes the requirements for the procurement, management, and administration of engineering and design related services using FAHP funding and directly related to a construction project. As such, this rule would not impose any direct compliance requirements on Indian tribal governments nor would it have any economic or other impacts on the viability of Indian tribes. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We determined that this proposed action would not be a significant energy action under that order because any action contemplated would not be likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, FHWA certifies that a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12630 (Taking of Private Property)

The FHWA analyzed this rule and determined that this proposed action would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

This action 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.

Executive Order 13045 (Protection of Children)

The FHWA analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, and certifies that this proposed action would not cause an environmental risk to health or safety that may disproportionately affect children.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned 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. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 172

Government procurement, Grant programs-transportation, Highways and roads.

Issued On: May 13, 2015.

Gregory G. Nadeau,

Deputy Administrator.

In consideration of the foregoing, FHWA revises part 172 of title 23, Code of Federal Regulations, to read as follows:

PART 172—PROCUREMENT, MANAGEMENT, AND ADMINISTRATION OF ENGINEERING AND DESIGN RELATED SERVICES

Sec.
172.1 Purpose and applicability.
172.3 Definitions.
172.5 Program management and oversight.
172.7 Procurement methods and procedures.
172.9 Contracts and administration.
172.11 Allowable costs and oversight.

Authority: 23 U.S.C. 106, 112, 114(a), 302, 315, and 402; 40 U.S.C. 1101 *et seq.;* 48 CFR part 31; 49 CFR 1.48(b); and 2 CFR part 200.

§ 172.1 Purpose and applicability.

This part prescribes the requirements for the procurement, management, and administration of engineering and design related services under 23 U.S.C. 112 and as supplemented by the Uniform Administrative Requirements For Federal Awards rule. The Uniform Administrative Requirements, Cost Principles and Audit Requirements For Federal Awards rule (2 CFR part 200) shall apply except where inconsistent with the requirements of this part and other laws and regulations applicable to the Federal-aid highway program (FAHP). The requirements herein apply to federally funded contracts for engineering and design related services for projects subject to the provisions of 23 U.S.C. 112(a) (related to construction) and are issued to ensure that a qualified consultant is obtained through an equitable qualifications-based selection procurement process, that prescribed work is properly accomplished in a timely manner, and at fair and reasonable cost. State transportation agencies (STA) (or other recipients) shall ensure that subrecipients comply with the requirements of this part and the Uniform Administrative Requirements, Cost Principles and Audit Requirements For Federal Awards rule. Federally funded contracts for services not defined as engineering and design related, or for services not in furtherance of a highway construction project or activity subject to the provisions of 23 U.S.C. 112(a), are not subject to the requirements of this part and shall be procured and administered under the requirements of the Uniform Administrative Requirements, Cost Principles and Audit Requirements For Federal Awards rule and procedures applicable to such activities.

§ 172.3 Definitions.

As used in this part:

Audit means a formal examination, in accordance with professional standards, of a consultant's accounting systems, incurred cost records, and other cost presentations to test the reasonableness, allowability, and allocability of costs in accordance with the Federal cost principles (as specified in 48 CFR part 31).

Cognizant agency means any governmental agency that has performed an audit in accordance with generally accepted government auditing standards to test compliance with the requirements of the Federal cost principles (as specified in 48 CFR part 31) and issued an audit report of the consultant's indirect cost rate, or any described agency that has conducted a review of an audit report and related workpapers prepared by a certified public accountant and issued a letter of concurrence with the audited indirect cost rate(s). A cognizant agency may be any of the following:

(1) A Federal agency;

(2) A State transportation agency of the State where the consultant's accounting and financial records are located; or

(3) A State transportation agency to which cognizance for the particular indirect cost rate(s) of a consulting firm has been delegated or transferred in writing by the State transportation

agency identified in paragraph (2) of this definition.

Competitive negotiation means qualifications-based selection procurement procedures complying with 40 U.S.C. 1101–1104, commonly referred to as the Brooks Act.

Consultant means the individual or firm providing engineering and design related services as a party to a contract with a recipient or subrecipient of Federal assistance (as defined in 2 CFR 200.86 or 2 CFR 200.93, respectively).

Contract means a written procurement contract or agreement between a contracting agency and consultant reimbursed under a FAHP grant or subgrant and includes any procurement subcontract under a contract.

Contracting agencies means a State transportation agency or a procuring agency of the State acting in conjunction with and at the direction of the State transportation agency, other recipients, and all subrecipients that are responsible for the procurement, management, and administration of engineering and design related services.

Contract modification means an agreement modifying the terms or conditions of an original or existing contract.

Engineering and design related services means:

(1) Program management, construction management, feasibility studies, preliminary engineering, design engineering, surveying, mapping, or architectural related services with respect to a highway construction project subject to 23 U.S.C. 112(a) as defined in 23 U.S.C. 112(b)(2)(A); and

(2) Professional services of an architectural or engineering nature, as defined by State law, which are required to or may logically or justifiably be performed or approved by a person licensed, registered, or certified to provide the services with respect to a highway construction project subject to 23 U.S.C. 112(a) and as defined in 40 U.S.C. 1102(2).

Federal cost principles means the cost principles contained in 48 CFR part 31 of the Federal Acquisition Regulation for determination of allowable costs of commercial, for-profit entities.

Fixed fee means a sum expressed in U.S. dollars established to cover the consultant's profit and other business expenses not allowable or otherwise included as a direct or indirect cost.

Management support role means performing engineering management services or other services acting on the contracting agency's behalf, which are subject to review and oversight by agency officials, such as a program or project administration role typically performed by the contracting agency and necessary to fulfill the duties imposed by title 23 of the United States Code, other Federal and State laws, and applicable regulations.

Noncompetitive means the method of procurement of engineering and design related services when it is not feasible to award the contract using competitive negotiation or small purchase procurement methods.

One-year applicable accounting period means the annual accounting period for which financial statements are regularly prepared by the consultant.

Scope of work means all services, work activities, and actions required of the consultant by the obligations of the contract.

Small purchases means the method of procurement of engineering and design related services where an adequate number of qualified sources are reviewed and the total contract costs do not exceed an established simplified acquisition threshold.

State transportation agency (STA) means that department or agency maintained in conformity with 23 U.S.C. 302 and charged under State law with the responsibility for highway construction (as defined in 23 U.S.C. 101); and that is authorized by the laws of the State to make final decisions in all matters relating to, and to enter into, all contracts and agreements for projects and activities to fulfill the duties imposed by title 23 United States Code, title 23 Code of Federal Regulations, and other applicable Federal laws and regulations.

Subconsultant means the individual or firm contracted by a consultant to provide engineering and design related or other types of services that are part of the services which the consultant is under contract to provide to a recipient (as defined in 23 CFR 200.86) or subrecipient (as defined in 2 CFR 200.93) of Federal assistance.

§ 172.5 Program management and oversight.

(a) *STA responsibilities.* STAs or other recipients shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding, as specified in 23 U.S.C. 302(a). Responsibilities shall include the following:

(1) Preparing and maintaining written policies and procedures for the procurement, management, and administration of engineering and design related consultant services in accordance with paragraph (c) of this section;

(2) Establishing a procedure for estimating the level of effort, schedule, and costs of needed consultant services and associated agency staffing and resources for management and oversight in support of project authorization requests submitted to FHWA for approval, as specified in 23 CFR 630.106;

(3) Procuring, managing, and administering engineering and design related consultant services in accordance with applicable Federal and State laws, regulations, and approved policies and procedures, as specified in 23 CFR 1.9(a); and

(4) Administering subawards in accordance with State laws and procedures as specified in 2 CFR part 1201, and the requirements of 23 U.S.C. 106(g)(4), and 2 CFR 200.331. Administering subawards includes providing oversight of the procurement, management, and administration of engineering and design related consultant services by subrecipients to ensure compliance with applicable Federal and State laws and regulations. Nothing in this part shall be taken as relieving the STA (or other recipient) of its responsibility under laws and regulations applicable to the FAHP for the work performed under any consultant agreement or contract entered into by a subrecipient.

(b) *Subrecipient responsibilities.* Subrecipients shall develop and sustain organizational capacity and provide the resources necessary for the procurement, management, and administration of engineering and design related consultant services, reimbursed in whole or in part with FAHP funding as specified in 23 U.S.C. 106(g)(4)(A). Responsibilities shall include the following:

(1) Adopting written policies and procedures prescribed by the awarding STA or other recipient for the procurement, management, and administration of engineering and design related consultant services in accordance with applicable Federal and State laws and regulations; or when not prescribed, shall include:

(i) Preparing and maintaining its own written policies and procedures in accordance with paragraph (c) of this section; or

(ii) Submitting documentation associated with each procurement and subsequent contract to the awarding STA or other grantee for review to assess compliance with applicable Federal and State laws, regulations, and the requirements of this part;

(2) Procuring, managing, and administering engineering and design related consultant services in accordance with applicable Federal and State laws, regulations, and approved policies and procedures, as specified in 23 CFR 1.9(a).

(c) *Written policies and procedures.* The contracting agency shall prepare and maintain written policies and procedures for the procurement, management, and administration of engineering and design related consultant services. The FHWA shall approve the written policies and procedures, including all revisions to such policies and procedures, of the STA or recipient to assess compliance with applicable requirements. The STA or other recipient shall approve the written policies and procedures, including all revisions to such policies and procedures, of a subrecipient to assess compliance with applicable requirements. These policies and procedures shall address, as appropriate for each method of procurement a contracting agency proposes to use, the following items to ensure compliance with Federal and State laws, regulations, and the requirements of this part:

(1) Preparing a scope of work and evaluation factors for the ranking/selection of a consultant;

(2) Soliciting interests, qualifications, or proposals from prospective consultants;

(3) Preventing, identifying, and mitigating conflicts of interest for employees of both the contracting agency and consultants and promptly disclosing in writing any potential conflict to the STA and FHWA, as specified in 2 CFR 200.112 and 23 CFR 1.33, and the requirements of this part.

(4) Verifying suspension and debarment actions and eligibility of consultants, as specified in 2 CFR part 1200 and 2 CFR part 180;

(5) Evaluating interests, qualifications, or proposals and the ranking/selection of a consultant;

(6) Determining, based upon State procedures and the size and complexity of a project, the need for additional discussions following RFP submission and evaluation;

(7) Preparing an independent agency estimate for use in negotiation with the selected consultant;

(8) Selecting appropriate contract type, payment method, and terms and incorporating required contract provisions, assurances, and certifications in accordance with § 172.9;

(9) Negotiating a contract with the selected consultant including instructions for proper disposal of concealed cost proposals of unsuccessful bidders;

(10) Establishing elements of contract costs, accepting indirect cost rate(s) for application to contracts, and assuring consultant compliance with the Federal cost principles in accordance with § 172.11;

(11) Ensuring consultant costs billed are allowable in accordance with the Federal cost principles and consistent with the contract terms as well as the acceptability and progress of the consultant's work;

(12) Monitoring the consultant's work and compliance with the terms, conditions, and specifications of the contract;

(13) Preparing a consultant's performance evaluation when services are completed and using such performance data in future evaluation and ranking of consultant to provide similar services;

(14) Closing-out a contract;

(15) Retaining supporting programmatic and contract records, as specified in 2 CFR 200.333 and the requirements of this part;

(16) Determining the extent to which the consultant, which is responsible for the professional quality, technical accuracy, and coordination of services, may be reasonably liable for costs resulting from errors and omissions in the work furnished under its contract;

(17) Assessing administrative, contractual, or legal remedies in instances where consultants violate or breach contract terms and conditions, and providing for such sanctions and penalties as may be appropriate; and

(18) Resolving disputes in the procurement, management, and administration of engineering and design related consultant services.

(d) A contracting agency may formally adopt, by statute or within approved written policies and procedures as specified in paragraph (c) of this section, any direct Federal Government or other contracting regulation, standard, or procedure provided its application does not conflict with the provisions of 23 U.S.C. 112, the requirements of this part, and other laws and regulations applicable to the FAHP.

(e) Notwithstanding paragraph (d) of this section, a contracting agency shall have a reasonable period of time, not to exceed 12 months from the effective date of this rule unless an extension is granted for unique or extenuating circumstances, to issue or update current written policies and procedures for review and approval in accordance with paragraph (c) of this section and consistent with the requirements of this part.

§ 172.7 Procurement methods and procedures.

(a) *Procurement methods.* The procurement of engineering and design related services funded by FAHP funds and related to a highway construction project subject to the provisions of 23 U.S.C. 112(a) shall be conducted in accordance with one of three methods: Competitive negotiation (qualifications-based selection) procurement, small purchases procurement for small dollar value contracts, and noncompetitive procurement where specific conditions exist allowing solicitation and negotiation to take place with a single consultant.

(1) *Competitive negotiation (qualifications-based selection).* Except as provided in paragraphs (a)(2) and (3) of this section, contracting agencies shall use the competitive negotiation method for the procurement of engineering and design related services when FAHP funds are involved in the contract, as specified in 23 U.S.C. 112(b)(2)(A). The solicitation, evaluation, ranking, selection, and negotiation shall comply with the qualifications-based selection procurement procedures for architectural and engineering services codified under 40 U.S.C. 1101–1104, commonly referred to as the Brooks Act. In accordance with the requirements of the Brooks Act, the following procedures shall apply to the competitive negotiation procurement method:

(i) *Solicitation.* The solicitation process shall be by public announcement, public advertisement, or any other public forum or method that assures qualified in-State and out-of-State consultants are given a fair opportunity to be considered for award of the contract. Procurement procedures may involve a single step process with issuance of a request for proposal (RFP) to all interested consultants or a multiphase process with issuance of a request for statements or letters of interest or qualifications (RFQ) whereby responding consultants are ranked based on qualifications and a RFP is then provided to three or more of the most highly qualified consultants. Minimum qualifications of consultants to perform services under general work categories or areas of expertise may also be assessed through a prequalification process whereby annual statements of qualifications and performance data are encouraged. Regardless of any process utilized for prequalification of consultants or for an initial assessment

of a consultant's qualifications under a RFQ, a RFP specific to the project, task, or service is required for evaluation of a consultant's specific technical approach and qualifications.

(ii) *Request for proposal (RFP).* The RFP shall provide all information and requirements necessary for interested consultants to provide a response to the RFP and compete for the solicited services. The RFP shall:

(A) Provide a clear, accurate, and detailed description of the scope of work, technical requirements, and qualifications of consultants necessary for the services to be rendered. To the extent practicable, the scope of work should detail the purpose and description of the project, services to be performed, deliverables to be provided, estimated schedule for performance of the work, and applicable standards, specifications, and policies;

(B) Identify the requirements for any discussions that may be conducted with three or more of the most highly qualified consultants following submission and evaluation of proposals;

(C) Identify evaluation factors including their relative weight of importance in accordance with paragraph (a)(1)(iii) of this section;

(D) Specify the contract type and method(s) of payment anticipated to contract for the solicited services in accordance with § 172.9;

(E) Identify any special provisions or contract requirements associated with the solicited services;

(F) Require that submission of any requested cost proposals or elements of cost be in a concealed format and separate from technical/qualifications proposals, since these shall not be considered in the evaluation, ranking, and selection phase; and

(G) Provide an estimated schedule for the procurement process and establish a submittal deadline for responses to the RFP that provides sufficient time for interested consultants to receive notice, prepare, and submit a proposal, which except in unusual circumstances shall be not less than 14 calendar days from the date of issuance of the RFP.

(iii) *Evaluation factors.* (A) Criteria used for evaluation, ranking, and selection of consultants to perform engineering and design related services must assess the demonstrated competence and qualifications for the type of professional services solicited. These qualifications-based factors may include, but are not limited to, technical approach (*e.g.,* project understanding, innovative concepts or alternatives, quality control procedures), work experience, specialized expertise, professional licensure, staff capabilities, workload capacity, and past performance.

(B) Price shall not be used as a factor in the evaluation, ranking, and selection phase. All price or cost related items which include, but are not limited to, cost proposals, direct salaries/wage rates, indirect cost rates, and other direct costs are prohibited from being used as evaluation criteria.

(C) In-State or local preference shall not be used as a factor in the evaluation, ranking, and selection phase. State licensing laws are not preempted by this provision and professional licensure within a jurisdiction may be established as a requirement for the minimum qualifications and competence of a consultant to perform the solicited services.

(D) The following nonqualifications-based evaluation criteria are permitted under the specified conditions and provided the combined total of these criteria do not exceed a nominal value of 10 percent of the total evaluation criteria to maintain the integrity of a qualifications-based selection:

(*1*) A local presence may be used as a nominal evaluation factor where appropriate. This criteria shall not be based on political or jurisdictional boundaries and may be applied on a project-by-project basis for contracts where a need has been established for a consultant to provide a local presence, a local presence will add value to the quality and efficiency of the project, and application of this criteria leaves an appropriate number of qualified consultants, given the nature and size of the project. If a consultant from outside of the locality area indicates as part of a proposal that it will satisfy the criteria in some manner, such as establishing a local project office, that commitment shall be considered to have satisfied the local presence criteria.

(*2*) The participation of qualified and certified Disadvantaged Business Enterprise (DBE) subconsultants may be used as a nominal evaluation criterion where appropriate in accordance with 49 CFR part 26 and a contracting agency's FHWA-approved DBE program.

(iv) *Evaluation, ranking, and selection.* (A) The contracting agency shall evaluate consultant proposals based on the criteria established and published within the public solicitation.

(B) Although the contract will be with the consultant, proposal evaluations shall consider the qualifications of the consultant and any subconsultants identified within the proposal with respect to the scope of work and established criteria.

(C) The contracting agency shall specify in the RFP discussion requirements that shall follow submission and evaluation of proposals and based on the size and complexity of the project or as defined in contracting agency written policies and procedures, as specified in § 172.5(c). Discussions, as required by the RFP, may be written, by telephone, video conference, or by oral presentation/interview and shall be with at least three of the most highly qualified consultants to clarify the technical approach, qualifications, and capabilities provided in response to the RFP.

(D) From the proposal evaluation and any subsequent discussions which may have been conducted, the contracting agency shall rank, in order of preference, at least three consultants determined most highly qualified to perform the solicited services based on the established and published criteria. In instances where only two qualified consultants respond to the solicitation, the contracting agency may proceed with evaluation and selection if it is determined that the solicitation did not contain conditions or requirements that arbitrarily limited competition. Alternatively, a contracting agency may pursue procurement following the noncompetitive method when competition is determined to be inadequate and it is determined to not be feasible or practical to re-compete under a new solicitation as specified in paragraph (a)(3)(iii)(C) of this section.

(E) Notification must be provided to responding consultants of the final ranking of the three most highly qualified consultants.

(F) The contracting agency shall retain supporting documentation of the solicitation, proposal, evaluation, and selection of the consultant in accordance with this section and the provisions of 2 CFR 200.333.

(v) *Negotiation.* (A) The process for negotiation of the contract shall comply with the requirements codified in 40 U.S.C. 1104(b) for the order of negotiation.

(B) *Independent estimate.* Prior to receipt or review of the most highly qualified consultant's cost proposal, the contracting agency shall prepare a detailed independent estimate with an appropriate breakdown of the work or labor hours, types or classifications of labor required, other direct costs, and consultant's fixed fee for the defined scope of work. The independent estimate shall serve as the basis for negotiation.

(C) The contracting agency shall establish elements of contract costs (*e.g.,* indirect cost rates, direct salary or wage rates, fixed fee, and other direct costs) separately in accordance with § 172.11.

The use of the independent estimate and determination of cost allowance in accordance with § 172.11 shall ensure contracts for the consultant services are obtained at a fair and reasonable cost, as specified in 40 U.S.C. 1104(a).

(D) If concealed cost proposals were submitted in conjunction with technical/qualifications proposals, the contracting agency may consider only the cost proposal of the consultant with which negotiations are initiated. Due to the confidential nature of this data, as specified in 23 U.S.C. 112(b)(2)(E), concealed cost proposals of unsuccessful consultants may be disposed of in accordance with written policies and procedures established under § 172.5(c).

(E) The contracting agency shall retain documentation of negotiation activities and resources used in the analysis of costs to establish elements of the contract in accordance with the provisions of 2 CFR 200.333. This documentation shall include the consultant cost certification and documentation supporting the acceptance of the indirect cost rate to be applied to the contract, as specified in § 172.11(c).

(2) *Small purchases.* The contracting agency may use the State's small purchase procedures that reflect applicable State laws and regulations for the procurement of engineering and design related services provided the total contract costs do not exceed the Federal simplified acquisition threshold (as defined in 48 CFR 2.101). When a lower threshold for use of small purchase procedures is established in State law, regulation, or policy, the lower threshold shall apply to the use of FAHP funds. The following additional requirements shall apply to the small purchase procurement method:

(i) The scope of work, project phases, and contract requirements shall not be broken down into smaller components merely to permit the use of small purchase procedures.

(ii) A minimum of three consultants are required to satisfy the adequate number of qualified sources reviewed. In instances where only two qualified consultants respond to the solicitation, the contracting agency may proceed with evaluation and selection if it is determined that the solicitation did not contain conditions or requirements which arbitrarily limited competition. Alternatively, a contracting agency may pursue procurement following the noncompetitive method when competition is determined to be inadequate and it is determined to not be feasible or practical to re compete under a new solicitation as specified in § 172.7(a)(3)(iii)(C).

(iii) Contract costs may be negotiated in accordance with State small purchase procedures; however, the allowability of costs shall be determined in accordance with the Federal cost principles.

(iv) The full amount of any contract modification or amendment that would cause the total contract amount to exceed the established simplified acquisition threshold is ineligible for Federal-aid funding. The FHWA may withdraw all Federal-aid from a contract if it is modified or amended above the applicable established simplified acquisition threshold.

(3) *Noncompetitive.* The following requirements shall apply to the noncompetitive procurement method:

(i) A contracting agency may use its own noncompetitive procedures that reflect applicable State and local laws and regulations and conform to applicable Federal requirements.

(ii) A contracting agency shall establish a process to determine when noncompetitive procedures will be used and shall submit justification to, and receive approval from FHWA before using this form of contracting.

(iii) A contracting agency may award a contract by noncompetitive procedures under the following limited circumstances:

(A) The service is available only from a single source;

(B) There is an emergency which will not permit the time necessary to conduct competitive negotiations; or

(C) After solicitation of a number of sources, competition is determined to be inadequate.

(iv) Contract costs may be negotiated in accordance with contracting agency noncompetitive procedures; however, the allowability of costs shall be determined in accordance with the Federal cost principles.

(b) *Additional procurement requirements*—(1) *Uniform administrative requirements, cost principles and audit requirements for Federal awards.* (i) STAs or other recipients and their subrecipients shall comply with procurement requirements established in State and local laws, regulations, policies, and procedures that are not addressed by or are not in conflict with applicable Federal laws and regulations, as specified in 2 CFR part 1201.

(ii) When State and local procurement laws, regulations, policies, or procedures are in conflict with applicable Federal laws and regulations, a contracting agency shall comply with Federal requirements to be eligible for Federal-aid reimbursement of the associated costs of the services incurred following FHWA authorization, as specified in 2 CFR 200.102(c).

(2) *Disadvantaged Business Enterprise (DBE) program.* (i) A contracting agency shall give consideration to DBE consultants in the procurement of engineering and design related service contracts subject to 23 U.S.C. 112(b)(2) in accordance with 49 CFR part 26. When DBE program participation goals cannot be met through race-neutral measures, additional DBE participation on engineering and design related services contracts may be achieved in accordance with a contracting agency's FHWA approved DBE program through either:

(A) Use of an evaluation criterion in the qualifications-based selection of consultants, as specified in § 172.7(a)(1)(iii)(D); or

(B) Establishment of a contract participation goal.

(ii) The use of quotas or exclusive set-asides for DBE consultants is prohibited, as specified in 49 CFR 26.43.

(3) *Suspension and debarment.* A contracting agency shall verify suspension and debarment actions and eligibility status of consultants and subconsultants prior to entering into an agreement or contract in accordance with 2 CFR part 1200 and 2 CFR part 180.

(4) *Conflicts of interest.* (i) A contracting agency shall maintain a written code of standards of conduct governing the performance of their employees engaged in the award and administration of engineering and design related services contracts under this part and governing the conduct and roles of consultants in the performance of services under such contracts to prevent, identify, and mitigate conflicts of interest in accordance with 2 CFR 200.112, 23 CFR 1.33 and the provisions of this paragraph (b)(4).

(ii) No employee, officer, or agent of the contracting agency shall participate in selection, or in the award or administration of a contract supported by Federal-aid funds if a conflict of interest, real or apparent, would be involved. Such a conflict arises when there is a financial or other interest in the consultant selected for award by:

(A) The employee, officer, or agent;

(B) Any member of his or her immediate family;

(C) His or her partner; or

(D) An organization that employs or is about to employ any of the above.

(iii) The contracting agency's officers, employees, or agents shall neither solicit nor accept gratuities, favors, or anything of monetary value from consultants, potential consultants, or

parties to subagreements. A contracting agency may establish dollar thresholds where the financial interest is not substantial or the gift is an unsolicited item of nominal value.

(iv) A contracting agency may provide additional prohibitions relative to real, apparent, or potential conflicts of interest.

(v) To the extent permitted by State or local law or regulations, the standards of conduct required by this paragraph shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the contracting agency's officers, employees, or agents, or by consultants or their agents.

(vi) A contracting agency shall promptly disclose in writing any potential conflict of interest to FHWA.

(5) *Consultant services in management support roles.* (i) When FAHP funds participate in a consultant services contract, the contracting agency shall receive approval from FHWA, or the recipient as appropriate, before utilizing a consultant to act in a management support role for the contracting agency; unless an alternate approval procedure has been approved. Use of consultants in management support roles does not relieve the contracting agency of responsibilities associated with the use of FAHP funds, as specified in 23 U.S.C. 302(a) and 23 U.S.C. 106(g)(4) and should be limited to large projects or circumstances where unusual cost or time constraints exist, unique technical or managerial expertise is required, and/or an increase in contracting agency staff is not a viable option.

(ii) Management support roles may include, but are not limited to, providing oversight of an element of a highway program, function, or service on behalf of the contracting agency or may involve managing or providing oversight of a project, series of projects, or the work of other consultants and contractors on behalf of the contracting agency. Contracting agency written policies and procedures as specified in § 172.5(c) may further define allowable management roles and services a consultant may provide, specific approval responsibilities, and associated controls necessary to ensure compliance with Federal requirements.

(iii) Use of consultants or subconsultants in management support roles requires appropriate conflicts of interest standards as specified in paragraph (b)(4) of this section and adequate contracting agency staffing to administer and monitor the management consultant contract, as specified in § 172.9(d). A consultant serving in a management support role may be precluded from providing additional services on projects, activities, or contracts under its oversight due to potential conflicts of interest.

(iv) FAHP funds shall not participate in the costs of a consultant serving in a management support role where the consultant was not procured in accordance with Federal and State requirements, as specified in 23 CFR 1.9(a).

(v) Where benefiting more than a single Federal-aid project, allocability of consultant contract costs for services related to a management support role shall be distributed consistent with the cost principles applicable to the contracting agency, as specified in 2 CFR part 200, subpart E—Cost Principles.

§ 172.9 Contracts and administration.

(a) *Contract types.* The contracting agency shall use the following types of contracts:

(1) *Project-specific.* A contract between the contracting agency and consultant for the performance of services and defined scope of work related to a specific project or projects.

(2) *Multiphase.* A project-specific contract where the solicited services are divided into phases whereby the specific scope of work and associated costs may be negotiated and authorized by phase as the project progresses.

(3) *On-call or indefinite delivery/indefinite quantity (IDIQ).* A contract for the performance of services for a number of projects, under task or work orders issued on an as-needed or on-call basis, for an established contract period. The procurement of services to be performed under on-call or IDIQ contracts shall follow either competitive negotiation or small purchase procurement procedures, as specified in § 172.7. The solicitation and contract provisions shall address the following requirements:

(i) Specify a reasonable maximum length of contract period, including the number and period of any allowable contract extensions, which shall not exceed 5 years;

(ii) Specify a maximum total contract dollar amount that may be awarded under a contract;

(iii) Include a statement of work, requirements, specifications, or other description to define the general scope, complexity, and professional nature of the services; and

(iv) If multiple consultants are to be selected and multiple on-call or IDIQ contracts awarded through a single solicitation for specific services:

(A) Identify the number of consultants that may be selected or contracts that may be awarded from the solicitation; and

(B) Specify the procedures the contracting agency will use in competing and awarding task or work orders among the selected, qualified consultants. Task or work orders shall not be competed and awarded among the selected, qualified consultants on the basis of costs under on-call or IDIQ contracts for services procured with competitive negotiation procedures. Under competitive negotiation procurement, each specific task or work order shall be awarded to the selected, qualified consultants:

(*1*) Through an additional qualifications-based selection procedure, which may include, but does not require, a formal RFP in accordance with § 172.5(a)(1)(ii); or

(*2*) On a regional basis whereby the State is divided into regions and consultants are selected to provide on-call or IDIQ services for an assigned region(s) identified within the solicitation.

(b) *Payment methods.* (1) The method of payment to the consultant shall be set forth in the original solicitation, contract, and in any contract modification thereto. The methods of payment shall be: Lump sum, cost plus fixed fee, cost per unit of work, or specific rates of compensation. A single contract may contain different payment methods as appropriate for compensation of different elements of work.

(2) The cost plus a percentage of cost and percentage of construction cost methods of payment shall not be used.

(3) The lump sum payment method shall only be used when the contracting agency has established the extent, scope, complexity, character, and duration of the work to be required to a degree that fair and reasonable compensation, including a fixed fee, can be determined at the time of negotiation.

(4) When the method of payment is other than lump sum, the contract shall specify a maximum amount payable which shall not be exceeded unless adjusted by a contract modification.

(5) The specific rates of compensation payment method provides for reimbursement on the basis of direct labor hours at specified fixed hourly rates, including direct labor costs, indirect costs, and fee or profit, plus any other direct expenses or costs, subject to an agreement maximum amount. This payment method shall only be used when it is not possible at the time of procurement to estimate the extent or duration of the work or to estimate costs

with any reasonable degree of accuracy. This specific rates of compensation payment method should be limited to contracts or components of contracts for specialized or support type services where the consultant is not in direct control of the number of hours worked, such as construction engineering and inspection. When using this payment method, the contracting agency shall manage and monitor the consultant's level of effort and classification of employees used to perform the contracted services.

(6) A contracting agency may withhold retainage from payments in accordance with prompt pay requirements, as specified in 49 CFR 26.29. When retainage is used, the terms and conditions of the contract shall clearly define agency requirements, including periodic reduction in retention and the conditions for release of retention.

(c) *Contract provisions.* (1) All contracts and subcontracts shall include the following provisions, either by reference or by physical incorporation into the language of each contract or subcontract, as applicable:

(i) Administrative, contractual, or legal remedies in instances where consultants violate or breach contract terms and conditions, and provide for such sanctions and penalties as may be appropriate;

(ii) Notice of contracting agency requirements and regulations pertaining to reporting;

(iii) Contracting agency requirements and regulations pertaining to copyrights and rights in data;

(iv) Access by recipient, the subrecipient, FHWA, the U.S. Department of Transportation's Inspector General, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the consultant which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions;

(v) Retention of all required records for not less than 3 years after the contracting agency makes final payment and all other pending matters are closed;

(vi) Standard DOT Title VI Assurances (DOT Order 1050.2);

(vii) Disadvantaged Business Enterprise (DBE) assurance, as specified in 49 CFR 26.13(b);

(viii) Prompt pay requirements, as specified in 49 CFR 26.29;

(ix) Determination of allowable costs in accordance with the Federal cost principles;

(x) Contracting agency requirements pertaining to consultant errors and omissions;

(xi) Contracting agency requirements pertaining to conflicts of interest, as specified in 23 CFR 1.33 and the requirements of this part; and

(xii) A provision for termination for cause and termination for convenience by the contracting agency including the manner by which it will be effected and the basis for settlement.

(2) All contracts and subcontracts exceeding $100,000 shall contain, either by reference or by physical incorporation into the language of each contract, a provision for lobbying certification and disclosure, as specified in 49 CFR part 20.

(d) *Contract administration and monitoring*—(1) *Responsible charge.* A full-time, public employee of the contracting agency qualified to ensure that the work delivered under contract is complete, accurate, and consistent with the terms, conditions, and specifications of the contract shall be in responsible charge of each contract or project. While an independent consultant may be procured to serve in a program or project management support role, as specified in § 172.7(b)(5), or to provide technical assistance in review and acceptance of engineering and design related services performed and products developed by other consultants, the contracting agency shall designate a public employee as being in responsible charge. A public employee may serve in responsible charge of multiple projects and contracting agencies may use multiple public employees to fulfill monitoring responsibilities. The term responsible charge is intended to be applied only in the context defined within this regulation. It may or may not correspond to its usage in State laws regulating the licensure and/or conduct of professional engineers. The public employee's responsibilities shall include:

(i) Administering inherently governmental activities including, but not limited to, contract negotiation, contract payment, and evaluation of compliance, performance, and quality of services provided by consultant;

(ii) Being familiar with the contract requirements, scope of services to be performed, and products to be produced by the consultant;

(iii) Being familiar with the qualifications and responsibilities of the consultant's staff and evaluating any requested changes in key personnel;

(iv) Scheduling and attending progress and project review meetings, commensurate with the magnitude, complexity, and type of work, to ensure the work is progressing in accordance with established scope of work and schedule milestones;

(v) Ensuring consultant costs billed are allowable in accordance with the Federal cost principles and consistent with the contract terms as well as the acceptability and progress of the consultant's work;

(vi) Evaluating and participating in decisions for contract modifications; and

(vii) Documenting contract monitoring activities and maintaining supporting contract records, as specified in 2 CFR 200.333.

(2) *Performance evaluation.* The contracting agency shall prepare an evaluation summarizing the consultant's performance on a contract. The performance evaluation should include, but not be limited to, an assessment of the timely completion of work, adherence to contract scope and budget, and quality of the work conducted. The contracting agency shall provide the consultant a copy of the performance evaluation and an opportunity to provide written comments to be attached to the evaluation. The contracting agency should prepare additional interim performance evaluations based on the scope, complexity, and size of the contract as a means to provide feedback, foster communication, and achieve desired changes or improvements. Completed performance evaluations should be archived for consideration as an element of past performance in the future evaluation of the consultant to provide similar services.

(e) *Contract modification.* (1) Contract modifications are required for any amendments to the terms of the existing contract that change the cost of the contract; significantly change the character, scope, complexity, or duration of the work; or significantly change the conditions under which the work is required to be performed.

(2) A contract modification shall clearly define and document the changes made to the contract, establish the method of payment for any adjustments in contract costs, and be in compliance with the terms and conditions of the contract and original procurement.

(3) A contracting agency shall negotiate contract modifications following the same procedures as the negotiation of the original contract.

(4) A contracting agency may add to a contract only the type of services and work included within the scope of services of the original solicitation from

which a qualifications-based selection was made.

(5) For any additional engineering and design related services outside of the scope of work established in the original request for proposal, a contracting agency shall:

(i) Procure the services under a new solicitation;

(ii) Perform the work itself using contracting agency staff; or

(iii) Use a different, existing contract under which the services would be within the scope of work.

(6) Overruns in the costs of the work shall not automatically warrant an increase in the fixed fee portion of a cost plus fixed fee reimbursed contract. Permitted changes to the scope of work or duration may warrant consideration for adjustment of the fixed fee portion of cost plus fixed fee or lump sum reimbursed contracts.

§ 172.11 Allowable costs and oversight.

(a) *Allowable costs.* (1) Costs or prices based on estimated costs for contracts shall be eligible for Federal-aid reimbursement only to the extent that costs incurred or cost estimates included in negotiated prices are allowable in accordance with the Federal cost principles.

(2) Consultants shall be responsible for accounting for costs appropriately and for maintaining records, including supporting documentation, adequate to demonstrate that costs claimed have been incurred, are allocable to the contract, and comply with Federal cost principles.

(b) *Elements of contract costs.* The following requirements shall apply to the establishment of the specified elements of contract costs:

(1) *Indirect cost rates.* (i) Indirect cost rates shall be updated on an annual basis in accordance with the consultant's annual accounting period and in compliance with the Federal cost principles.

(ii) Contracting agencies shall accept a consultant's or subconsultant's indirect cost rate(s) established for a 1-year applicable accounting period by a cognizant agency that has:

(A) Performed an audit in accordance with generally accepted government auditing standards to test compliance with the requirements of the Federal cost principles and issued an audit report of the consultant's indirect cost rate(s); or

(B) Conducted a review of an audit report and related workpapers prepared by a certified public accountant and issued a letter of concurrence with the related audited indirect cost rate(s).

(iii) When the indirect cost rate has not been established by a cognizant agency in accordance with paragraph (b)(1)(ii) of this section, a STA or other recipient shall perform an evaluation of a consultant's or subconsultant's indirect cost rate prior to acceptance and application of the rate to contracts administered by the recipient or its subrecipients. The evaluation performed by STAs or other recipients to establish or accept an indirect cost rate shall provide assurance of compliance with the Federal cost principles and may consist of one or more of the following:

(A) Performing an audit in accordance with generally accepted government auditing standards and issuing an audit report;

(B) Reviewing and accepting an audit report and related workpapers prepared by a certified public accountant or another STA;

(C) Establishing a provisional indirect cost rate for the specific contract and adjusting contract costs based upon an audited final rate at the completion of the contract; or

(D) Conducting other evaluations in accordance with a risk-based oversight process as specified in paragraph (c)(2) of this section and within the agency's approved written policies and procedures, as specified in § 172.5(c).

(iv) A lower indirect cost rate may be accepted for use on a contract if submitted voluntarily by a consultant; however, the consultant's offer of a lower indirect cost rate shall not be a condition or qualification to be considered for the work or contract award.

(v) Once accepted in accordance with paragraphs (b)(1)(ii) through (iv) of this section, contracting agencies shall apply such indirect cost rate for the purposes of contract estimation, negotiation, administration, reporting, and contract payment and the indirect cost rate shall not be limited by administrative or de facto ceilings of any kind.

(vi) A consultant's accepted indirect cost rate for its 1-year applicable accounting period shall be applied to contracts; however, once an indirect cost rate is established for a contract, it may be extended beyond the 1-year applicable period, through the duration of the specific contract, provided all concerned parties agree. Agreement to the extension of the 1-year applicable period shall not be a condition or qualification to be considered for the work or contract award.

(vii) *Disputed rates.* If an indirect cost rate established by a cognizant agency in paragraph (b)(1)(ii) of this section is in dispute, the contracting agency does not have to accept the rate. A contracting agency may perform its own audit or other evaluation of the consultant's indirect cost rate for application to the specific contract, until or unless the dispute is resolved. A contracting agency may alternatively negotiate a provisional indirect cost rate for the specific contract and adjust contract costs based upon an audited final rate. Only the consultant and the parties involved in performing the indirect cost audit may dispute the established indirect cost rate. If an error is discovered in the established indirect cost rate, the rate may be disputed by any prospective contracting agency.

(2) *Direct salary or wage rates.* (i) Compensation for each employee or classification of employee must be reasonable for the work performed in accordance with the Federal cost principles.

(ii) To provide for fair and reasonable compensation, considering the classification, experience, and responsibility of employees necessary to provide the desired engineering and design related services, contracting agencies may establish consultant direct salary or wage rate limitations or ''benchmarks'' based upon an objective assessment of the reasonableness of proposed rates performed in accordance with the reasonableness provisions of the Federal cost principles.

(iii) When an assessment of reasonableness in accordance with the Federal cost principles has not been performed, contracting agencies shall use and apply the consultant's actual direct salary or wage rates for estimation, negotiation, administration, and payment of contracts and contract modifications.

(3) *Fixed fee.* (i) The determination of the amount of fixed fee shall consider the scope, complexity, contract duration, degree of risk borne by the consultant, amount of subcontracting, and professional nature of the services as well as the size and type of contract.

(ii) The establishment of fixed fee shall be contract or task order specific.

(iii) Fixed fees in excess of 15 percent of the total direct labor and indirect costs of the contract may be justified only when exceptional circumstances exist.

(4) *Other direct costs.* A contracting agency shall use the Federal cost principles in determining the reasonableness, allowability, and allocability of other direct contract costs.

(c) *Oversight*—(1) *Agency controls.* Contracting agencies shall provide reasonable assurance that consultant costs on contracts reimbursed in whole or in part with FAHP funding are allowable in accordance with the Federal cost principles and consistent

with the contract terms considering the contract type and payment method. Contracting agency written policies, procedures, contract documents, and other controls, as specified in §§ 172.5(c) and 172.9 shall address the establishment, acceptance, and administration of contract costs to assure compliance with the Federal cost principles and requirements of this section.

(2) *Risk-based analysis.* The STAs or other recipient may employ a risk-based oversight process to provide reasonable assurance of consultant compliance with Federal cost principles on FAHP funded contracts administered by the recipient or its subrecipients. If employed, this risk-based oversight process shall be incorporated into STA or other recipient written policies and procedures, as specified in § 172.5(c). In addition to ensuring allowability of direct contract costs, the risk-based oversight process shall address the evaluation and acceptance of consultant and subconsultant indirect cost rates for application to contracts. A risk-based oversight process shall consist of the following:

(i) *Risk assessments.* Conducting and documenting an annual assessment of risks of noncompliance with the Federal cost principles per consultant doing business with the agency, considering the following factors:

(A) Consultant's contract volume within the State;

(B) Number of States in which the consultant operates;

(C) Experience of consultant with FAHP contracts;

(D) History and professional reputation of consultant;

(E) Audit history of consultant;

(F) Type and complexity of consultant accounting system;

(G) Size (number of employees or annual revenues) of consultant;

(H) Relevant experience of certified public accountant performing audit of consultant;

(I) Assessment of consultant's internal controls;

(J) Changes in consultant organizational structure; and

(K) Other factors as appropriate.

(ii) *Risk mitigation and evaluation procedures.* Allocating resources, as considered necessary based on the results of the annual risk assessment, to provide reasonable assurance of compliance with the Federal cost principles through application of the following types of risk mitigation and evaluation procedures appropriate to the consultant and circumstances:

(A) Audits performed in accordance with generally accepted government audit standards to test compliance with the requirements of the Federal cost principles;

(B) Certified public accountant or other STA workpaper reviews;

(C) Other analytical procedures;

(D) Consultant cost certifications in accordance with paragraph (c)(3) of this section; and

(E) Consultant and certified public accountant training on the Federal cost principles.

(iii) *Documentation.* Maintaining supporting documentation of the risk-based analysis procedures performed to support the allowability and acceptance of consultant costs on FAHP funded contracts.

(3) *Consultant cost certification.* (i) Indirect cost rate proposals for the consultant's 1-year applicable accounting period shall not be accepted and no agreement shall be made by a contracting agency to establish final indirect cost rates, unless the costs have been certified by an official of the consultant as being allowable in accordance with the Federal cost principles. The certification requirement shall apply to all indirect cost rate proposals submitted by consultants and subconsultants for acceptance by a STA or other recipient. Each consultant or subconsultant is responsible for certification of its own indirect cost rate and may not certify the rate of another firm.

(ii) The certifying official shall be an individual executive or financial officer of the consultant's organization at a level no lower than a Vice President or Chief Financial Officer, or equivalent, who has the authority to represent the financial information utilized to establish the indirect cost rate proposal submitted for acceptance.

(iii) The certification of final indirect costs shall read as follows:

Certificate of Final Indirect Costs

This is to certify that I have reviewed this proposal to establish final indirect cost rates and to the best of my knowledge and belief:

1. All costs included in this proposal (identify proposal and date) to establish final indirect cost rates for (identify period covered by rate) are allowable in accordance with the cost principles of the Federal Acquisition Regulation (FAR) of title 48, Code of Federal Regulations (CFR), part 31; and

2. This proposal does not include any costs which are expressly unallowable under applicable cost principles of the FAR of 48 CFR part 31.

Firm: _____

Signature: _____

Name of Certifying Official: _____

Title: _____

Date of Execution: _____

(4) *Sanctions and penalties.* Contracting agency written policies, procedures, and contract documents, as specified in §§ 172.5(c) and 172.9(c), shall address the range of administrative, contractual, or legal remedies that may be assessed in accordance with Federal and State laws and regulations where consultants violate or breach contract terms and conditions. Where consultants knowingly charge unallowable costs to a FAHP funded contract:

(i) Contracting agencies shall pursue administrative, contractual, or legal remedies and provide for such sanctions and penalties as may be appropriate; and

(ii) Consultants are subject to suspension and debarment actions as specified in 2 CFR part 1200 and 2 CFR part 180, potential cause of action under the False Claims Act as specified in 32 U.S.C. 3729–3733, and prosecution for making a false statement as specified in 18 U.S.C. 1020.

(d) *Prenotification; confidentiality of data.* FHWA, recipients, and subrecipients of FAHP funds may share audit information in complying with the recipient's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part provided that the consultant is given notice of each use and transfer. Audit information shall not be provided to other consultants or any other government agency not sharing the cost data, or to any firm or government agency for purposes other than complying with the recipient's or subrecipient's acceptance of a consultant's indirect cost rates pursuant to 23 U.S.C. 112 and this part without the written permission of the affected consultants. If prohibited by law, such cost and rate data shall not be disclosed under any circumstance; however, should a release be required by law or court order, such release shall make note of the confidential nature of the data.

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