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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–8557; Airspace Docket No. 16–AGL–17]

Amendment of Class E Airspace for the Following Wisconsin Towns; Antigo, WI; Ashland, WI; Black River Falls, WI; Cable Union, WI; Cumberland, WI; Eagle River, WI; Hayward, WI; and Wausau, WI; and Revocation of Class E Airspace; Wausau, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Langlade County Airport, Antigo, WI; John F. Kennedy Memorial Airport, Ashland, WI; Black River Falls Area Airport, Black River Falls, WI; Cable Union Airport, Cable Union, WI; Cumberland Municipal Airport, Cumberland, WI; Eagle River Union Airport, Eagle River, WI; Sawyer County Airport, Hayward, WI; and Wausau Downtown Airport, Wausau, WI. Decommissioning of non-directional radio beacon (NDB), cancellation of NDB approaches, and implementation of area navigation (RNAV) procedures have made this action necessary for the safety and management of Instrument Flight Rules (IFR) operations at the above airports. This action also removes Class E surface area airspace at Wausau Municipal Airport (Wausau Downtown Airport), Wausau, WI, as a review has determined that the airport no longer meets the requirements for this airspace. Additionally, the geographic coordinates at Langlade County Airport, John F. Kennedy Memorial Airport, Cumberland Municipal Airport, Eagle River Union Airport, and Wausau Downtown Airport (formerly Wausau Municipal Airport) are adjusted to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, April 27, 2017. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface at Langlade County Airport, Antigo, WI; John F. Kennedy Memorial Airport, Ashland, WI; Black River Falls Area Airport, Black River Falls, WI; Cable Union Airport, Cable Union, WI; Cumberland Municipal Airport, Cumberland, WI; Eagle River Union Airport, Eagle River, WI; Sawyer County Airport, Hayward, WI; and Wausau Downtown Airport, Wausau, WI; and removes Class E surface area airspace at Wausau Downtown Airport (formerly Wausau Municipal Airport), Wausau, WI.

History

On August 11, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM), (81 FR 53093) Docket No. FAA–2016–8557, to modify Class E airspace extending upward from 700 feet above the surface at Langlade County Airport, Antigo, WI; John F. Kennedy Memorial Airport, Ashland, WI; Black River Falls Area Airport, Black River Falls, WI; Cable Union Airport, Cable Union, WI; Cumberland Municipal Airport, Cumberland, WI; Eagle River Union Airport, Eagle River, WI; Sawyer County Airport, Hayward, WI; and Wausau Downtown Airport, Wausau, WI, and to remove Class E surface area airspace at Wausau Municipal Airport (Wausau Downtown Airport), Wausau, WI. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6002 and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E airspace extending upward from 700 feet above the surface at the following airports:

Within a 6.5-mile radius (increasing from the previous 6.4-mile radius) of Langlade County Airport, Antigo, WI, removing the extension to the north of the airport, and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 7.0-mile radius (increasing from the previous 6.5-mile radius) of John F. Kennedy Memorial Airport, Ashland, WI, with an extension southwest of the airport from the 7.0-mile radius to 8.2 miles, removing extensions to the southwest and southeast of the airport, and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 7.1-mile radius (increasing from the previous 6.4-mile radius) of Black River Falls Area Airport, Black River Falls, WI, with an extension southwest of the airport from the 7.1-mile radius to 11.7 miles, with an extension northeast of the airport from the 7.1-mile radius to 11.4 miles;

Within a 6.9-mile radius (increasing from the previous 6.4-mile radius) of Cable Union Airport, Cable Union, WI, and removing the extension to the southwest of the airport;

Within a 6.4-mile radius of Cumberland Municipal Airport, Cumberland, WI, with extensions from the 6.4-mile radius to 10.2 miles west and east; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 6.5-mile radius (reducing from the previous 6.6-mile radius) of Eagle River Union Airport, Eagle River, WI, with an extension southwest of the airport from the 6.5-mile radius to 9.2 miles, and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 6.6-mile radius (increasing from the previous 6.5-mile radius) of Sawyer County Airport, Hayward, WI, with an extension northeast of the airport from the 6.6-mile radius to 8.5 miles;

And within a 6.8-mile radius (increasing from the previous 6.5-mile radius) of Wausau Downtown Airport, Wausau, WI, and updating the name and geographic coordinates of the airport to coincide with the FAA's aeronautical database.

The Class E airspace designated as a surface area at Wausau Municipal Airport, Wausau, WI, is removed as the airport no longer meets the requirements for this airspace.

These airspace reconfigurations are necessary due to the decommissioning of NDBs, cancellation of NDB approaches, or implementation of RNAV standard instrument procedures at these airports. Controlled airspace is necessary for the safety and management of standard instrument approach procedures for IFR operations at these airports.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AGL WI E2 Wausau, WI [Removed]

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL WI E5 Antigo, WI [Amended]

Langlade County Airport, WI
(Lat. 45°09′14″ N., long. 89°06′38″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Langlade County Airport.

AGL WI E5 Ashland, WI [Amended]

John F. Kennedy Memorial Airport, WI
(Lat. 46°32′55″ N., long. 90°55′08″ W.)

That airspace extending upward from 700 feet above the surface within a 7.0-mile radius of John F. Kennedy Memorial Airport, and within 2.9 miles each side of the 201° bearing from the airport extending from the 7.0-mile radius to 8.2 miles southwest of the airport.

* * * * *

AGL WI E5 Black River Falls, WI [Amended]

Black River Falls Area Airport, WI
(Lat. 44°15′03″ N., long. 90°51′19″ W.)

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of Black River Falls Area Airport, and within 2 miles each side of the 081° bearing from the airport extending from the 7.1-mile radius to 11.4 miles east of the airport, and within 2 miles each side of the 260° bearing from the airport extending from the 7.1-mile radius to 11.7 miles west of the airport.

* * * * *

AGL WI E5 Cable Union, WI [Amended]

Cable Union Airport, WI
(Lat. 46°11′42″ N., long. 91°14′54″ W.)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Cable Union Airport.

* * * * *

AGL WI E5 Cumberland, WI [Amended]

Cumberland Municipal Airport, WI
(Lat. 45°30′22″ N., long. 91°58′51″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Cumberland Municipal Airport, and within 2 miles each side of the 091° bearing from the airport extending from the 6.4-mile radius to 10.2 miles east of the airport, and

within 2 miles each side of the 270° bearing from the airport extending from the 6.4-mile radius to 10.2 miles west of the airport.

* * * * *

AGL WI E5 Eagle River, WI [Amended]

Eagle River Union Airport, WI
(Lat. 45°55′56″ N., long. 89°16′06″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Eagle River Union Airport, and within 2 miles each side of the 225° bearing from the airport extending from the 6.5-mile radius to 9.2 miles southwest of the airport.

* * * * *

AGL WI E5 Hayward, WI [Amended]

Sawyer County Airport, WI
(Lat. 46°01′31″ N., long. 91°26′39″ W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Sawyer County Airport, and within 2 miles each side of the 025° bearing from the airport extending from the 6.6-mile radius to 8.5 miles northeast of the airport.

* * * * *

AGL WI E5 Wausau, WI [Amended]

Wausau Downtown Airport, WI
(Lat. 44°55′35″ N., long. 89°37′37″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Wausau Downtown Airport.

Issued in Fort Worth, Texas, on December 28, 2016.

Thomas L. Lattimer,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–00287 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

Cardiovascular Devices

CFR Correction

■ In Title 21 of the Code of Federal Regulations, Parts 800 to 1299, revised as of April 1, 2016, on page 371, § 870.5800 is reinstated to read as follows:

§ 870.5800 Compressible limb sleeve.

(a) *Identification.* A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) *Classification.* Class I (performance standards).

[FR Doc. 2017–00796 Filed 1–12–17; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 35

[Docket No. FR–5816–F–02]

RIN 2501–AD77

Requirements for Notification, Evaluation and Reduction of Lead-Based Paint Hazards in Federally Owned Residential Property and Housing Receiving Federal Assistance; Response to Elevated Blood Lead Levels

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's lead-based paint regulations to reduce blood lead levels in children under age six (6) who reside in federally-owned or -assisted pre-1978 housing, formally adopting a revised definition of ''elevated blood lead level'' (EBLL) in children under the age of six (6), in accordance with Centers for Disease Control and Prevention (CDC) guidance. It also establishes more comprehensive testing and evaluation procedures for the housing where such children reside. This final rule also addresses certain additional elements of the CDC guidance pertaining to assisted housing and makes technical corrections and clarifications. This final rule, which follows HUD's September 1, 2016, proposed rule, takes into consideration public comments submitted in response to the proposed rule.

DATES: *Effective Date:* February 13, 2017.

Compliance Date: July 13, 2017.

FOR FURTHER INFORMATION CONTACT: Warren Friedman, Office of Lead Hazard Control and Healthy Homes, Department of Housing and Urban Development, 451 7th Street SW., Room 8236, Washington, DC 20410; telephone number 202–402–7698 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service, toll-free at 800–877–8339.

SUPPLEMENTARY INFORMATION:

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I. Background

A. HUD's Long-Term and Ongoing Efforts To Reduce Lead Poisoning in Children

Childhood lead poisoning has long been documented as causing reduced intelligence, low attention span, and reading and learning disabilities; it has additionally been linked to juvenile delinquency, behavioral problems, and many other adverse health effects.[1] Despite public health efforts successfully reducing toxic lead exposure in children nationwide, blood lead monitoring continues to reveal children with elevated blood lead levels due to exposure in their specific housing environments. The Centers for Disease Control and Prevention (CDC) has consistently affirmed its position that lead-based paint and lead-contaminated dust are the most hazardous sources of lead for U.S. children.[2] Over the past decade, HUD has dramatically reduced housing-based lead exposure among children through lead paint abatement and interim controls.[3] Nevertheless, a considerable number of children under age six (6) currently reside in HUD-assisted housing units that contain lead-based paint.

[1] *See* HUD's proposed rule and the accompanying regulatory impact assessment, *available at www.regulations.gov/document?D=HUD-2016-0096.*

[2] *See* CDC, *Lead: Prevention Tips, http://www.cdc.gov/nceh/lead/tips.htm.*

[3] *See, e.g.,* HUD's lead hazard control grant programs *and* the lead hazard control work required of landlords under settlements HUD has reached in enforcing the Lead Disclosure Statute and related regulations at 42 U.S.C. 4852d and 24 CFR part 35, subpart A.

To address this issue, HUD issued a proposed rule on September 1, 2016, at 81 FR 60304, to revise HUD's Lead Safe Housing Rule (LSHR) by adopting the CDC's guidance on when an environmental intervention should be conducted in response to a child's blood lead level, thereby establishing HUD's definition of elevated blood lead level (EBLL) as the level for which environmental intervention is required in certain federally-owned and federally-assisted housing, among other changes. This final rule considers public comments submitted on the September 1, 2016, proposed rule and defines ''elevated blood lead level'' (EBLL) as the level at which the CDC recommends environmental intervention.

B. Authority for HUD's Lead-Based Paint Regulation

HUD's LSHR is codified in Title 24 of the Code of Federal Regulations (CFR) part 35, subparts B through R. The LSHR implements sections 1012 and 1013 of the Residential Lead-Based Paint Hazard Reduction Act of 1992, which is Title X of the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992); sections 1012 and 1013 are codified at 42 U.S.C. 4822.

Under Title X, HUD has specific authority to control lead-based paint and lead-based paint hazards in HUD-assisted housing that may have lead-based paint, called ''target housing.'' [4] The LSHR aims in part to ensure that federally-owned or federally-assisted target housing is free of lead-based paint hazards. Lead-based paint hazards are lead-based paint and all residential lead-containing dusts and soils, regardless of the source of the lead, which, due to their condition and location, would result in adverse human health effects.

HUD recognizes that there is no safe level of lead exposure. Consistent with Title X and the LSHR, HUD's primary focus is on minimizing childhood lead exposures, rather than on waiting until children have elevated blood lead levels to undertake actions to eliminate lead-based paint hazards. HUD's Office of Lead Hazard Control and Healthy Homes (OLHCHH) has spearheaded major efforts to that end by taking actions feasible and authorized by law to reduce lead exposure in children.[5]

II. Regulatory Approach

A. Overview

This final rule revises HUD's criteria under the LSHR for responding to the identification of children under age six (6) with high blood lead levels residing in covered federally-assisted and federally-owned target housing. The final rule also addresses lead hazard evaluation and control for additional assisted housing units in the same properties as those in which children under age six (6) with high blood lead levels have been discovered. The final rule adopts an approach based on the previously codified LSHR, the CDC's reference range value for blood lead levels in children under age six (6),[6] the HUD *Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing* (HUD Guidelines), HUD's experience implementing the LSHR since its 1999 promulgation, and public comments received on the September 1, 2016, proposed rule.

Specifically, under this final rule, when a child under age six (6) with an EBLL is identified, the ''designated party'' and/or the housing owner shall undertake certain actions.[7] This protocol is the same for each of the four applicable HUD subparts (H, I, L, M), and slightly narrower for the subpart covering other agencies (D), under which those agencies must decide how to treat housing units in multi-unit properties other than the unit in which the child with an EBLL resides. Figure 1 provides an overview of the protocol for addressing EBLL cases in housing covered by the LSHR.

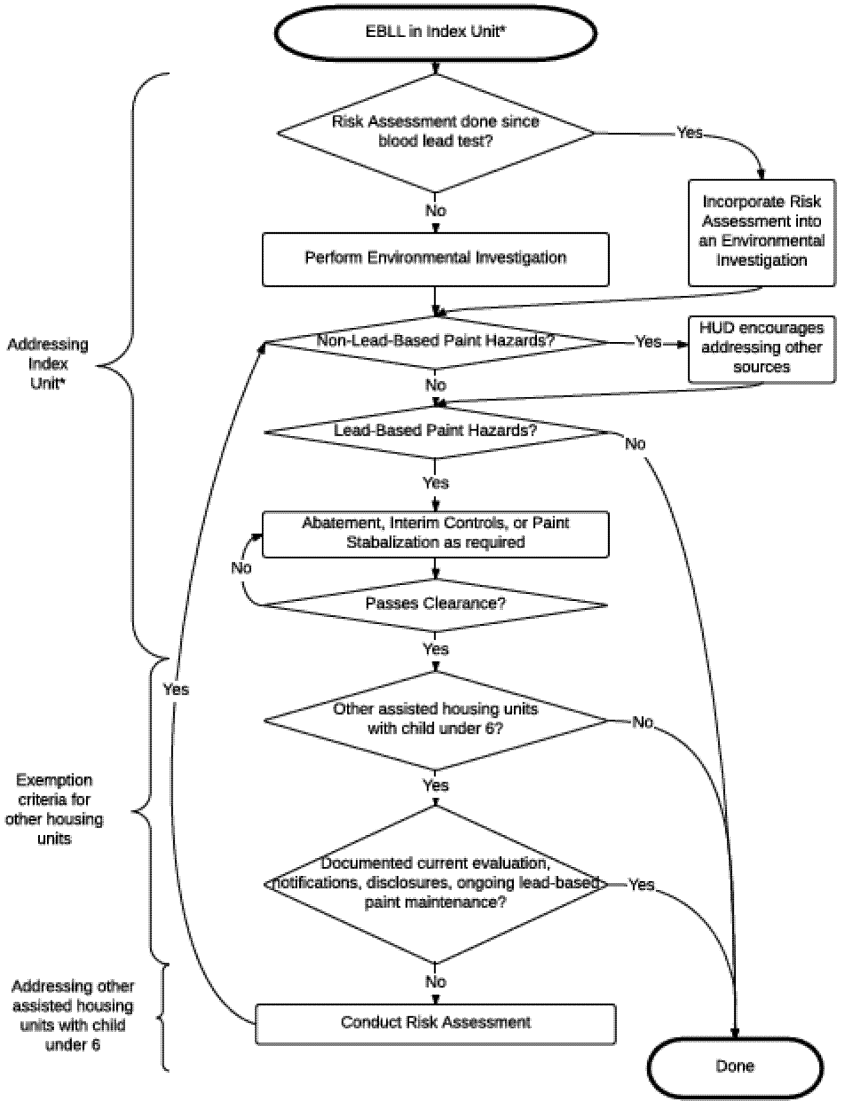
[4] HUD's regulation at 24 CFR 35.110, based on the Title X definition at 42 U.S.C. 4851b(27), defines ''target housing'' as any housing constructed prior to 1978, but not including housing for the elderly or persons with disabilities where no child less than 6 years of age resides or is expected to reside, or any zero-bedroom dwelling.

[5] These actions include administering a successful Lead Hazard Control program of grants, enforcement, research, and outreach, and providing conditions of funding through the office's notices of funding availability, updating guidelines and best practices, and working collaboratively with other Federal agencies such as the U.S. Department of Health and Human Services (HHS), particularly its CDC, *and* the U.S. Environmental Protection Agency (EPA). See Advancing Healthy Housing, a Strategy for Action, *http://portal.hud.gov/hudportal/documents/huddoc?id=stratplan_final_11_13.pdf.*

[6] CDC's ''reference range value'' method for defining EBLLs is based on the blood lead level equaled or exceeded by 2.5 percent of U.S. children aged 1–5 years as determined by CDC's most recent National Health and Nutritional Examination Survey. Currently, CDC's reference range value is 5 µg/dL (5 micrograms of lead per deciliter of blood).

[7] The designated party is the owner or other entity (*e.g.,* federal agency, state, local government, public housing agency, tribally designated housing entity, sponsor, etc.) designated under the LSHR as responsible for complying with applicable requirements of the LSHR for the residential property or dwelling unit, as applicable. *See* 24 CFR 35.110.

Fig. 1. Flowchart overview of the elevated blood lead level protocol.[8]



B. Changes Made at the Final Rule Stage

This final rule follows publication of, and takes into consideration, public comments received on the September 1, 2016, proposed rule. Based on that review, HUD makes the following changes to the proposed rule at the final rule stage. For some of those changes, the wording changes in multiple instances.

1. In §§ 35.325(b)(2)(i), 35.730(f)(4)(i), 35.830(f)(3)(i), 35.1130(f)(4)(i), and 35.1225(f)(3)(i), HUD changes the requirements for other assisted dwelling units covered by §§ 35.325(b)(1), 35.730(f)(1), 35.830(f)(1), 35.1130(f)(1), and 35.1225(f)(1), respectively, by clarifying that they do not apply if the owner both conducted a risk assessment of those units and the common areas servicing them and conducted interim controls of identified lead-based paint hazards after the date the child's blood was last sampled.

2. In § 35.730(f)(1), regarding assisted units, other than the index unit, with a child or children under age six (6), in a project-based assisted property with a child or children under age six (6) with an EBLL in a household for which the project-based rental assistance is up to $5,000 per year, and in § 35.1225(f), regarding units, other than the index unit, with a child or children under age six (6), occupied by households receiving tenant-based rental assistance, in a property with a child or children under age six (6) with an EBLL in a household receiving tenant-based rental assistance, HUD revises the proposed rule to require the designated party, *i.e.,* the owner or, as discussed in section III.B.10.h of this preamble, the public housing agency, HOME grantee or subrecipient, or HOPWA grantee or sponsor, as applicable, to conduct a risk assessment,[9] in accordance with

[8] ''Index Unit'' refers to the housing unit in which the child who has an EBLL resides, with the terminology adapted from the traditional epidemiology term, ''index case, the case that is first reported to public health authorities.'' CDC, Guidelines for the Control of Pertussis Outbreaks. Centers for Disease Control and Prevention: Atlanta, GA, 2000. Chapter 11, Definitions. *www.cdc.gov/pertussis/outbreaks/guide/downloads/chapter-11.pdf.*

[9] Throughout this Final Rule, ''risk assessment'' has the meaning of the term as used in the LSHR (at 24 CFR 35.110, Definitions), which is derived from the Title X definition (42 U.S.C. 4851b(25) (for HUD rules) and 15 U.S.C. 2681(16) (for EPA rules); it does not have the meaning of the same term under Superfund (the Comprehensive

Continued

methods and standards established either by a state or tribal program authorized by the EPA, or by the EPA at 40 CFR 745.227(d) with procedures defined by the EPA—rather than a visual assessment—of the other units for which the household receives tenant-based rental assistance in the property, and interim controls of the lead-based paint hazards identified by the risk assessment, using the proposed rule's schedule for completion of lead-based paint hazard reduction activities.

3. In § 35.730(f)(2), HUD replaces the provision regarding paint stabilization following a visual assessment with a provision regarding interim controls following a risk assessment.

4. HUD is not including in this final rule proposed §§ 35.730(g), 35.1130(g) and 35.1225(g), which contained language encouraging owners to evaluate and control for sources of lead exposure other than those covered by this subpart.

5. In § 35.1225(f)(1), HUD changes the reference to a ''visual assessment'' to ''risk assessment'' and changes the cross-reference to the section that describes procedures for such an assessment.

6. In § 35.1225(f)(2), HUD clarifies that the discussion concerns ''lead-based paint hazards'' rather than ''deteriorated paint'' to emphasize reduction of lead-based paint hazards rather than paint stabilization.

7. In § 35.1225(f)(3), HUD removes reference to visual assessment and amends and adds language to clarify that the discussion is of ''interim controls'' of ''lead-based paint'' rather than ''deteriorated paint'' and to emphasize reduction of lead-based paint hazards rather than paint stabilization.

Additionally, HUD takes this opportunity to make the following technical corrections and conforming changes.

1. In § 35.105, HUD removes past effective dates and reserves the section.

2. In § 35.110, HUD makes a technical correction to indicate the correct section number for the Definitions section, and revises the definition of ''Certified''.

3. In § 35.155(a), on minimum requirements for lead-based paint hazard evaluation or reduction, HUD makes a technical correction by changing both instances of ''designated party or occupant'' to ''designated party or owner,'' in order to identify correctly who may be required to conduct additional lead-based paint hazard evaluation or reduction, beyond the minimum under the LSHR.

4. In §§ 35.325(b)(1), 35.830(f)(3)(i), 35.1225(f)(1), and 35.1225(f)(3)(i), HUD makes a technical correction to grammar by replacing the verb ''serving'' with the verb ''servicing'' in the first sentence.

5. In § 35.325(b)(1), HUD replaces the auxiliary verb ''would'' with the auxiliary verb ''shall,'' in the second sentence.

6. In § 35.325(b)(1), HUD adds language to clarify that the hazards referenced in the third sentence are those identified in accordance with § 35.1325 or § 35.1330. In § 35.325(d), HUD clarifies that the timetable referenced therein shall include provision of documentation on the lead hazard evaluation and control activities to the agency.

7. In §§ 35.730(a), 35.830(a), 35.1130(a), and 35.1225(a), the rule discusses the requirements that apply if a public health department has already conducted an evaluation of the dwelling unit. HUD revises the proposed rule to state explicitly that in order to exempt the designated party from conducting an environmental investigation, the public health department's evaluation must have been conducted in response to the current case.

8. In §§ 35.730(f)(2), 35.830(f)(2), 35.1130(f)(2), and 35.1225(f)(2), HUD clarifies when lead-based paint hazard reduction is considered complete.

9. In § 35.730(f)(4), HUD clarifies when the requirements of paragraph (f) do not apply.

10. In § 35.830(h), HUD clarifies that ''clearance'' is among the deadline-driven activities covered by this section.

11. In § 35.1330(a)(4)(iii) on training requirements for interim control workers and supervisors, which are applicable to some of the work conducted under this rule, HUD makes a technical correction by replacing all references to the defunct HUD course approval process, with references to the current EPA and EPA-authorized state renovator course accreditation process.

C. Applicability of Civil Rights Laws

HUD notes that housing-based lead exposure has a disproportionate impact on children of some racial and ethnic groups and those living in older housing.[10] Lead hazard evaluation and control activities in federally-assisted and federally-owned target housing are subject to the requirements of the applicable civil rights laws, including the Fair Housing Act, as amended (and its prohibition of discrimination on several bases, including, but not limited to, race, disability, and familial status, including the presence of a child under age of 18, or of a pregnant woman), Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race, color, and national origin), Title IX of the Education Amendments of 1972 (prohibiting discrimination on the basis of sex), and section 504 of the Rehabilitation Act of 1973 (prohibiting discrimination on the basis of disability). Under this final rule, these and other applicable Federal laws, and their associated HUD regulations and guidance, which were incorporated into the current LSHR, continue to apply to these activities without change.

III. Public Comments Submitted on Proposed Rule and HUD's Responses

A. Overview of Public Comments

The public comment period for the September 1, 2016, proposed rule closed on October 31, 2016. As of the close of the comment period, HUD received 62 public comments, including one mass mailing. Comments and HUD's responses are summarized below. All comments can be accessed at *http://www.regulations.gov.*

The overwhelming majority of comments were supportive of the rule. Some commenters, while supporting the rule, suggested ways that it could be improved. In the comments received, the Department identified 378 distinct recommendations. The Department thanks the commenters for their thoughtful insights, and their efforts to improve the current LSHR. The commenters' recommendations fell into 11 broad categories, discussed below. Many comments addressed the four specific questions for comments HUD requested. Most commenters (53) also had concerns about one or more technical issues in applying and administering the LSHR.

Although they presented a range of foci and approaches, commenters were nearly unanimous in expressing their support for increasing the protection of America's children from lead hazards, and the importance of aligning HUD's regulations with the current science from the CDC. These sentiments are best summed up by a comment submitted on behalf of the 13,765 individuals who signed a letter circulated by the commenter that stated that they, ''fully support [HUD's] proposal to update the Lead Safe Housing Rule by lowering the threshold of lead exposure to align with

Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)), or other statutes, regulations or policies. *See, e.g., https://www.epa.gov/risk/risk-assessment-guidelines.*

[10] *See* CDC, *Lead: Prevention Tips, http://www.cdc.gov/nceh/lead/tips.htm;* CDC, *Recommendations for Blood Lead Screening of Medicaid-Eligible Children Aged 1–5 Years: an Updated Approach to Targeting a Group at High Risk* (Aug. 2009), *available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5809a1.htm.*

the Centers for Disease Control and Prevention's recommendations and allow for HUD to move more quickly to protect children's health. Given the risks, anything your agency can do to reduce lead exposure is appreciated.''

B. Significant Public Comments and HUD's Responses

1. Primary Prevention

Comment: Almost half of the commenters (32) identified the importance of primary prevention. Many recommended conducting a risk assessment in a unit before a family with a child occupied the unit. Other commenters noted that recent CDC–HUD research shows children in HUD-assisted housing already have lower blood lead levels than children in comparable low-income housing.[11] However, as the article notes, while the result provides a favorable assessment of the benefits of HUD's assistance requirements and assistance monitoring programs, the size of the study's filtered sample was not sufficiently large to identify patterns within particular types of housing assistance.

HUD Response: HUD has adopted the position of CDC and other federal agencies that no amount of lead in a child's blood can be considered safe,[12] and that primary prevention is critical to protecting America's children. However, it must be noted that the primary purposes of this rulemaking are adopting the revised definition of ''elevated blood lead level'' (EBLL) in children under the age of six (6), and strengthening designated parties' or owners' responses in cases where children with high blood lead levels reside in federally-assisted and federally-owned target housing. Therefore, the currently codified LSHR's primary prevention requirements associated with pre-occupancy activities and ongoing lead-based maintenance programs not associated with EBLL cases in federally-assisted and federally-owned target housing are outside the scope of this rulemaking. The Department will consider addressing pre-occupancy activities and ongoing lead-based maintenance programs in future rulemaking.

2. Resources Available

Comment: Almost half of the commenters (30) expressed a need for appropriate resources for grantees to implement this rule correctly. Resources mentioned included additional funding for environmental investigation and appropriate training and technical assistance. Some commenters stated that, without these additional resources, the rule could not be properly implemented, and encouraged HUD to wait until such resources were available before implementing the rule.

HUD Response: HUD is sensitive to the cost of implementation, especially in an era of tightened budgets among grantees, state, local, and tribal governments, and other federal assistance recipients–and in the face of competing priorities, including those related to health of vulnerable populations, such as young children. However, a delay in implementation to wait for potential additionally appropriated resources could result in avoidable long-term harm to children in federally-assisted and federally-owned target housing. Furthermore, as calculated in the Regulatory Impact Assessment accompanying this rule, the benefits of the rule outweigh the costs. One commenter said, regarding, ''the Regulatory Impact Assessment [that they] believe that it is a reasonable estimate. If anything, we believe (as discussed in the RIA) that the benefits of the proposed regulation are underestimated, because some benefits cannot be quantified or monetized, such as avoided stress on parents and children. We also believe that some costs are likely to be lower than those estimated by HUD,'' because, for example, HUD assumes the presence of only one child with EBLL in each unit, when some units may have more.

HUD will work with grantees and owners to identify ways in which this rule can be implemented with as little burden as feasible, and how existing resources can be directed to implementation, particularly in rural and underserved areas. HUD will also provide training opportunities to assist in implementing the rule.

Comment: Two commenters requested that public housing agencies be allowed to compete for lead hazard control grants from HUD's Office of Healthy Homes and Lead Hazard Control.

HUD Response: Eligibility for that grant program is outside the scope of this rulemaking However, HUD wishes to advise that public housing agencies, per Title X, are eligible for those grants only if they are an agency of a unit of state or local government. Similarly, housing units are eligible for enrollment under a grant (and, thus for lead-based paint inspection and risk assessment, and, if lead-based paint hazards are found, lead hazard control) only if they are target housing and meet certain other qualifications, *e.g.,* the housing does not receive any federal housing assistance, or the family is receiving tenant-based rental assistance, such as a housing choice voucher. The housing is ineligible for enrollment in a lead hazard control grant if it is ''federally assisted housing, federally owned housing, or public housing.''[13] The first of these includes housing receiving project-based rental assistance, the second, housing for which the mortgagee has defaulted on a federally-insured mortgage, and the third, housing owned by a public housing agency.

HUD has been reaching out to public housing agencies to encourage owners of housing units in which the families receive a Housing Choice Voucher to enroll those units in the lead hazard control grant (funded by the OLHCHH), whose target area includes the location of the units. Because most families eligible for this type of voucher have incomes which make them eligible for enrolling in a lead hazard control grant, HUD has expedited the process for the grantees to enroll them. HUD will continue to promote lead hazard control grantee-public housing agency partnerships.

3. Tenant Protections

a. Anti-Retaliation Protections

Comment: Many commenters (36) remarked on the need for protections for tenants. Generally, these commenters were worried about possible ''retaliation'' or ''reprisal'' against tenants and ''blame shifting.'' Retaliation or reprisal meant, as described by one commenter, the ''loss of benefits, lease violations, termination of assistance, or reporting to a child-welfare agency.'' Several of these commenters suggested specifying in the rule that this type of retaliation would be prohibited. They also suggested that HUD revise the rule to include an anti-retaliation clause that would prohibit penalties if a child with an EBLL is identified who is not included on the occupant list of the rental or assistance agreement or contract. In addition, commenters proposed several family

[11] *See* Ahrens KA, Haley BA, Rossen LM, Lloyd PC, Aoki Y, *Housing Assistance and Blood Lead Levels: Children in the United States, 2005–2012,* American Journal of Public Health: November 2016, Vol. 106, No. 11: 2049–2056, abstract *available at https://www.regulations.gov/document?D=HUD-2016-0096-0027 (as part of comment docket for this final rule); full text available with subscription at http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2016.303432.*

[12] *See* President's Task Force on Environmental Health Risks and Safety Risks to Children, *Key Federal Programs to Reduce Childhood Lead Exposures and Eliminate Associated Health Impacts,* 2 (Nov. 30, 2016), *https://ptfceh.niehs.nih.gov/.*

[13] 42 U.S.C. 4852(a), regarding housing unit eligibility, and (b), regarding grant applicant eligibility.

interview methods to provide further protection to households.

HUD Response: HUD already has regulations and policies in place that protect families against retaliation by landlords and has determined that these policies should be sufficient to protect tenants from discrimination and retaliation. Under existing fair housing regulations, interviewers will be required to abide by policies about limited English proficiency, which require HUD, its grantees, and sub-grantees to make reasonable efforts to provide language assistance to ensure meaningful access for persons with limited English proficiency to the recipient's programs and activities.

However, HUD cannot establish a policy that would negate regulations requiring that every individual living in the household be listed on the lease. These regulations are in place to prevent overcrowding, which is associated with its own negative effects on children's well-being, including their health.[14] They are also in place to ensure proper subsidy calculations and enforce lease provisions. Ensuring these regulations and policies are appropriately integrated with the implementation of the LSHR amendments will be addressed through program management. Thus, in this rulemaking, HUD declines to adopt a provision specifically prohibiting penalties if a child with an EBLL is identified who is not included on the occupant list of the rental or assistance agreement or contract.

b. Relocation Protections

Comment: Many commenters (18) offered recommendations about tenant relocation, either permanently or while work was being done in their unit.

HUD Response: HUD understands that relocation may be necessary in some circumstances but it can also be very expensive for the designated party or owner. Existing HUD regulations, policies and guidance on when relocation is appropriate, including those in the currently codified LSHR, have already considered these issues, and HUD was not presented with any evidence that requires reopening those discussions. Thus, in this rulemaking, HUD declines to adopt a provision specifically pertaining to tenant relocation.

[14] *See* Solari CD, Mare RD, *Housing Crowding Effects on Children's Wellbeing,* Social Science Research (Mar. 2012), 41(2): 464–476, *available at www.sciencedirect.com/science/article/pii/S0049089X11001694.*

4. Coordination Between the Involved Parties

a. Coordination Between HUD and Grantees

Comment: Many commenters (36) addressed the proposed rule's reporting requirements for property owners—specifically their requirements for reporting EBLL discovery and responsive activities to their HUD field office and the OLHCHH—from a variety of viewpoints. Some expressed concerns that reporting would impose difficult burdens on public housing agencies and assisted private owners. Many of these commenters provided helpful suggestions on methods to reduce that burden. Some asked for increases in reporting. Others provided helpful suggestions on mandates, penalties for noncompliance, and the importance of public data profiles. One commenter asked HUD to clarify why public housing authorities must contact both the field office and OLHCHH, instead of having the field office contact OLHCHH.

HUD Response: HUD is mindful of the need to minimize burdens on owners and public housing authorities, the necessity of having appropriate information received timely in order to ensure efficient and effective program administration and monitoring, and the public's interest in open and transparent government information and operation. HUD is also mindful that public health authorities, HUD Field Offices, and the OLHCHH each have distinct roles in addressing an EBLL case, and that time is often of the essence in fulfilling those roles.

The concurrent notification is necessary to ensure that the OLHCHH is aware of the EBLL case timely and knows, upon receiving the notification, the same information that has been provided to the Field Office without having to conduct a verification, which would delay its ability to respond effectively to requests for assistance from the Field Office and monitor the case. HUD also notes that the concurrent notification was proposed for all LSHR subparts in the proposed rule, a scope retained in this final rule, so that public housing authorities are not being subjected to a different requirement than are owners who have this case notification responsibility under certain LSHR subparts.

Considering the necessary balancing of interests, potential future changes in federal and local laws, and the rapid pace of technological advances in sharing and reporting on data, HUD does not believe it is appropriate to be prescriptive in codifying a particular notification process in regulation. Instead, HUD retains the requirement as drafted in the proposed rule. Specific processes for reporting EBLLs and actions taken will be developed, including an electronic submission pathway. In developing pathways for reporting, HUD will continue to carefully balance these interests.

b. Coordination With Parents, Guardians, and Other Non-Medical Professional Sources

Comment: Several commenters (5) recommended that designated parties and owners accept notification of EBLLs from parents, guardians, and other non-professional sources when notification is accompanied by sufficient documentation such as a doctor's letter.

HUD Response: A letter or report from a medical health care provider, such as a physician or nurse, or the public health department, has always been acceptable notification under the LSHR (because HUD has never required or expected that the provider would come to the office of the designated party personally to deliver the notification). This will continue to be the case under this final rule. Similarly, in the absence of a medically reliable notification that a child under age six (6) has an EBLL, it would be imprudent for HUD to require the designated party and/or the owner to undertake an environmental intervention. When presented with notification of an EBLL from a non-medical-professional source, the designated party is required to contact the local health department or another medical health care provider to verify the notification. This rule details the procedure (including contacting HUD) to be used when a public health department or provider declines to verify a report from a non-medical professional source.

c. Coordination With HIPAA and Local Data Privacy Laws

Comment: Several commenters (8) requested clarification of the protocols for reporting, including the interaction with other federal laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191), and state and local privacy laws.

HUD Response: For the purpose of preventing or controlling childhood lead poisoning, in regard to lead hazard evaluation and control activities, the OLHCHH and its lead hazard control grantees acting on its behalf, are considered public health authorities under HIPAA; thus, they may receive related private health information that is minimally necessary to accomplish the intended purpose of the disclosure,

including the addresses of housing units and vital information about the children and their families, and must protect that information.

5. Technical Concerns

a. Environmental Investigations of Lead Hazards That Are Not Lead-Based Paint Hazards

Comment: Many comments (18) expressed concerns about whether federally-assisted housing providers should look for sources of lead exposure that are not lead-based paint hazards, or would be responsible for such sources of lead exposure if they were identified in the environmental investigation. Some commenters raised concerns about the responsibility for controlling lead exposure if the source of lead was a non-lead-based paint hazard or at another property outside of the control of the designated party or owner, as applicable. Additionally, some commenters requested that HUD add safeguards to ensure that owners are not penalized for missing other sources of exposure if a public health department decides not to, or is unable to work with a designated party or owner on the child's case.

HUD Response: This final rule requires that the owner or designated party, as applicable, ensure that an environmental investigation of the child's lead exposure is completed, which includes investigating sources that are or are not lead-based paint hazards. Environmental investigations must be performed by EPA, state, or tribally certified risk assessors, and the contents of their report must meet EPA, state or tribal requirements, as applicable. The rule also provides that, if a public health department has already conducted an evaluation of the dwelling unit in response to the case, the owner or designated party does not need to conduct another one. HUD has clarified applicable sections of the proposed rule [15] to provide that the evaluation be in response to the current case. This clarification eliminates the potential confusion that a previous case in the same housing unit, whether for an EBLL or other reason, that had prompted a public health department evaluation, however long before the current EBLL case, might allow an environmental investigation or public health department evaluation not to be conducted for the current case. HUD is not aware of this having occurred, but the technical clarification provides transparency on this issue.

Because children can be exposed to lead by toys, dishes, homeopathic remedies, certain cultural practices, and other non-paint-related sources, the family interview portion of the environmental investigation will include questions on these sources. The designated party or owner is responsible for ensuring that an environmental investigation in accordance with federal, state, and local requirements is conducted timely, regardless of whether it is done by staff or through contract, or that the public health department has conducted an evaluation in response to the case.

In some areas of the country, the public health department will perform the environmental investigation or a comparable evaluation, as may be required by a public health department initiative or state, tribal, or local law, the latter of which may also specify how the environmental investigation is performed and what follow-up actions must be taken by the designated party. In these cases, the most stringent of the federal, State, tribal, or local requirements must be followed.

Regardless of who performs the environmental investigation, HUD is not establishing a requirement that the designated party or owner address sources of exposure that are not lead-based paint hazards, or sources from housing not controlled by the designated party or owner, such as a relative's home, because HUD does not have authority to require that those sources be addressed. As discussed elsewhere in this preamble, risk assessments of certain other housing units in the property may be conducted; as with the environmental investigation of the index unit,[16] these risk assessments may identify non-paint-related sources of lead exposure. Indeed, the HUD Guidelines encourage risk assessors to note other obvious sources of lead exposure, and many risk assessors routinely test items other than paint for lead. The Guidelines also explicitly include such testing as a part of environmental investigations. Nevertheless, HUD does not believe that such activities would subject property owners to expanded legal vulnerability under this rule. In both the index unit and other units, the designated party or owner is not responsible for controlling these sources. In the 22 years since the Guidelines were first published, this has not created a legal liability problem for risk assessors or building owners and managers.

HUD, such as through its OLHCHH, will continue to encourage designated parties and owners to address such lead hazards as part of its broader effort to ensure the safety and health of residents of its assisted housing, but, for regulatory clarity, not do so through this rulemaking.

Additionally, the EPA regulations at 40 CFR 745.235, 745.237, and 745.327 (or the equivalent regulations of an EPA authorized state or tribal lead-based paint program as applicable) prescribe the training and certification requirements for risk assessors as well as the work practice standards for conduct of a risk assessment and the reporting of the assessment results. This rule does not hold the designated party or owner responsible for a certified risk assessor performing the environmental investigation missing a source of exposure (except, of course, in the case of collusion).

b. Lead in Water

Comment: Several comments (7) specifically addressed the issue of lead-contaminated water, the desirability of testing and controlling lead levels in water, and the responsibilities of owners if high lead levels are found in the water supply.

HUD Response: Controlling exposures to lead from water is outside of HUD's authority for this rulemaking, because Title X, which the LSHR implements, does not authorize HUD to regulate lead in water. The HUD Guidelines' chapter 16 on environmental investigations, discussed in the preamble to the proposed rule, indicates when water testing as part of the investigation is appropriate and provides guidance on how to conduct such testing. Further information on lead in water testing is available from EPA.[17] Requiring control of drinking water lead levels is outside the scope of this rule. Thus, HUD declines to specifically address the issue of lead-contaminated water in this rulemaking.

[15] 24 CFR 35.730(a), 35.830(a), 35.1130(a), and 35.1225(a) have been revised to read: ''If a public health department has already conducted an evaluation of the dwelling unit *in regard to the child's elevated blood lead level case,* the requirements of this paragraph shall not apply'' (emphasis added).

[16] Here, this refers to the housing unit in which the child who has an EBLL resides, with the terminology adapted from the traditional epidemiology term, ''index case, the case that is first reported to public health authorities.'' CDC, Guidelines for the Control of Pertussis Outbreaks. Centers for Disease Control and Prevention: Atlanta, GA, 2000. Chapter 11, Definitions. *www.cdc.gov/pertussis/outbreaks/guide/downloads/chapter-11.pdf.*

[17] *See, e.g.,* EPA, *Protect Your Family from Exposures to Lead* (Drinking Water), *www.epa.gov/lead/protect-your-family-exposures-lead#testdw;* EPA, *Basic Information about Lead in Drinking Water, https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water.*

c. Visual Assessment of Housing Units in the Tenant-Based Rental Assistance Program

Comment: Many commenters (28) claimed that the visual assessment protocol in the Housing Choice Voucher (HCV) Program, which provides tenant-based rental assistance, was insufficient to protect children from lead, and that a more rigorous assessment protocol was needed when children under age six (6) will be moving into a unit of target housing with the family receiving assistance through an HCV. Several commenters also recommended that evaluations should be conducted on every unit in a building, regardless of subsidy.

HUD Response: As noted in this preamble, the primary purpose of this rule is adopting the revised definition of ''elevated blood lead level'' in children under the age of six (6), and the response in cases of children with such a level who reside in federally-assisted target housing. Therefore, pre-occupancy activities are outside the scope of this rule, as are activities in non-federally-assisted units.

Comment: Many commenters (20) addressed the need for assessment of other assisted units in the same property as that of a child under age six (6) with an EBLL in which a child under age six (6) resides or is expected to reside (''other units''), which is within the scope of this rule, as part of the response to the child with an EBLL. Most commenters (18) recommended that HUD strengthen the assessment in the units of other households receiving tenant-based rental assistance to a risk assessment, or, in the alternative, a lead hazard screen.[18] Commenters noted both that the CDC strongly recommends a more stringent risk assessment, and that lead hazards do not discriminate among victims by the type of subsidy they receive.

HUD Response: Under this final rule, risk assessments will be required in other HUD-assisted units in which a child under age six (6) resides or is expected to reside, and the common areas servicing those units. HUD has always distinguished between pre-occupancy and post-occupancy activities in assisted housing. Prior to this final rule, the LSHR distinguished between general, pre-occupancy activities in tenant-based rental assistance housing units and specific responses to the identification of a child under age six (6) with an environmental intervention blood lead level (EIBLL)[19] who had a housing-related lead exposure. It did so by going beyond the visual assessment and paint stabilization requirement of pre-occupancy activities to requiring risk assessments and interim controls for EIBLL cases.[20] These measures are being extended by this final rule to the other housing choice voucher units in properties where children under age six (6) reside or are expected to reside.

HUD is basing this approach on the CDC guidance that other housing units should receive the same evaluation and controls as the index unit, while narrowing the application of that guidance by not requiring action where statutory authority clearly does not support HUD require action (*e.g.,* in unassisted units), and reducing the overall costs and increasing the effectiveness of the controls by requiring a risk assessment to identify with specificity the lead-based paint hazards in the other units before the controls are undertaken.

The increased burden on a landlord of a family receiving tenant-based rental assistance is expected to be modest, because a certified risk assessor will already be at the property to conduct the environmental investigation in the index unit, and the cost of the risk assessment will be borne by the designated party, *i.e.,* the public housing agency, or the HOME or HOPWA grantee, as applicable. Giving that risk assessor an expanded scope of work to conduct a risk assessment in other units will be an additional cost to the designated party, as will the cost to the owner for control of any lead-based paint hazards that would not have been detected by visual assessments conducted as part of the initial and periodic inspections of the units, but were detected by the risk assessment. These other units of an owner who has been properly implementing the required ongoing lead-based paint maintenance program are more likely not to have hazards and, if they are present, for them to be fewer in number and less extensive. This risk assessment, and the interim control of any lead-based paint hazards found will provide substantial additional protection to the other children under age six (6) residing or expected to reside in the property, and increased liability protection for the owner as a result of the more comprehensive evaluation of the housing and resulting lead hazard control, in comparison to the otherwise routine use of the visual assessment and paint stabilization process.

Similarly to how HUD considered commenters' arguments related to other tenant-based rental assisted units and is responding by requiring risk assessments and interim controls for such units in this final rule—instead of visual assessment and paint stabilization, as proposed—HUD is applying the commenters' logic to housing receiving project-based assistance of up to $5,000 per unit per year by requiring risk assessments and interim controls in this final rule, instead of visual assessment and paint stabilization, as proposed.

The Regulatory Impact Assessment has been revised accordingly and continues to show that the benefits of this regulation substantially outweigh the costs.

d. Sampling of Other Units in Large Properties

Comment: Two commenters inquired if the sampling protocols for larger properties (with over 20 housing units in properties built before 1960, or over 10 units in properties build between 1960–1977) in the existing HUD Guidelines' Chapter 7 would apply to buildings where a child under age six (6) has developed an EBLL, and the child's unit was found to have lead-based paint hazards, so that examinations of other housing units in the property were required.

HUD Response: As noted in the preamble to the proposed rule, the existing housing unit random sampling protocols for multi-family housing would apply, because, procedurally, they are not being amended by this rule, and substantively, because the statistical foundation for the protocols applies to the EBLL situation just as it does to lead-based paint inspections and risk assessments in general.

e. Interim Controls

Comment: Four commenters recommended that, for at least the types of housing affected under this rule, if not all housing under the LSHR, HUD require abatement, as opposed to mere interim controls, in a unit in which lead-based paint hazards (or, for a visual assessment, deteriorated painted surfaces) were found.

HUD Response: HUD is aware from its experience with its lead hazard control grant program that there can be a substantial cost difference between interim controls of lead-based paint

[18] The EPA's work practice standards for conducting lead hazard screens and lead risk assessments are provided at 40 CFR 745.227(c) and (d), respectively; both may be conducted only by a person certified by EPA or an EPA-authorized state or tribal lead-based activities program as a risk assessor.

[19] A confirmed concentration of lead in whole blood equal to or greater than 20 μg/dL (micrograms of lead per deciliter) for a single test or 15–19 μg/dL in two tests taken at least 3 months apart, per 24 CFR 35.110.

[20] *See* 24 CFR 35.730(a).

hazards and abatement of them. As noted in the RIA for the proposed rule, the interim controls used under HUD's lead hazard control grant programs were found to be effective for at least 6 years following the intervention, with window replacement and lead hazard control effective after 12 years. Thus, even if an owner did not implement an ongoing lead-based paint management program after the interim control work (such a program is not required under the grants), the duration of the protection of the children's environment regarding lead in the housing would extend beyond the child's sixth birthday. If the owner did implement the management program, as the LSHR requires, the duration of the protection would be at least as long as the period found for protection resulting from work under the grants, and, HUD believes, longer.

HUD also notes that, as described above, the evaluation activity in the other assisted units with a child under age six (6) is being changed from a visual assessment, as proposed, to a risk assessment.

Therefore, HUD declines to modify the proposed rule. However, the designated party or owner may choose to require abatement in circumstances when they do not believe interim controls will sufficiently protect their resident children under age six (6).

f. Update the Standards for Lead Based Paint, Lead Based Paint Hazards and Various Lead Hazard Control Protocols

Comment: Eight commenters requested that HUD, either alone or in partnership with EPA, update various other lead regulations, standards and protocols.

HUD Response: Such changes are beyond the scope of this rulemaking. HUD will collaborate with EPA, as it considers any updates to revise those standards. In the interim, HUD will continue to use existing protocols, including paint-testing requirements,[21] and lead-safe work practices requirements that were of specific interest to some commenters.

HUD declines a commenter's request to further define the responsibilities of particular owners of a building with multiple owners as related to notices of lead-based paint hazard evaluation and reduction, because its interest is in having the designated party provide notices to occupants as required, not in establishing criteria for which of the ownership partners within the designated party, which is as a whole, responsible for complying with applicable requirements (*see* § 35.110), should carry out that responsibility. That is an internal matter for the partners to decide.

g. Pregnant Women Under the LSHR

Comment: Two commenters requested that HUD extend the protections of the LSHR in child-occupied units to units where a pregnant woman resides.

HUD Response: The LSHR has always defined units occupied by pregnant women as units where a child is expected to reside. The Title X and LSHR definitions of ''target housing'' encompass units where a child under age six (6) ''resides or is expected to reside,'' and, in the LSHR, HUD further clarified the phrase ''expected to reside'' to mean that ''there is actual knowledge that a child will reside in a dwelling unit . . . If a resident is known to be pregnant, there is actual knowledge that a child will reside in the dwelling unit.'' (*See,* § 35.110) That definition remains unchanged by the current rule.

h. Landlord Exemptions

Comment: Multiple commenters (16) made recommendations about the provisions that would exempt landlords in certain cases from performing additional risk assessments in their building once a child with an EBLL had been identified. Some of these commenters (5) felt the exemptions were too broad and would not sufficiently protect the other residents of a building that had exposed at least one child to a lead hazard. Most of these commenters (11) felt that the exemptions should be expanded, either for work done in the last 24 months, for work done while the same family occupied the unit, or until such time as the CDC updated its EBLL guidance, or if a unit is scheduled to undergo redevelopment.

HUD Response: HUD's rule provides that a lead risk assessment remains applicable for 12 months. HUD will continue to use this period (vs. the longer 24 months, or the indefinite period of a family's continued occupancy in a unit, for which there is no reason to believe that hazards would not form) in the exemption criteria for when the owner has documentation, ''throughout the 12 months preceding the date the owner received the environmental investigation report, of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-based paint management requirements.'' Given that the LSHR requires retention of documentation of the owner's compliance with these operational LSHR requirements for the period when ongoing lead-based paint maintenance is required, and for at least 3 years beyond that period, the absence of such documentation for just the past 12 months allows for a reasonable inference that the owner has not complied with the operational requirements of the LSHR, so that a risk assessment is required in the other units. Thus, HUD declines to change this implementation period.

HUD also declines to exempt units that are scheduled for redevelopment. Redevelopment timelines are often uncertain by many months, and it would violate the intent of the LSHR to leave a child exposed to potential lead hazards for such an uncertain length of time. If preliminary work on the redevelopment is sufficiently far advanced that building occupant vacating and/or relocating is under way with completion of vacating and/or relocating and the start of construction both scheduled to be within 45 days (*i.e.,* the sum of the 15-day period for conducting the environmental investigation of the index child's unit and common areas servicing that unit and the 30-day period for conducting lead hazard control there) after the designated party was notified of a child under age six (6) with EBLL, the lead activities need not be conducted in one or more of the other assisted units with a child under age six (6) by that due date if the family in each of those un-assessed or uncontrolled units is relocated within 15 days after the designated party received the environmental investigation report, with the lead safety of the family's destination housing meeting the criteria of the preface to § 35.1345(a)(2), and with the family continuing to receive housing assistance without interruption and having their relocation costs covered. Making the original housing lead safe is required by the LSHR (subparts H, J, and/or L, as applicable) to be part of the redevelopment.

At the same time, HUD understands that evaluating additional units poses a burden for owners, and there are some circumstances where documented past performance makes the possibility of future lead hazards substantially less likely. Therefore, HUD also declines to make the exemptions more stringent.

6. Time Available To Complete Work

Comment: Multiple commenters (15) made recommendations about timelines for investigating lead hazards,

[21] *E.g.,* by requiring the paint testing before interim controls involving RRP work in assisted target housing covered by the LSHR be conducted by a certified lead-based paint inspector or risk assessor (24 CFR 35.110), versus a renovation contractor's using a spot-test kit (40 CFR 745.82(a)(2)).

completing hazard control work, and relocating families if necessary. Most of these commenters (11) felt that the timelines were aggressive and may be unrealistic for owners, particularly owners who operate under complex procurement rules, or owners in communities without adequate numbers of certified risk assessors, lead hazard control workers, and firms who employ them. Other commenters (4) felt that the timelines were too lax, and left families exposed to lead hazards in their home longer than necessary.

HUD Response: None of the commenters provided data on lead hazard control activity durations, temporary relocation costs, or the health effects of lead exposure for the number of days they recommended versus the number of days proposed to support their recommendations. Accordingly, HUD determined that it would retain the timelines in the currently codified LSHR, as proposed. If a designated party or owner believes they will be unable to meet the timelines in a specific circumstance, they should discuss their concerns with HUD when they report the EBLL.

HUD also declines to apply a business day schedule instead of a calendar day schedule to these evaluation and hazard control timelines. The primary victims of lead poisoning are children, who are most likely to be exposed to hazards in their home on non-business days, and many risk assessors and lead hazard control contractors are available to work on weekends for high priority projects, such as responding to the case of a child under age six (6) with an EBLL. With respect to providing notifications to HUD, for which the rule uses business day schedules, HUD will adopt the practice already used by HUD for hearings before hearing officers, that when the due date is a Saturday, Sunday, national holiday, or other day on which the relevant HUD office is closed, the due date is extended until the end of the next following business day. (*See,* 24 CFR 26.11(a).)

7. Penalties for Noncompliance

Comment: Several commenters (11) recommended that this rule include enforcement remedies and civil money penalties for non-compliance.

HUD Response: The Lead Disclosure Rule, also issued under Title X, allows for violators to be subject to civil money penalties. (*See,* 24 CFR 35.96, implementing 42 U.S.C. 4852d(b)(1).) In contrast, as the preamble to the original LSHR states (at 64 FR 50168), ''The Lead-Based Paint Poisoning Prevention Act does not provide any independent enforcement provisions. Remedies will vary based on which [assistance] program's requirements have been violated.'' For example, a designated party or owner not in compliance with the LSHR, including this rule, may be considered in default of its regulatory agreement or annual contributions contract, as applicable, with the Department. Noncompliance may also result in the designated party or owner being debarred from receiving assistance from the Department or denied future participation in HUD or federal programs. A designated party or owner in noncompliance may be forced to surrender grant funds, or may be otherwise subject to civil money penalties or other sanctions. HUD plans to enhance its monitoring for LSHR compliance, but does not have the authority to create penalties under this rule or the currently codified LSHR.

8. Future Changes in CDC Recommendations

Comment: Multiple commenters (20) recommended keeping the LSHR synchronized with expected future CDC guidance that may further change the blood lead level that triggers an investigation. A majority (10) of these commenters recommended that future updates to CDC guidance automatically cause HUD's guidance to change. The remainder recommended variations on using CDC's current definition, including allowing the level to decrease, but not increase; creating local levels based on the data from a given geography; changing the terminology from CDC's current usage; or simply waiting for the CDC to update their guidance again before amending the LSHR.

HUD Response: The purpose of this rulemaking is to bring HUD's requirements into alignment with CDC guidance in regard to environmental investigations for cases of elevated blood lead levels in children under age six (6), while placing the minimum necessary burden on assisted property owners and other designated parties. To do so, while also maximizing the effectiveness of environmental investigations and remedial actions taken as a result of those investigations, HUD proposed that the EBLL under this rule would be a confirmed blood lead level at least that for which U.S. Department of Health and Human Services recommends that an environmental intervention be conducted. This level may be the CDC's reference range value, as it is at the publication of this rule, or it could be higher, if CDC found recommending environmental interventions to be appropriate only at a higher level than the reference range value. Accordingly, HUD declines to apply any of the recommended variations.

To respect the potential burden placed on assisted property owners before adjusting its EBLL standard in the LSHR, and to provide transparency in its decision-making, HUD will provide for public notice and comment as described in the proposed rule so that potentially affected parties, including designated parties, their property management firms, risk assessment firms, renovation firms, and tenants, and advocates for all of these parties will have the opportunity to provide comments on proposed EBLL changes. Therefore, HUD declines to modify the proposed process for revising the blood lead level in children under age six (6).

9. Timing of Implementation

Comment: Half of the commenters (29) addressed the issue of the rule's effective date or implementation date. Of these, some recommended a longer implementation time to adequately prepare, and some recommended a shorter implementation time to begin increasing the protection of children's health more rapidly. A few commenters felt that the initially proposed 6 months was appropriate.

HUD Response: HUD is mindful of the need to update policies and procedures for planning purposes, and that, as one commenter noted, ''it is doubly important that the rule is implemented in such a way that Housing Authorities will be able to comply.'' That commenter, and others, noted that CDC has not yet revised its 2012 reference range value, and recommended waiting until some period after CDC's update. HUD believes it likely that CDC will issue its update in 2017, but it does not want to delay for an indeterminate period the additional protections for children with blood lead levels in the range between the currently codified LSHR's EIBLL threshold and this rule's proposed EBLL threshold. Therefore, HUD cannot agree with either the majority or minority of commenters and declines to implement the rule faster than 6 months, nor after a longer period. Instead, the compliance date of the rule will be 6 months from publication, as proposed.

10. Other Issues

a. Low Income Communities, Communities of Color, and Affirmatively Furthering Fair Housing

Comment: Five commenters requested that HUD consider that lead poisoning occurs more frequently in low-income communities and communities of color,

and that, furthermore, this may have implications under its fair housing rules.

HUD Response: HUD agrees that research clearly shows higher incidence of EBLLs in low-income communities and in communities of color.[22] However, the fair housing implications of this information are governed by fair housing statutes and regulations, and are therefore beyond the scope of this rulemaking; this rule needs to be issued with nationwide applicability. Nevertheless, such comments will be considered as HUD develops future outreach and enforcement strategies for implementing this rule.

b. EPA's Renovation, Repair, and Painting Rule

Comment: Five commenters recommended clarifying and making more explicit the relationship between the LSHR and the EPA's Renovation, Repair and Painting Rule (RRP Rule, 40 CFR part 745, especially subparts E and Q; implementing 15 U.S.C. 2682(c), Renovation and remodeling).

HUD Response: The original LSHR predated the RRP Rule, and therefore could not reference it explicitly. The RRP Rule defines ''renovation'' broadly in the context of lead-based paint, saying in essence that the term ''means the modification of any existing structure, or portion thereof, that results in the disturbance of painted surfaces, unless that activity is performed as part of an abatement . . . [but not] minor repair and maintenance activities,'' (40 CFR 745.83) where ''abatement'' and ''minor repair and maintenance activities'' are defined for purposes of that rule at 40 CFR 745.223 and 745.83, respectively. Accordingly, most of the lead-based paint hazard reduction activities to be conducted as a result of the environmental investigation of the index unit and the risk assessment in other units, will be renovations covered by the RRP Rule, and must be conducted by contractors and individual renovators who are certified renovation firms or certified renovators. The relationship between this rule and the RRP Rule needs to be made explicit for the sake of transparency; doing so will have the additional benefit of making the other portions of the LSHR that require the use of certified renovation firms and certified renovators more transparent. Because this requirement has been operationally in effect for the LSHR since the RRP Rule went into full effect, clarifying this creates no change in the burden or benefits of implementing the LSHR.

Accordingly, the relationship between the RRP rule and the LSHR is being made explicit through this rulemaking.

First, for the sake of transparency, HUD is adding ''renovation'' to the list of ''activities'' within the scope of the definition of ''certified'' in 24 CFR 35.110, along with the current listing of ''risk assessment, lead-based paint inspection, or abatement supervision.'' HUD notes that the scope of activities in its definition of ''certified'' is broader than EPA's scope of ''Lead-based paint activities,'' which they define at 40 CFR 745.223, because HUD's definition uses the unmodified term ''activities'' and includes, in the definition, the phrase ''such as'' the listed activities of ''risk assessment, lead-based paint inspection, or abatement supervision,'' while the EPA definition is limited to the specific listed activities of ''inspection, risk assessment, and abatement.'' Because HUD's definition is broader, this clarification in the definition will have no effect on the operations of HUD, owners, contractors or employees.

Second, the current LSHR language on interim controls training requirements in § 35.1330(a)(4)(iii), which allowed for approval of certain lead-safe work practices courses by HUD after consultation with the EPA, will be replaced with wording that recognizes renovator courses accredited under the EPA's or by an EPA-authorized state or tribe's renovation program.

HUD also notes that ''abatement'' of lead-based paint or lead-based paint hazards as defined by EPA at 40 CFR 745.223, and by HUD in the LSHR at 24 CFR 35.110, may be conducted under the LSHR when interim controls are required, because the LSHR already allows conducting additional lead-based paint hazard evaluation or reduction beyond the minimum under the rule. Abatements must be conducted, in accordance with the work practice standards developed by EPA at 40 CFR 745.227(e) or by an EPA authorized state or tribal lead-based paint activities program by certified abatement supervisors and certified abatement workers. HUD encourages the use of abatement as a permanent (at least 20-year-long, or eternally, in the case of paint removal abatement) method of addressing exposures from lead-based paint, dust, and soil in a home, particularly where it may be cost-effective, such as during a major rehabilitation (*e.g.,* a ''gut rehab'').

c. Other Partnerships

Comment: Five commenters suggested partnerships, or approaches to partnerships that would aid in the implementation of the LSHR.

HUD Response: HUD welcomes these suggestions and fully expects to engage in numerous partnerships to fully implement the LSHR and protect America's children from lead poisoning. However, codifying these partnerships in regulation is unnecessary, so HUD declines to do so.

d. Other Sections of the LSHR Not Amended

Comment: Two commenters recommended that HUD amend the LSHR's subparts C (Disposition of Residential Property Owned by a Federal Agency Other Than HUD), E (which had been proposed in the original LSHR to cover Single Family Insured Property,[23] but was reserved in the final LSHR rulemaking, with 24 CFR part 200, subpart O, being revised at that time) and F (HUD-Owned Single Family Property).

HUD Response: HUD appreciates these suggestions and, while noting that they are outside of the scope of the current rulemaking, will consider future rulemaking to amend these subparts.

e. Accessibility of Inspection Reports

Comment: One commenter recommended protecting a renter's ability to access inspection reports.

HUD Response: This issue is governed by the Lead Disclosure Rule (24 CFR part 35, subpart A) and is therefore outside the scope of this rule.

f. Uniform Physical Condition Standards for the Voucher Program (UPCS–V) Demonstration

Comment: One commenter requested clarifying language on the relationship between the LSHR and the UPCS–V pilot program.

HUD Response: As noted on HUD's Web site (*http://portal.hud.gov/hudportal/HUD?src=/program_offices/public_indian_housing/reac/oed/upcs-v*), to help improve tenant safety and HUD's oversight of the HCV program, HUD is introducing the UPCS–V inspection protocol with new measures to enhance the consistency and objectivity of the inspection process, and provide more information about the condition of individual housing units. The UPCS–V Demonstration is HUD's formal mechanism to test the protocol with up to 250 public housing agencies

[22] See, *e.g.,* CDC, *Lead: Prevention Tips, http://www.cdc.gov/nceh/lead/tips.htm;* CDC, *Recommendations for Blood Lead Screening of Medicaid-Eligible Children Aged 1–5 Years: an Updated Approach to Targeting a Group at High Risk* (Aug. 2009), *available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5809a1.htm.*

[23] Proposed 24 CFR part 36, subpart E; 61 FR 29170–29232, at 29210 (*see also* 29180), June 7, 1996.

(*www.regulations.gov/document?D=HUD-2016-0044-0001*).

Participation in the UPCS–V pilot program does not affect whether or how a housing unit or property is covered under the LSHR or this rule amending the LSHR, nor an owner's or designated party's responsibilities under the LSHR. Questions on specific interactions between the LSHR and the UPCS–V pilot, such as one commenter's question, ''If a PHA does not complete the hazard reduction on a voucher unit, would that dwelling be in violation of UPCS–V?'', are outside the scope of this rulemaking, and should be directed to HUD's Office of Public and Indian Housing.

g. Liability Safeguards

Comment: One commenter expressed concern that because of the lapse in time between CDC issuing guidance and HUD issuing a proposed rule on EBLLs, tenants of HUD-assisted housing may decide to take legal action against PHAs once they learn that the PHA was not in compliance with CDC guidelines. The commenter requested that the LSHR include, ''Safeguards that protect PHAs from any litigious behavior that may result from HUD's delayed rulemaking process.''

HUD Response: HUD cannot speculate on the merits or costs of any potential litigation, nor to address PHAs' compliance with other federal agencies' guidance, as both are outside the scope of this rulemaking.

h. Determining the Responsible Party

Comment: One commenter requested that, ''HUD clarify that there is a single responsible party in areas of the proposed rule where there is an option for one of two entities to assume responsibility. As currently written, sections of the rule would assign responsibility to either the PHA (the designated party) or the property owner.''

HUD Response: As defined by the LSHR, a designated party is an entity responsible for complying with applicable requirements of the rule.

This commenter does not identify which LSHR subparts are of concern to it, but an examination of subpart H, L, and M, with which public housing agencies may be involved, shows that subparts H and L each specify only one such entity; so the concern must be for subpart M (Tenant-Based Rental Assistance). Within that subpart, §§ 35.1200(b)(2) through (6) identify the designated party for the assistance programs covered by each of those regulatory paragraphs. In the example of the HCV program, paragraph (2) has identified the public housing agency as the designated party, with responsibilities under certain provisions of that subpart (*e.g.,* engaging an inspector on its behalf to conduct the pre-occupancy visual assessment (*see,* § 35.1215(a)(1))) and the owner has had certain responsibilities under other provisions of that subpart (*e.g.,* stabilizing the deteriorated paint surfaces identified by the visual assessment (*see,* § 35.1215(b))). Regarding EBLL cases under the HCV program, this rule as proposed and made final here uses the same approach: The designated party, *i.e.,* the PHA, is responsible for the environmental investigation and, if needed, verification of the case (*see,* §§ 35.1225(a) and (b)), while the owner is, for the lead-based paint hazard reduction (*see,* § 35.1225(c)).

Similarly, in the example of tenant-based rental assistance under the HOME Investment Partnerships Program (HOME) (*see,* § 92.209), under which HUD's Office of Community Planning and Development (CPD) awards grants to state and local governments (''participating jurisdictions'') that provide rental assistance to households and contract with owners of the units they rent, the designated party for the unit occupied by a household receiving tenant-based rental assistance is the participating jurisdiction, or if the tenant-based rental assistance program is administered by a subrecipient, that entity.

Also, the Housing Opportunities for Persons with AIDS (HOPWA) Program provides tenant-based rental assistance to households as an eligible activity (*see,* § 574.300(b)(5)). HUD's CPD office awards HOPWA entitlement formula grant funds to state and local government grantees (''eligible states and qualifying cities'') and HOPWA competitive grant funds to state, local government and non-profit grantees. In this example, if a grantee provides rental assistance to households and contracts directly with owners of the units they rent, the designated party for a unit in which the assisted household occupies is the grantee. In another example, if the tenant-based rental assistance program is administered by a project sponsor, the designated party for a unit in which the assisted household occupies is the project sponsor.

i. Ongoing Lead-Based Paint Maintenance Program

Comment: One commenter recommended that the written notice provided to each dwelling unit asking occupants to report deteriorated paint and, if applicable, failure of encapsulation or enclosure, along with contact information, be provided to each individual tenant (*see,* § 35.1355(a)(7)). The same commenter recommended adding ''and reporting deteriorated paint'' to the heading of § 35.130, Lead hazard information pamphlet, because the reporting notification required by § 35.1355(a)(7) as discussed above, goes to the recipients of the lead hazard information pamphlet provided under § 35.130. The same commenter suggested adding a paragraph (8) to § 35.1355(a), to require that each property covered by the ongoing lead-based paint maintenance requirement must have a written maintenance plan on how to address lead-based activities and who will be able to conduct the activities.

HUD Response: As to the first suggestion, typical notification practice is to provide one notification on a housing operations topic to the dwelling unit, rather than multiple copies for each adult in the unit. HUD will consider the effectiveness and burden of a change for this notification as it develops future rulemaking. As to the second suggestion, while § 35.130 pertains to providing a pamphlet rather than property-specific information, this comment raises the idea of having the Lead Disclosure Rule disclosure form, for at least housing covered by the LSHR, include a confirmation that the reporting notification was provided. HUD will consider the feasibility of such an addition in its implementation of the LSHR.

As to the third suggestion, this would implement the HUD Guidelines Chapter 6, Ongoing Lead-Based Paint Maintenance, Step-by-Step Summary, item 1, that ''owners should develop a written program [regarding] lead-safe maintenance that apply to each pre-1978 property and should assign responsibilities,'' and similarly at unit III.B, Assignment of Responsibilities, of that chapter. HUD will consider this suggestion in further rulemaking.

j. Technical Corrections

Comment: One commenter noted that the grammar of subpart D might be incorrect.

HUD Response: The commenter's insight was accurate, and a technical correction is necessary. The second sentence of proposed § 35.325, Child with an elevated blood lead level, paragraph (b), begins by stating that, ''The risk assessments would be conducted within'' a certain period, while the other requirements of the paragraph are specified by using ''shall'' instead of the conditional ''would;'' in addition, ''shall'' is used in the

corresponding provisions of other sections. HUD is replacing ''would'' in this instance with ''shall.''

Comment: One commenter noted that § 35.155 implies that occupants would conduct lead-based paint hazard evaluation or reduction, a requirement which would not be supported by Title X.

HUD Response: HUD is also making a technical correction to § 35.155 by changing both instances of ''designated party or occupant'' to ''designated party or owner,'' to correct the language regarding who may be required to conduct additional lead-based paint hazard evaluation or reduction beyond the minimum under the LSHR. While occupants are mentioned in the LSHR many times, the LSHR does not establish any requirements for them to conduct lead-based paint hazard evaluations or reductions. (An assisted-property owner who resides in one of the units of a property covered by the LSHR is subject to that rule's requirements as the owner, not as an occupant.) This correction is particularly timely because of the requirements being amended by this rule for owners who are not designated parties.

C. Public Comments in Response to HUD's Questions

HUD is particularly grateful for the comments responding to specific questions:

1. To facilitate effective HUD monitoring of responses to a case of an elevated blood lead level, the proposed rule would have designated parties provide documentation to HUD that the response actions have been conducted in the child's unit and in all other assisted units with a child under age six (6), or if there are such other units, that the designated party has been complying with the LSHR for the past 12 months, and need not evaluate those other units.

a. Is this approach sufficient for HUD to effectively monitor response actions in these cases, and why? Are there areas in which reporting and oversight could be strengthened?

b. Can the approach to monitoring response actions in these cases be streamlined while maintaining its effectiveness, and if so, how?

Comment: Many commenters provided input regarding the information that needed to be shared to effectively monitor the responses to a case of an elevated blood lead level.

HUD Response: Commenters took a wide variety of positions, which are primarily summarized under comments section III.B.4 of this preamble entitled, Coordination Between the Involved Parties. The sub-issue of when a designated party need not evaluate other units was discussed in comments and responses in section III.B.6 of this preamble entitled, Landlord Exemptions.

2. *Regarding the definition of elevated blood lead level in the proposed rule, is the definition appropriately protective of the health of children in assisted housing covered by the rule? Too protective? Not protective enough? Why?*

Comment: Commenters were nearly unanimous in expressing their support for aligning HUD's regulations with the current definition of elevated blood lead level from the CDC. Commenters did have concerns that the LSHR as proposed was not protective enough, as discussed in comments and responses provided in section III.B.1, Primary Prevention, and section III.B.5, Technical Concerns. No commenters felt that the rule was too protective of America's children, however, some commenters worried that they would not have sufficient resources available to meet their obligations under the rule.

HUD Response: HUD responds to these concerns in section III.B.2, Resources Available.

3. *Regarding the set of types of housing assistance covered by the proposed rule (i.e., in the covered subparts D, H, I, L, and M), is this set appropriately protective of the health of children in assisted housing?*

a. If it is too protective, why, and which types of housing assistance should be removed from the proposed rule?

b. If it is not protective enough, why, which additional type or types of housing assistance should be included, and how would sufficient resources be provided to ensure implementation and monitoring of the rule in that additional assisted housing?

Comment: No commenters felt that certain types of housing assistance should be removed from the proposed rule, although several commenters recommended that Public Housing's history of superior performance entitled it to a lower standard of monitoring. (As discussed in commenting subsection 1, Primary Prevention, the study did not have the capacity to address the performance of particular housing assistance programs.) A few commenters felt that additional HUD programs should be included in the rule.

HUD Response: HUD response to these comments are provided in section III.B.11.d of this preamble entitled, Other Sections of the LSHR Not Amended.

Comment: Two commenters also suggested the LSHR should be extended to the Low-Income Housing Credit program administered by the United States Treasury.

HUD Response: According to the Low Income Housing Credit regulations, 26 CFR 1.42–5(d), the state allocating agency may opt to use HUD's Uniform Physical Condition Standards as the compliance standard, in which case the LSHR applies.

4. If interim controls or abatement in a housing unit takes longer than 5 calendar days, or if other occupant protection requirements of 24 CFR 35.1345(a)(2) are not met, the occupants of the unit shall be temporarily relocated before and during lead-based paint hazard reduction activities.

a. HUD is seeking data on the fraction of lead hazard control activities that take longer than 5 calendar days, including the type of activity (e.g., interim control or abatement; the hazard control method used (e.g., if abatement, component removal, paint stripping, enclosure, encapsulation, etc.), the extent of the work, the reason that the activities cannot be completed within 5 calendar days, whether the housing is a single family, duplex, triplex, quad, or multifamily housing, whether it is located in an urban, suburban, or rural area, whether the EPA has authorized the state to administer the applicable lead certification program (i.e., renovation or abatement), and other factors that are causing temporary relocation to be required under the rule.

b. HUD is seeking information on the costs of temporary relocation, on a per day basis (average amount or day-specific amounts, as is available), including breakouts of expenses for such categories as lodging, transportation, meals, and incidental expense amounts, if the information is available that way, or as lump sum per-day or per relocation period amounts.

Comment: HUD did not receive any data (let alone data supported by robust quality assurance) on either the time work took, or the costs of relocation. A few anecdotal comments were provided, *e.g.,* that it can be hard to find good lead professionals and contractors in rural portions of the country, and that the costs of temporary stays in Manhattan can be quite high.

HUD Response: In the absence of actionable data, HUD left the current standards unchanged. As HUD stated in responding to comments in subsection 2, Resources Available, of this preamble, HUD is encouraging designated parties and owners in remote rural areas to contact HUD if they encounter difficulty

in finding lead professionals and contractors, to see if the Department can help find them, and will keep these comments in mind as it implements this rule.

III. Findings and Certifications

A. Regulatory Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. OMB reviewed this final rule under Executive Order 12866 (entitled ''Regulatory Planning and Review''). This rule was determined to be a ''significant regulatory action,'' (but not economically significant) as defined in 3(f) of the order. The docket file is available for public inspection electronically at Federal eRulemaking Portal at *http://www.regulations.gov* under the title and docket number of this rule, HUD–2016–0096.

B. Regulatory Impact Assessment

HUD is publishing, concurrently with this final rule, its final Regulatory Impact Analysis (RIA) that examines the costs and benefits of the final regulatory action in conjunction with this final rule, organized into three sections: Cost-Benefit Analysis; Sensitivity Analysis; and Economic Impacts. The RIA is available on-line at: *http://www.regulations.gov.* The major findings in the RIA are presented in this summary.

The analysis of net benefits reflects costs and benefits associated with the first year of hazard evaluation and reduction activities under the final rule. These costs and benefits, however, include the present value of future costs and benefits associated with first year lead-based paint hazard reduction activities. Similarly, the benefits of first year activities include the present value of lifetime earnings benefits for children living in the affected unit during that first year, and for children living in that unit during the second and subsequent years after lead-based paint hazard reduction activities.

In regard to the discount rate used for this regulatory analysis, HUD is using both the 3 percent, and the 7 percent discount rates in accordance with OMB guidance in OMB Circulars A–4, Regulatory Analysis (*https://www.whitehouse.gov/omb/circulars_a004_a-4/*), and A–94, Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs (*https://www.whitehouse.gov/omb/circulars_a094*). By presenting results using both 3 and 7 percent discount rates, HUD is providing a broad view of costs and benefits.

Employing a 3 percent discount rate of the lifetime earnings estimates, the RIA concludes that monetized benefits of activities have a present value of $98.96 million; while first-year costs are $29.04 million. Thus the estimated net benefit is $69.92 million using a 3 percent discount rate. If a 7 percent discount rate is used for lifetime earnings benefits, the monetized present value of the benefits of the final rule are estimated to be $32.15 million, with estimated first year costs remaining at $29.04 million. The final rule would therefore be seen as having a net benefit of $3.11 million using the 7 percent discount rate.

Further, the monetized benefit estimates represent a lower bound on benefits, as they only account for lifetime earnings resulting from cognitive impacts on children under age six. Reductions in lead exposure would be expected to result in additional health benefits for these children, as well as older children and adults living in or visiting the housing units addressed by the rule. Such additional benefits include avoidance of harmful symptoms of lead poisoning such as: Decreased attention, increased impulsivity, hyperactivity, impaired hearing, slowed growth, and delayed menarche.[24]

Costs are overestimated, such as by assuming that only one environmental investigation is conducted in a property at a time, that that each housing unit has at most one child with an EBLL. The analysis also assumes that no designated parties are eligible for (nor take, if they are eligible) the exemptions from conducting a risk assessment of other housing units covered by this rule, and that each index unit has lead-based paint hazards, whether or not the environmental investigation identifies non-lead-based paint lead hazards. These assumptions would tend to overestimate both the costs and benefits of the regulation.

That the benefit-cost calculation giving lower weight to future generations shows a smaller net benefit is not surprising, given that the monetized benefits of the rule pertain to the future earnings of children under age six (6), while the costs pertain to the designated parties of the housing in which the young children currently reside. As noted above, the calculation included monetized benefits but not non-monetized quality of life factors associated with children's lower intelligence, fewer skills, and reduced education and job potential, and adults' cognitive function decrements, psychopathological effects (self-reported symptoms of depression and anxiety), hypertension, coronary heart disease, blood system effects (decreased red blood cell survival and function, and altered heme synthesis), male reproductive function decrements, among other effects.[25]

C. Paperwork Reduction Act Statement

The information collection requirements contained in this rule have been approved by or are pending with the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2539–0009. In accordance with the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid OMB control number.

D. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), HUD has reviewed this final rule before publication and by approving it for publication, certifies that the regulatory

[24] *See, e.g.,* CDC, *Educational Interventions for Children Affected by Lead* (Apr. 2015), *available at https://www.cdc.gov/nceh/lead/publications/educational_interventions_children_affected_by_lead.pdf;* Selevan SG, Rice DC, Hogan KA, Euling SY, Pfahles-Hutchens A, Bethel J, *Blood lead concentration and delayed puberty in girls, N Engl J Med.* 17;348(16):1527–36, (Apr. 17, 2003), *available at www.nejm.org/doi/full/10.1056/NEJMoa020880;* Mayo Clinic, *Lead Poisoning: Symptoms and Causes, http://www.mayoclinic.org/diseases-conditions/lead-poisoning/symptoms-causes/dxc-20275054.*

[25] *See, e.g.,* CDC, *Educational Interventions for Children Affected by Lead* (Apr. 2015), *available at https://www.cdc.gov/nceh/lead/publications/educational_interventions_children_affected_by_lead.pdf;* Mayo Clinic, *Lead Poisoning: Symptoms and Causes, http://www.mayoclinic.org/diseases-conditions/lead-poisoning/symptoms-causes/dxc-20275054.*

requirements would not have a significant economic impact on a substantial number of small entities, other than those impacts specifically required to be applied universally by the statute. As discussed below, the requirements of the final rule are applicable only to a limited and specifically defined portion of the nation's housing stock. To the extent that the requirements affect small entities, the impact is generally discussed in the economic analysis that accompanies this final rule. Specifically, the economic analysis estimated the number of small entities and voucher owners that would be impacted by the rule, as well as the number of index units and other assisted units to be evaluated and, possibly, based on the evaluation, having lead hazard control work done.

HUD has estimated that this final rule affects two types of small entities, Public Housing Agencies (PHAs) and private lessors and owners. There are 2,334 small PHAs, defined as PHAs with fewer than 250 units, which make up for 75 percent of the public housing stock across the country. HUD has estimated that there are approximately 42,618 private landlords/lessors of residential real estate, or approximately 99 percent of the 42,911 lessors of residential real estate counted in the 2012 Economic Census, where SBA defines a ''small'' business as one that earns annual revenues (sales receipts) of less than $27.5 million. Finally, HUD has estimated the number of owners who participate in the housing choice voucher program. It is noted that based on HUD data, the overwhelming proportion of owners rent to very few voucher tenants. Approximately two-thirds of owners who rent to voucher tenants rent to only one voucher tenant household. Many of these are likely owners of single-family homes for whom the rental income is not the primary source of income. Approximately 90 percent rent to no more than 4 voucher tenant households, which could be housed in a large two-story building. Very few owners rent to enough voucher tenants to occupy multiple buildings. Fewer than 0.6 percent of voucher tenant owners will be affected by this rule (out of the 647,956 owners with voucher tenant households, at most, an estimated 3,383 such owners, assuming that each EBLL case occurs in a housing unit owned by an owner none of whose other properties with voucher tenant households have children with an EBLL.

HUD has determined, for each type of assistance and for all types of assistance together, the economic analysis also estimated:

- The cost per unit of the evaluation (environmental investigation for index units, and risk assessments for other units that are assisted and have a child under age six (6) residing, as per the current LSHR);
- The total cost of the evaluation and hazard control (for index units, other units, and both); and
- The percentage of units evaluated and possibly, based on the evaluation results, hazard controlled (again, for index units, other units, and both).

The annual estimates are summarized in the table below.

TABLE 1—REGULATORY FLEXIBILITY ANALYSIS

Unit cost activity	Public housing	HUD project-based assistance	Tenant-based assistance	USDA project-based assistance	Total
Unit cost of evaluation, and weighted hazard control and temporary relocation for index units	$2,890.33	$2,890.33	$2,890.33	$2,890.33	.....
Est. no. buildings/complexes with child having EBLL	1,899	1,494	3,383	112	6,887
Presume LBP hazard prevalence in index units	100%	100%	100%	100%	.....
Cost of evaluation, hazard control and temporary relocation in index units	$5,488,724	$4,318,158	$9,776,541	$323,720	$19,907,143
Unit cost of evaluation, and weighted hazard control and temporary relocation for other units	$611.37	$611.37	$611.37	$611.37	.....
Est. no. other units with assisted rental units having child under age 6	8,014	3,783	2,855	284	14,936
Total number of units evaluated	9,913	5,277	6,238	396	21,823
Estimated LBP hazard prevalence in other units, per the American Healthy Homes Survey	12.30%	12.30%	12.30%	12.30%	.....
Estimated no. other units with LBP hazards identified and controlled	986	465	351	35	1,837
Cost for other assisted rental units having child under age 6	$4,899,521	$2,312,806	$1,745,456	$173,629	$9,131,412
Total cost	$10,388,245	$6,630,964	$11,521,998	$497,349	$29,038,556
Total number of units evaluated and having hazards controlled	2,885	1,959	3,734	147	8,725
Program assistance per unit	$5,849.09	$9,013.33	$9,329.09	$4,911.00	.....
Total number of assisted units	1,100,000	1,200,000	2,200,000	286,108	$4,786,108
Percent of assisted units evaluated	0.90%	0.44%	0.28%	0.14%	0.46%
Percent of assisted units evaluated and having hazards controlled	0.26%	0.16%	0.17%	0.05%	0.18%
# assisted units that would be forgone if funding were from funding agency with no appropriation increase	1,776	736	1,235	101	3,848
% assisted units that would be forgone if funding were from funding agency with no appropriation increase	0.161%	0.061%	0.056%	0.035%	0.080%

Among the key results are that, in each year:

- About 6,887 housing units are estimated to have a child under age six (6) with a blood lead level that is elevated but not an environmental intervention blood lead level; these units would be required to have an environmental investigation and have any lead-based paint hazards controlled. An additional 152 housing units would have a child under age six (6) with a

blood lead level that is an environmental intervention blood lead level; these units would be required to have an environmental investigation, rather than a risk assessment, as under the current rule, and have any lead-based paint hazards controlled.

• About 14,936 other housing units would have a risk assessment, of which about 1,837 are estimated to have lead-based paint hazards, and to have these hazards controlled by certified firms and workers using lead-safe work practices and clearance (*i.e.,* conservatively, all of the lead-based paint hazards are assumed to be significant, that is, above the de minimis levels of § 35.1350(d)).

• About 0.46 percent of the assisted housing stock covered by this rulemaking would be evaluated (*i.e.,* have an environmental investigation or a risk assessment), specifically, 0.90 percent of the public housing stock, 0.44 percent of the HUD project-based rental assisted housing stock, 0.28 percent of the tenant-based rental assisted housing stock, and 0.14 percent of the U.S. Department of Agriculture (USDA) project-based rental assisted housing stock.

• About 0.18 percent of the assisted housing stock covered by this rulemaking would have lead-based paint hazards controlled, specifically, 0.26 percent of the public housing stock, 0.16 percent of the HUD project-based rental assisted housing stock, 0.17 percent of the tenant-based rental assisted housing stock, and 0.05 percent of the USDA project-based rental assisted housing stock.

• The total cost of evaluation and control (and the small amount of temporary relocation of occupants) would be $29.04 million, including $10.39 million for public housing, $6.63 million for HUD project-based rental assisted housing, $11.52 million for tenant-based rental assisted housing, and $497 thousand for USDA project-based rental assisted housing.

• Using the 3 percent discount rate, benefits are estimated at $98.96 million, with net benefits (*i.e.,* benefits less the $29.04 million in costs) estimated at $69.92 million. Using the OMB's 7 percent discount rate, benefits are estimated at $32.15 million, with costs remaining at $29.04 million, so the net benefits would be $3.11 million.

• Regarding index units, for FY 2017, an estimated 1,899 units of public housing, 1,494 units of HUD project-based rental assisted housing, 3,383 units of tenant-based rental assisted housing, and 112 units of USDA project-based rental assisted housing have children under age 6 with EBLLs that are not EIBLLs, that is, children for whom an environmental investigation and possible (*i.e.,* if hazards are found) interim control of their housing unit and common area servicing it would be newly required under the final rule.

• Regarding other units in the same property to have risk assessments conducted because they have children under age six (6) residing, there would be an estimated 8,014 units of public housing, 3,783 units of HUD project-based rental assisted housing, 2,855 units of tenant-based rental assisted housing, and 284 units of USDA project-based rental assisted housing.

• Regarding these other units having interim controls conducted based on the risk assessments finding lead-based paint hazards, there would be an estimated 986 units of public housing, 465 units of HUD project-based rental assisted housing, 351 units of tenant-based rental assisted housing, and 35 units of USDA project-based rental assisted housing that would have such controls.

• The conservative (*i.e.,* intentionally high, in this instance) assumption about the properties in which these children reside is that each of them is a different property (vs. there being more than one such child in a property); a similarly conservative assumption about the private entities (*i.e.,* the ones that lease units receiving project-based rental assistance to the families of these children, or that lease units occupied by households receiving tenant-based rental assistance to their families) is that all of them are small entities and all have just one such child (vs. an entity having more than one property with such a child), and that all index units in such properties have lead-based paint hazards. The economic analysis used the FY 2017 Congressional Justifications of the estimated number of housing units assisted by the several programs, recognizing that the actual numbers assisted vary over time: 1,100,000 public housing units, 1,200,000 HUD project-based rental assistance units, 2,200,000 tenant-based rental assistance units, and 286,108 USDA project-based rental assistance units.

E. Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implements section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The Finding of No Significant Impact is available for public inspection electronically at Federal eRulemaking Portal at *http://www.regulations.gov* under the title and docket number of this rule.

F. Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments or is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule will not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

G. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This rule does not impose any federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of UMRA.

List of Subjects in 24 CFR Part 35

Grant programs—housing and community development, Lead poisoning, Mortgage insurance, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, HUD amends 24 CFR part 35 to read as *follows*:

PART 35—LEAD-BASED PAINT POISONING PREVENTION IN CERTAIN RESIDENTIAL STRUCTURES

■ 1. The authority citation for 24 CFR part 35 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 4821, and 4851.

§ 35.105 [Removed and Reserved]

■ 2. Remove and reserve § 35.105.

■ 3. In § 35.110, add, in alphabetical order the definitions of ''Elevated blood lead level'' and ''Environmental investigation'', revise the definitions of ''Certified'', ''Evaluation'' and ''Expected to reside'' and remove the definition of ''Environmental intervention blood lead level'', to read as follows:

§ 35.110 Definitions.

* * * * *

Certified means certified to perform such activities as risk assessment, lead-

based paint inspection, abatement supervision, or renovation, either by a State or Indian tribe with a lead-based paint certification program authorized by the Environmental Protection Agency (EPA), in accordance with 40 CFR part 745, subpart Q, or by the EPA, in accordance with 40 CFR part 745, subparts E or L.

* * * * *

Elevated blood lead level means a confirmed concentration of lead in whole blood of a child under age 6 equal to or greater than the concentration in the most recent guidance published by the U.S. Department of Health and Human Services (HHS) on recommending that an environmental intervention be conducted. (When HHS changes the value, HUD will publish a notice in the **Federal Register**, with the opportunity for public comment, on its intent to apply the changed value to this part, and, after considering comments, publish a notice on its applying the changed value to this part.)

* * * * *

Environmental investigation means the process of determining the source of lead exposure for a child under age 6 with an elevated blood lead level, consisting of administration of a questionnaire, comprehensive environmental sampling, case management, and other measures, in accordance with chapter 16 of the HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing (''Guidelines'').

Evaluation means a risk assessment, a lead hazard screen, a lead-based paint inspection, paint testing, or a combination of these to determine the presence of lead-based paint hazards or lead-based paint, or an environmental investigation.

Expected to reside means there is actual knowledge that a child will reside in a dwelling unit reserved or designated exclusively for the elderly or reserved or designated exclusively for persons with disabilities. If a resident woman is known to be pregnant, there is actual knowledge that a child will reside in the dwelling unit.

* * * * *

■ 4. Amend § 35.125 by adding paragraph (c)(4)(iii) to read as follows:

§ 35.125 Notice of evaluation and hazard reduction activities.

* * * * *

(c) * * *

(4) * * *

(iii) However, for the protection of the privacy of the child and the child's family or guardians, no notice of environmental investigation shall be posted to any centrally located common area.

§ 35.155 [Amended]

■ 5. Amend § 35.155(a) by removing the phrase ''designated party or occupant'' wherever it appears and adding in its place the phrase ''designated party or owner''.

§ 35.165 [Amended]

■ 6. Amend § 35.165(b)(4) by removing the term ''environmental intervention blood lead level'' wherever it appears and adding its place the term ''elevated blood lead level''.

■ 7. Revise § 35.325 to read as follows:

§ 35.325 Child with an elevated blood lead level.

(a) If a child less than 6 years of age living in a federally assisted dwelling unit has an elevated blood lead level, the owner shall immediately conduct an environmental investigation. Interim controls of identified lead-based paint hazards shall be conducted in accordance with § 35.1330.

(b) *Other assisted dwelling units in the property.* (1) If the environmental investigation conducted under paragraph (a) of this section identifies lead-based paint hazards, the owner shall conduct a risk assessment for other assisted dwelling units covered by this subpart in which a child under age 6 resides or is expected to reside on the date interim controls are complete, and for the common areas servicing those units. The risk assessments shall be conducted within 30 calendar days after receipt of the environmental investigation report on the index unit if there are 20 or fewer such units, or 60 calendar days for risk assessments if there are more than 20 such units. If the risk assessment identifies lead-based paint hazards, the owner shall control identified hazards in accordance with § 35.1325 or § 35.1330 in those units and common areas within 30 calendar days, or within 90 calendar days if more than 20 units have lead-based paint hazards such that the control work would disturb painted surfaces that total more than the de minimis threshold of § 35.1350(d).

(2) The requirements for other assisted dwelling units covered by paragraph (b)(1) of this section do not apply if:

(i) The owner both conducted a risk assessment of the other assisted dwelling units covered by paragraph (b)(1), and the common areas servicing those units, and conducted reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330 between the date the child's blood was last sampled and the date the owner received the notification of the elevated blood lead level; or

(ii) The owner provides the Federal agency documentation of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-based paint management requirements under this part throughout the 12 months preceding the date the owner received the environmental investigation report.

(c) Interim controls are complete when clearance is achieved in accordance with § 35.1340.

(d) The Federal agency shall establish a timetable for completing, and providing documentation to the agency on the environmental investigation, risk assessments, and lead-based paint hazard reduction when a child is identified as having an elevated blood lead level.

§ 35.715 [Amended]

■ 8. Amend § 35.715 by:

■ a. Redesignating paragraph (d)(4) as paragraph (e); and

■ b. In newly redesignated paragraph (e), remove the term ''environmental intervention blood lead level'' wherever it appears and adding in its place ''elevated blood lead level''.

§ 35.720 [Amended]

■ 9. Amend § 35.720(c) by removing the term ''environmental intervention blood lead level'' wherever it appears and adding in its place ''elevated blood lead level''.

■ 10. Revise § 35.730 to read as follows:

§ 35.730 Child with an elevated blood lead level.

(a) *Environmental investigation.* Within 15 calendar days after being notified by a public health department or other medical health care provider that a child of less than 6 years of age living in a dwelling unit to which this subpart applies has been identified as having an elevated blood lead level, the owner shall complete an environmental investigation of the dwelling unit in which the child lived at the time the blood was last sampled and of common areas servicing the dwelling unit. The requirements of this paragraph apply regardless of whether the child is or is not still living in the unit when the owner receives the notification of the elevated blood lead level. The requirements of this paragraph shall not apply if the owner conducted an environmental investigation of the unit and common areas servicing the unit between the date the child's blood was last sampled and the date when the

owner received the notification of the elevated blood lead level. If the owner conducted a risk assessment of the unit and common areas servicing the unit during that period, the owner need not conduct another risk assessment there but shall conduct the elements of an environmental investigation not already conducted during the risk assessment. If a public health department has already conducted an evaluation of the dwelling unit in regard to the child's elevated blood lead level case, the requirements of this paragraph shall not apply.

(b) *Verification.* After receiving information from a person who is not a medical health care provider that a child of less than 6 years of age living in a dwelling unit covered by this subpart may have an elevated blood lead level, the owner shall immediately verify the information with the public health department or other medical health care provider. If the public health department or provider denies the request, such as because it does not have the capacity to verify that information, the owner shall send documentation of the denial to the HUD rental assistance program manager, who shall make an effort to verify the information. If the public health department or provider verifies that the child has an elevated blood lead level, such verification shall constitute notification, and the owner shall take the action required in paragraphs (a) and (c) of this section.

(c) *Lead-based paint hazard reduction.* Within 30 calendar days after receiving the report of the environmental investigation conducted pursuant to paragraph (a) of this section or the evaluation from the public health department, the owner shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330. Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the environmental investigation have been treated with interim controls or abatement or the public health department certifies that the lead-based paint hazard reduction is complete. The requirements of this paragraph do not apply if the owner, between the date the child's blood was last sampled and the date the owner received the notification of the elevated blood lead level, already conducted an environmental investigation of the unit and common areas servicing the unit and completed reduction of identified lead-based paint hazards. If the owner conducted a risk assessment of the unit and common areas servicing the unit during that period, the owner is not required to conduct another risk assessment there but shall conduct the elements of an environmental investigation not already conducted during the risk assessment.

(d) If an environmental investigation or lead-based paint hazard evaluation or reduction is undertaken, each owner shall provide notice to occupants in accordance with § 35.125.

(e) *Reporting requirement.* (1) The owner shall report the name and address of a child identified as having an elevated blood lead level to the public health department within 5 business days of being so notified by any other medical health care professional.

(2) The owner shall also report each confirmed case of a child with an elevated blood lead level to the HUD field office and HUD Office of Lead Hazard Control and Healthy Homes within 5 business days of being so notified.

(3) The owner shall provide to the HUD field office documentation that the designated party has conducted the activities of paragraphs (a) through (d) of this section, within 10 business days of the deadline for each activity.

(f) *Other assisted dwelling units in the property.* (1) If the environmental investigation conducted pursuant to paragraph (a) of this section identifies lead-based paint hazards, the owner shall, for other assisted dwelling units covered by this part in which a child under age 6 resides or is expected to reside on the date lead-based paint hazard reduction under paragraph (c) of this section is complete, and for the common areas servicing those units, conduct a risk assessment within 30 calendar days after receipt of the environmental investigation report if there are 20 or fewer such other units, or 60 calendar days if there are more than 20 such other units.

(2) *Control measures.* If the risk assessment conducted under paragraph (f)(1) of this section identifies lead-based paint hazards, the owner shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330 in those units and common areas within 30 calendar days, or within 90 calendar days if more than 20 units have lead-based paint hazards such that the control work would disturb painted surfaces that total more than the de minimis threshold of § 35.1350(d). Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the risk assessment have been treated with interim controls or abatement.

(3) The owner shall provide to the HUD field office documentation that the designated party has conducted the activities of paragraph (f)(1) and (f)(2) of this section, within 10 business days of the deadline for each activity.

(4) The requirements of this paragraph (f) do not apply if:

(i) The owner both conducted a risk assessment of the other assisted dwelling units covered by paragraph (f)(1) of this section and the common areas servicing those units, and conducted reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330 between the date the child's blood was last sampled and the date the owner received the notification of the elevated blood lead level; or

(ii) The owner has documentation of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-based paint management requirements under this part throughout the 12 months preceding the date the owner received the environmental investigation report pursuant to paragraph (a) of this section; and

(iii) In either case, the owner provides to the HUD field office documentation that it has conducted the activities of paragraphs (f)(4)(i) and (ii) of this section, within 10 business days of the deadline for each activity.

■ 11. Revise § 35.830 to read as follows:

§ 35.830 Child with an elevated blood lead level.

(a) *Environmental investigation.* Within 15 calendar days after being notified by a public health department or other medical health care provider that a child of less than 6 years of age living in a dwelling unit owned by HUD (or where HUD is mortgagee-in-possession) has been identified as having an elevated blood lead level, HUD shall complete an environmental investigation of the dwelling unit in which the child lived at the time the blood was last sampled and of common areas servicing the dwelling unit. The requirements of this paragraph apply regardless of whether the child is or is not still living in the unit when HUD receives the notification of the elevated blood lead level. The requirements of this paragraph shall not apply if HUD conducted an environmental investigation of the unit and common areas servicing the unit between the date the child's blood was last sampled and the date when HUD received the notification of the elevated blood lead level. If HUD conducted a risk

assessment of the unit and common areas servicing the unit during that period, HUD is not required to conduct another risk assessment there but it shall conduct the elements of an environmental investigation not already conducted during the risk assessment. If a public health department has already conducted an evaluation of the dwelling unit in regard to the child's elevated blood lead level case, the requirements of this paragraph shall not apply.

(b) *Verification.* After receiving information from a person who is not a medical health care provider that a child of less than 6 years of age living in a dwelling unit covered by this subpart may have an elevated blood lead level, HUD shall immediately verify the information with the public health department or other medical health care provider. If the public health department or provider denies the request, such as because it does not have the capacity to verify that information, the HUD Realty Specialist assigned to that property shall send documentation of the denial to the HUD Office of Lead Hazard Control and Healthy Homes, which shall make an effort to verify the information. If the public health department or provider verifies that the child has an elevated blood lead level, such verification shall constitute notification, and HUD shall take the action required in paragraphs (a) and (c) of this section.

(c) *Lead-based paint hazard reduction.* Within 30 calendar days after receiving the report of the environmental investigation conducted pursuant to paragraph (a) of this section or the evaluation from the public health department, HUD shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330. Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the environmental investigation have been treated with interim controls or abatement or the public health department certifies that the lead-based paint hazard reduction is complete. The requirements of this paragraph do not apply if HUD, between the date the child's blood was last sampled and the date HUD received the notification of the elevated blood lead level, already conducted an environmental investigation of the unit and common areas servicing the unit and completed reduction of identified lead-based paint hazards. If HUD conducted a risk assessment of the unit and common areas servicing the unit during that period, it is not required to conduct another risk assessment there but it shall conduct the elements of an environmental investigation not already conducted during the risk assessment.

(d) *Notice.* If lead-based paint hazard evaluation or reduction is undertaken, each owner shall provide a notice to occupants in accordance with § 35.125.

(e) *Reporting requirement.* (1) HUD shall report the name and address of a child identified as having an elevated blood lead level to the public health department within 5 business days of being so notified by any other medical health care professional.

(2) HUD shall also report each confirmed case of a child with an elevated blood lead level to the HUD Office of Lead Hazard Control and Healthy Homes within 5 business days of being so notified.

(3) HUD shall provide to the HUD Office of Lead Hazard Control and Healthy Homes documentation that it has conducted the activities of paragraphs (a) through (d) of this section, within 10 business days of the deadline for each activity.

(f) *Other assisted dwelling units in the property.* (1) If the environmental investigation conducted pursuant to paragraph (a) of this section identifies lead-based paint hazards, HUD shall, for other assisted dwelling units covered by this part in which a child under age 6 resides or is expected to reside on the date lead-based paint hazard reduction under paragraph (c) of this section, and the common areas servicing those units, is complete, conduct a risk assessment in accordance with § 35.815 within 30 calendar days after receipt of the environmental investigation report if there are 20 or fewer such other units, or 60 calendar days if there are more than 20 such other units.

(2) If the risk assessment conducted under paragraph (f)(1) of this section identifies lead-based paint hazards, HUD shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330 in those units and common areas within 30 calendar days, or within 90 calendar days if more than 20 units have lead-based paint hazards such that the control work would disturb painted surfaces that total more than the de minimis threshold of § 35.1350(d). Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the risk assessment have been treated with interim controls or abatement.

(3) The requirements of this paragraph (f) do not apply if:

(i) HUD, between the date the child's blood was last sampled and the date HUD received the notification of the elevated blood lead level, both conducted a risk assessment in the other assisted dwelling units covered by paragraph (f)(1) of this section and the common areas servicing those units, and conducted interim controls of identified lead-based paint hazards in accordance with § 35.820; or

(ii) HUD has documentation of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-based paint management requirements under this part throughout the 12 months preceding the date HUD received the environmental investigation report pursuant to paragraph (a) of this section.

(4) HUD shall provide to the HUD Office of Lead Hazard Control and Healthy Homes documentation that it has conducted the activities of paragraph (f)(1) through (2) of this section, or that it has complied with the requirements in paragraph (f)(3) of this section, within 10 business days of the deadline for each activity.

(g) *Closing.* If the closing of a sale is scheduled during the period when HUD is responding to a case of a child with an elevated blood lead level, HUD may arrange for the completion of the procedures required by paragraphs (a) through (d) of this section by the purchaser within a reasonable period of time.

(h) *Extensions.* The Assistant Secretary for Housing-Federal Housing Commissioner or designee may consider and approve a request for an extension of deadlines established by this section for lead-based paint inspection, risk assessment, environmental investigation, lead-based paint hazard reduction, clearance, and reporting. Such a request may be considered, however, only during the first six months during which HUD is owner or mortgagee-in-possession of a multifamily property.

■ 12. Revise § 35.1130 to read as follows:

§ 35.1130 Child with an elevated blood lead level.

(a) *Environmental investigation.* Within 15 calendar days after being notified by a public health department or other medical health care provider that a child of less than 6 years of age living in a dwelling unit to which this subpart applies has been identified as having an elevated blood lead level, the PHA shall complete an environmental investigation of the dwelling unit in which the child lived at the time the

blood was last sampled and of common areas servicing the dwelling unit. The environmental investigation is considered complete when the PHA receives the environmental investigation report. The requirements of this paragraph apply regardless of whether the child is or is not still living in the unit when the PHA receives the notification of the elevated blood lead level. The requirements of this paragraph shall not apply if the PHA conducted an environmental investigation of the unit and common areas servicing the unit between the date the child's blood was last sampled and the date when the PHA received the notification of the elevated blood lead level. If the PHA conducted a risk assessment of the unit and common areas servicing the unit during that period, the PHA need not conduct another risk assessment there but shall conduct the elements of an environmental investigation not already conducted during the risk assessment. If a public health department has already conducted an evaluation of the dwelling unit in regard to the child's elevated blood lead level case, the requirements of this paragraph shall not apply.

(b) *Verification.* After receiving information from a person who is not a medical health care provider that a child of less than 6 years of age living in a dwelling unit covered by this subpart may have an elevated blood lead level, the PHA shall immediately verify the information with the public health department or other medical health care provider. If that department or provider denies the request, such as because it does not have the capacity to verify that information, the PHA shall send documentation of the denial to its HUD field office, who shall make an effort to verify the information. If that department or provider verifies that the child has an elevated blood lead level, such verification shall constitute notification, and the housing agency shall take the action required in paragraphs (a) and (c) of this section.

(c) *Lead-based paint hazard reduction.* Within 30 calendar days after receiving the report of the environmental investigation conducted pursuant to paragraph (a) of this section or the evaluation from the public health department, the PHA shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330. Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the environmental investigation have been treated with interim controls or abatement or the local or State health department certifies that the lead-based paint hazard reduction is complete. The requirements of this paragraph do not apply if the PHA, between the date the child's blood was last sampled and the date the PHA received the notification of the elevated blood lead level, already conducted an environmental investigation of the unit and common areas servicing the unit and completed reduction of identified lead-based paint hazards. If the PHA conducted a risk assessment of the unit and common areas servicing the unit during that period, it is not required to conduct another risk assessment there but it shall conduct the elements of an environmental investigation not already conducted during the risk assessment. If the PHA does not complete the lead-based paint hazard reduction required by this section, the dwelling unit is in violation of the standards of 24 CFR 965.601, which incorporates the uniform physical condition standards of § 5.703(f), including that it be free of lead-based paint hazards.

(d) *Notice of lead-based paint hazard evaluation and reduction.* The PHA shall notify building residents of any lead-based paint hazard evaluation or reduction activities in accordance with § 35.125.

(e) *Reporting requirement.* (1) The PHA shall report the name and address of a child identified as having an elevated blood lead level to the public health department within 5 business days of being so notified by any other medical health care professional.

(2) The PHA shall report each confirmed case of a child with an elevated blood lead level to the HUD field office and the HUD Office of Lead Hazard Control and Healthy Homes within 5 business days of being so notified.

(3) The PHA shall provide to the HUD field office documentation that it has conducted the activities of paragraphs (a) through (d) of this section, within 10 business days of the deadline for each activity.

(f) *Other units in the property.* (1) If the environmental investigation conducted pursuant to paragraph (a) of this section identifies lead-based paint hazards, the PHA shall conduct a risk assessment of other units of the building in which a child under age 6 resides or is expected to reside on the date lead-based paint hazard reduction under paragraph (c) of this section is complete, and the common areas servicing those units within 30 calendar days after receipt of the environmental investigation report if there are 20 or fewer such other units, or 60 calendar days if there are more such units.

(2) If the risk assessment conducted under paragraph (f)(1) of this section identifies lead-based paint hazards, the PHA shall control the hazards, in accordance with Sec. 35.1325 or § 35.1330, in those units and common areas within 30 calendar days, or within 90 calendar days if more than 20 units have lead-based paint hazards such that the control work would disturb painted surfaces that total more than the de minimis threshold of § 35.1350(d). Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the risk assessment have been treated with interim controls or abatement.

(3) The PHA shall provide to the HUD field office documentation that it has conducted the activities of paragraphs (f)(1) and (2) of this section, within 10 business days of the deadline for each activity.

(4) The requirements of this paragraph (f) of this section do not apply if:

(i) The PHA, between the date the child's blood was last sampled and the date the PHA received the notification of the elevated blood lead level, both conducted a risk assessment of the other assisted dwelling units covered by paragraph (f)(1) of this section and the common areas servicing those units, and conducted interim controls of identified hazards in accordance with § 35.1120(b); or

(ii) If the PHA has documentation of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-based paint management requirements under this part throughout the 12 months preceding the date the PHA received the environmental investigation report pursuant to paragraph (a) of this section; and,

(iii) In either case, the PHA provided the HUD field office, within 10 business days after receiving the notification of the elevated blood lead level, documentation that it has conducted the activities described in this paragraph (f)(4) of this section.

§ 35.1135 [Amended]

■ 13. Amend § 35.1135(d) by removing the term ''*Environmental intervention blood lead level*'' and adding in its place the term ''*Elevated blood lead level*''.

■ 14. In § 35.1215, amend paragraph (b) by adding a sentence to the end of the paragraph to read as follows:

§ 35.1215 Activities at initial and periodic inspection.

* * * * *

(b) * * * For the unit subsequently to come under a HAP contract with the housing agency for occupancy by a family with a child under age 6, paint stabilization must be completed, including clearance being achieved in accordance with § 35.1340.

* * * * *

■ 15. Revise § 35.1225 to read as follows:

§ 35.1225 Child with an elevated blood lead level.

(a) Within 15 calendar days after being notified by a public health department or other medical health care provider that a child of less than 6 years of age living in a dwelling unit to which this subpart applies has been identified as having an elevated blood lead level, the designated party shall complete an environmental investigation of the dwelling unit in which the child lived at the time the blood was last sampled and of common areas servicing the dwelling unit. When the environmental investigation is complete, the designated party shall immediately provide the report of the environmental investigation to the owner of the dwelling unit. If the child identified as having an elevated blood lead level is no longer living in the unit when the designated party receives notification from the public health department or other medical health care provider, but another household receiving tenant-based rental assistance is living in the unit or is planning to live there, the requirements of this section apply just as they do if the child still lives in the unit. If a public health department has already conducted an evaluation of the dwelling unit in regard to the child's elevated blood lead level case, or the designated party conducted an environmental investigation of the unit and common areas servicing the unit between the date the child's blood was last sampled and the date when the designated party received the notification of the elevated blood lead level, the requirements of this paragraph shall not apply. If the designated party or the owner conducted a risk assessment of the unit and common areas servicing the unit during that period, the designated party need not conduct another risk assessment there but shall conduct the elements of an environmental investigation not already conducted during the risk assessment.

(b) *Verification.* After receiving information from a person who is not a medical health care provider that a child of less than 6 years of age living in a dwelling unit covered by this subpart may have an elevated blood lead level, the designated party shall immediately verify the information with the public health department or other medical health care provider. If the public health department or provider denies the request, such as because it does not have the capacity to verify that information, the designated party shall send documentation of the denial to the HUD rental assistance program manager, who shall make an effort to verify the information. If that department or provider verifies that the child has an elevated blood lead level, such verification shall constitute notification, and the designated party shall take the action required in paragraphs (a) and (c) of this section.

(c) *Lead-based paint hazard reduction.* Within 30 calendar days after receiving the report of the environmental investigation from the designated party or the evaluation from the public health department, the owner shall complete the reduction of identified lead-based paint hazards in accordance with § 35.1325 or § 35.1330. Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the environmental investigation have been treated with interim controls or abatement or the public health department certifies that the lead-based paint hazard reduction is complete. The requirements of this paragraph do not apply if the designated party or the owner, between the date the child's blood was last sampled and the date the designated party received the notification of the elevated blood lead level, already conducted an environmental investigation of the unit and common areas servicing the unit and the owner completed reduction of identified lead-based paint hazards. If the owner does not complete the lead-based paint hazard reduction required by this section, the dwelling unit is in violation of the standards of 24 CFR 982.401.

(d) *Notice of lead-based paint hazard evaluation and reduction.* The owner shall notify building residents of any lead-based paint hazard evaluation or reduction activities in accordance with § 35.125.

(e) *Reporting requirement.* (1) The owner shall report the name and address of a child identified as having an elevated blood lead level to the public health department within 5 business days of being so notified by any other medical health care professional.

(2) The owner shall also report each confirmed case of a child with an elevated blood lead level to the HUD field office and the HUD Office of Lead Hazard Control and Healthy Homes within 5 business days of being so notified.

(3) The owner shall provide to the HUD field office documentation that it has conducted the activities of paragraphs (a) through (d) of this section, within 10 business days of the deadline for each activity.

(f) *Other assisted dwelling units in the property.* (1) If the environmental investigation conducted pursuant to paragraph (a) of this section identifies lead-based paint hazards, the designated party or the owner shall, for other assisted dwelling units covered by this part in which a child under age 6 resides or is expected to reside on the date lead-based paint hazard reduction under paragraph (c) of this section is complete, and the common areas servicing those units, conduct a risk assessment in accordance with § 35.1320(b) within 30 calendar days after receipt of the environmental investigation report if there are 20 or fewer such units, or 60 calendar days if there are more such units.

(2) If the risk assessment conducted under paragraph (f)(1) of this section identifies lead-based paint hazards, the owner shall complete the reduction of the lead-based paint hazards in accordance with § 35.1325 or § 35.1330 within 30 calendar days, or within 90 calendar days if more than 20 units have lead-based paint hazards such that the control work would disturb painted surfaces that total more than the de minimis threshold of § 35.1350(d). Lead-based paint hazard reduction is considered complete when clearance is achieved in accordance with § 35.1340 and the clearance report states that all lead-based paint hazards identified in the risk assessment have been treated with interim controls or abatement.

(3) The requirements of this paragraph (f) of this section do not apply if:

(i) The designated party or the owner, between the date the child's blood was last sampled and the date the owner received the notification of the elevated blood lead level, both conducted a risk assessment of the other assisted dwelling units covered by paragraph (f)(1) of this section and the common areas servicing those units, and the owner conducted interim controls of identified lead-based paint hazards in accordance with § 35.1225(c); or

(ii) The owner has documentation of compliance with evaluation, notification, lead disclosure, ongoing lead-based paint maintenance, and lead-

based paint management requirements under this part throughout the 12 months preceding the date the owner received the environmental investigation report pursuant to paragraph (a) of this section; and,

(iii) In either case, the owner provided the HUD field office, within 10 business days after receiving the notification of the elevated blood lead level, documentation that it has conducted the activities described in this paragraph (f)(3).

(g) *Data collection and record keeping responsibilities.* At least quarterly, the designated party shall attempt to obtain from the public health department(s) with area(s) of jurisdiction similar to that of the designated party the names and/or addresses of children of less than 6 years of age with an identified elevated blood lead level. At least quarterly, the designated party shall also report an updated list of the addresses of units receiving assistance under a tenant-based rental assistance program to the same public health department(s), except that the report(s) to the public health department(s) is not required if the health department states that it does not wish to receive such report. If it obtains names and addresses of elevated blood lead level children from the public health department(s), the designated party shall match information on cases of elevated blood lead levels with the names and addresses of families receiving tenant-based rental assistance, unless the public health department performs such a matching procedure.

If a match occurs, the designated party shall carry out the requirements of this section.

■ 16. Revise § 35.1330(a)(4)(iii) to read as follows:

§ 35.1330 Interim controls.

(a) * * *

(4) * * *

(iii) A renovator course accredited in accordance with 40 CFR 745.225.

* * * * *

Dated: December 14, 2016.

Nani Coloretti,

Deputy Secretary.

[FR Doc. 2017–00261 Filed 1–12–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Part 401

RIN 2135–AA40

Civil Penalties

AGENCY: Saint Lawrence Seaway Development Corporation (SLSDC), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule updates the maximum civil penalty amounts for violations of statutes and regulations administered by SLSDC pursuant to the Federal Civil Penalties Inflation Adjustment Improvement Act of 2015. This final rule amends our regulations to reflect the new civil penalty amounts for violations of the Seaway Regulations and Rules under the authority of the Ports and Waterways Safety Act of 1972, as amended (PWSA).

DATES: This rule is effective on January 15, 2017.

FOR FURTHER INFORMATION CONTACT: Carrie Lavigne, Chief Counsel, SLSDC, telephone (315) 764–3231, 180 Andrews Street, Massena, NY 13362.

SUPPLEMENTARY INFORMATION:

Background

On November 2, 2015, the Federal Civil Penalties Inflation Adjustment Improvement Act (the 2015 Act), Public Law 114–74, was signed into law. The purpose of the 2015 Act is to improve the effectiveness of civil monetary penalties (CMPs) and to maintain their deterrent effect. The 2015 Act required agencies to make an initial catch up adjustment to the CMPs they administer through an interim final rule and then to make subsequent annual adjustments for inflation that shall take effect not later than January 15. The initial catch up adjustments for inflation to the SLSDC's CMP was published in the **Federal Register** on June 28, 2016 and as required, did not exceed 150 percent of the amount of the CMP on the date of enactment of the Federal Civil Penalties Inflation Adjustment Act of 2015. The revised methodology for agencies for 2017 and each year thereafter provides for the improvement of the effectiveness of CMPs and to maintain their deterrent effect. Effective 2017, agencies annual adjustments for in inflation to CMPs apply only to CMPs with a dollar amount.

The SLSDC's 2017 adjustments for inflation to the CMP set forth in this regulation were determined pursuant to the revised methodology prescribed by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which requires the maximum CMP to be increased by the cost-of-living adjustment. The term ''cost-of-living adjustment'' is defined by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. For the 2017 adjustments for inflation to CMPs, the percentage for each CMP by which the Consumer Price Index for the month of October 2016 exceeds the Consumer Price Index for the month of October 2015.

Classification

Pursuant to 5 U.S.C. 553(b)B, there is good cause to issue this rule without prior public notice or opportunity for public comment because it would be impracticable and unnecessary. The Federal Civil Penalties Inflation Adjustment Act of 2015 (Section 701(b)) requires agencies effective 2017, to make annual adjustments for inflation to CMPs notwithstanding section 553 of Title 5 United States Code. Additionally, the methodology used, effective 2017, for adjusting CMPs for inflation is given by statute, with no discretion provided to agencies regarding the substance of the adjustments for inflation to CMPs. The SLSDC is charged only with performing ministerial computations to determine the dollar amount of adjustments for inflation to CMPs. Accordingly, prior public notice and opportunity for public comment are not required for this rule.

Regulatory Analysis

E.O. 12866, Regulatory Review

SLSDC has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the Department of Transportation's regulatory policies and procedures. This rulemaking document was not reviewed under Executive Order 12866 or Executive Order 13563. This action is limited to the adoption of adjustments of civil penalties under statutes that the agency enforces, and has been determined to be not ''significant'' under the Department of Transportation's regulatory policies and procedures and the policies of the Office of Management and Budget. Because this rulemaking does not change the number of entities that are subject to civil penalties, the impacts are limited.

We also do not expect the increase in the civil penalty amount in 33 CFR 401.102 to be economically significant. Since January 1, 2010 to the present, the SLSDC assessed a total of approximately $27,000 in civil fines and penalties.

Thus, increasing the current civil penalty amount would not result in an annual effect on the economy of $100 million or more.

Regulatory Flexibility Act

We have also considered the impacts of this notice under the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact on a substantial number of small entities. The following provides the factual basis for this certification under 5 U.S.C. 605(b). The St. Lawrence Seaway Regulations and Rules primarily relate to the activities of commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

Executive Order 13132 (Federalism)

Executive Order 13132 requires SLSDC to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

The reason is that this rule will generally apply to commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels. Thus, the requirements of Section 6 of the Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually. Because this rule will not have a $100 million effect, no Unfunded Mandates assessment will be prepared.

Executive Order 12778 (Civil Justice Reform)

This rule does not have a retroactive or preemptive effect. Judicial review of a rule based on this proposal may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, we state that there are no requirements for information collection associated with this rulemaking action.

Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit *http://dms.dot.gov.*

List of Subjects in 33 CFR Part 401

Hazardous materials transportation, Navigation (water), Penalties, Radio, Reporting and recordkeeping requirements, Vessels, Waterways.

Accordingly, the Saint Lawrence Seaway Development Corporation is amending 33 CFR part 401 as follows:

PART 401—SEAWAY REGULATIONS AND RULES

Subpart A—Regulations

■ 1. The authority citation for subpart A of part 401 is amended to read as follows:

Authority: 33 U.S.C. 981–990, 1231 and 1232, 49 CFR 1.52, unless otherwise noted.

■ 2. In § 401.102, paragraph (a) is revised to read as follows:

§ 401.101 Criminal penalty.

(a) A person, as described in § 401.101(b) who violates a regulation is liable to a civil penalty of not more than $90,063.

* * * * *

Issued on December 30, 2016.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2016–32050 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AP66

Diseases Associated With Exposure to Contaminants in the Water Supply at Camp Lejeune

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its adjudication regulations regarding presumptive service connection, adding certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune (Camp Lejeune), North Carolina, from August 1, 1953, to December 31, 1987. This final rule establishes that veterans, former reservists, and former National Guard members, who served at Camp Lejeune for no less than 30 days (consecutive or nonconsecutive) during this period, and who have been diagnosed with any of eight associated diseases, are presumed to have incurred or aggravated the disease in service for purposes of entitlement to VA benefits. In addition, this final rule establishes a presumption that these individuals were disabled during the relevant period of service for purposes of establishing active military service for benefits purposes. Under this presumption, affected former reservists and National Guard members have veteran status for purposes of entitlement to some VA benefits. This amendment implements a decision by the Secretary of Veterans Affairs that service connection on a presumptive basis is warranted for claimants who served at Camp Lejeune during the relevant period and for the requisite amount of time and later develop certain diseases.

DATES: *Effective Date:* This final rule is effective March 14, 2017.

FOR FURTHER INFORMATION CONTACT: Eric Mandle, Policy Analyst, Regulations Staff (211D), Compensation Service,

Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION:

I. Purpose of the Final Rule

VA amends its adjudication regulations to add certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune, North Carolina, from August 1, 1953, to December 31, 1987. This final rule establishes that veterans, former reservists, and former National Guard members, who served at Camp Lejeune for no less than 30 days (consecutive or nonconsecutive) during this period and who have been diagnosed with any of eight associated diseases, are presumed to have incurred or aggravated the disease in service for purposes of entitlement to VA benefits. In addition, this final rule establishes a presumption that these individuals were disabled during the relevant period of service for purposes of establishing active military service for benefits purposes. Under this presumption, affected former reservists and National Guard members have veteran status for purposes of entitlement to some VA benefits.

Section 501(a)(1) of title 38, United States Code, provides that ''[t]he Secretary has authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws, including . . . regulations with respect to the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits under such laws.'' This broad authority encompasses the establishment of an evidentiary presumption of service connection and exposure under specified circumstances, provided there is a rational basis for the presumptions. In this case, the Secretary has determined that proof of qualifying service at Camp Lejeune, consistent with Public Law 112–154, the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012 (Camp Lejeune Act), and the subsequent development of one of the eight listed diseases is sufficient to support the presumption that the resulting disease was incurred in the line of duty during active military, naval, or air service, to include qualifying reserve or National Guard service, to establish entitlement to service connection. See 38 U.S.C. 1110 and 1131.

II. Summary of Major Provisions

The major provisions of this final rule include the following: VA will amend 38 CFR 3.307 to establish presumptions of service connection associated with exposure to contaminants in the water supply at Camp Lejeune. This amendment presumes exposure to contaminants in the water supply at Camp Lejeune for all active duty, reserve, and National Guard personnel who served for no less than 30 days (consecutive or nonconsecutive) at Camp Lejeune during the period beginning August 1, 1953, and ending on December 31, 1987. This presumption specifically allows former reservists and National Guard members to establish veteran status by presuming that a covered disease was incurred in the line of duty and was disabling during a period of qualifying service.

VA will also amend 38 CFR 3.309 to prescribe the eight conditions that are subject to presumptive service connection in relation to exposure to contaminants in the water supply at Camp Lejeune.

III. Technical Correction

In the proposed rule, VA proposed amending the heading of 38 CFR 3.307 to read ''Presumptive service connection for chronic, tropical or prisoner-of-war related disease, disease associated with exposure to certain herbicide agents, or disease associated with the contaminants in the water supply at Camp Lejeune; wartime and service on or after January 1, 1947.'' Additionally, VA proposed amending paragraph (a) of § 3.307 to mirror the title. In reviewing this amendment for the final rule, however, VA realized that the current and proposed text of paragraph (a) contain errors. Namely, they refer to a ''chronic, tropical, prisoner of war related disease'' rather than a ''chronic, tropical or prisoner of war related disease,'' as referenced in the heading of § 3.307. Additionally, the heading and proposed text omitted the words ''exposure to'' before ''contaminants in the water supply.'' This document corrects these errors by inserting ''or'' in place of the comma between ''tropical'' and ''prisoner of war'' in paragraph (a) to clarify that the terms ''chronic,'' ''tropical,'' and ''prisoner of war related'' refer to three separate categories of disease rather than characteristics of a single disease; and inserting ''exposure to'' in the heading and paragraph (a) in the phrase pertaining to contaminants in the water supply at Camp Lejeune.

IV. Public Comments

On September 9, 2016, VA published in the **Federal Register** (81 FR 62419) a notice of a proposed rulemaking to amend 38 CFR 3.307 and 3.309 to establish presumptive service connection for certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune, North Carolina, from August 1, 1953 to December 31, 1987. VA provided a 30-day public comment period, which ended on October 11, 2016, and received 290 comments on the proposed rule, one of which was received after the comment period. Although VA is not legally required to consider late-filed comments, it has reviewed, considered, and addressed all comments received in the interest of maximizing public dialogue to further serve veterans, claimants, and authorized representatives. VA received comments from various organizations and individuals, including Disabled American Veterans (DAV), Veterans of Foreign Wars (VFW), Vietnam Veterans of America (VVA), National Organization of Veterans' Advocates (NOVA), C–123 Veterans Association, Fort McClellan Veterans Stakeholders Group, Reserve Officers Association, Marine Corps Reserve Association, United Parkinson's Advocacy Council, Legal Counsel for the Elderly, Project on Government Oversight, a member of Congress, and other interested persons. VA responds to all commenters as follows.

All of the issues raised by the commenters that concerned at least one portion of the rule can be grouped together by similar topic, and VA has organized the discussion of the comments accordingly. VA also received 85 comments from veterans and surviving spouses regarding individual claims for veterans' benefits. VA does not respond to these comments in this document as they are beyond the scope of this rulemaking.

For the reasons set forth in the proposed rule and below, VA adopts the proposed rule as final, with changes, as explained below.

A. 30-Day Exposure Requirement

VA received 18 comments, including organizational comments from DAV, VVA, NOVA, Project on Government Oversight, and Legal Counsel for the Elderly, regarding its proposal that a veteran, or former reservist or National Guard member must serve no less than 30 days (consecutive or nonconsecutive) at Camp Lejeune during the period beginning August 1, 1953, and ending

on December 31, 1987, to receive a presumption of service connection for the eight listed diseases based on exposure to contaminants in the water supply. Two commenters suggested changing the exposure requirement to one week and two weeks, respectively; neither commenter offered a rationale for these time limits. Several commenters suggested eliminating the exposure requirement completely, noting that the 30-day requirement was inconsistent with other toxic exposure presumptions and that it was not supported with scientific evidence. One commenter stated that the 30-day requirement would essentially exclude National Guard members from eligibility. One commenter stated that a 30-day exposure requirement would exclude veterans serving in the Naval Amphibious Force who docked at Camp Lejeune.

1. Comparison to Prior Exposure Regulations

VA received several comments, including from DAV, NOVA, VVA, Legal Counsel for the Elderly, and Project on Government Oversight, stating that a 30-day exposure period is inconsistent with VA's requirements for presumptive service connection based on toxic and other exposures. For example, VA has previously established regulations governing presumptive service connection for diseases associated with exposure to certain herbicide agents and certain disabilities occurring in Persian Gulf veterans. *See* 38 CFR 3.307, 3.309, and 3.317. These regulations do not include a minimum exposure requirement; a veteran must show that he or she served in an identified location or under enumerated circumstances to receive a presumption of service connection.

While the commenters are correct in that VA does not require a minimum level or duration of exposure for some previously-established presumptions, VA notes that these regulations serve to provide presumptive service connection based on the specified and particular exposures, conditions, and nature of military service in accordance with the scientific and other evidence supporting them. They do not set a binding precedent for future rulemakings that address unrelated circumstances. For example, while presumptive service connection for certain disabilities occurring in Persian Gulf veterans does not require a minimum exposure during military service, 38 CFR 3.317 requires that the qualifying chronic disability must manifest to a degree of 10 percent or more no later than December 31, 2021. This regulation, though, does not require conditions associated with exposure to contaminants in the water supply at Camp Lejeune to manifest by a certain date. Similarly, 38 CFR 3.311 specifies that disabilities presumed to be associated with exposure to ionizing radiation must manifest within certain time periods after exposure to radiation (the time period varies depending on the condition in question). Nothing in this regulation requires a condition associated with exposure to contaminants in the water supply at Camp Lejeune to manifest within a certain period of time following service.

In addition to being based on different scientific, medical, and military evidence, the prior toxic exposure regulations often stem from a specific, separate statutory authority or requirement. These statutes prescribe the method by which the Secretary may create a regulatory presumption, to include the evidentiary basis for establishing a presumption, periods in which a disability must manifest, covered disabilities, how the Secretary shall determine that a condition is associated with a given toxic exposure, and other requirements specific to the toxic exposure under review. For example, the statutory authority to award presumptive service connection for certain disabilities associated with herbicide exposure in the Republic of Vietnam prescribes the dates during which the veteran must have served within the Republic of Vietnam. *See* 38 U.S.C. 1116. Similarly, 38 U.S.C. 1117 prescribes the requirements for eligibility for benefits associated with service in the Persian Gulf War. Notably, this statute also grants the Secretary the authority to determine the period of time following service during which a qualifying disability must manifest. *See* 38 U.S.C. 1117(b).

In the case of this regulation, Congress did not enact a specific statute authorizing the Secretary to establish compensation for disabilities presumptively related to exposure to contaminants in the water supply at Camp Lejeune. While creating this presumption via regulation fits within the authority conferred by section 501, the Secretary's rulemaking actions must have a rational basis. The Secretary has determined that, in the absence of evidence establishing an appropriate period of time for an exposure requirement, the soundest course is to maintain consistency with the Camp Lejeune Act, which establishes eligibility for VA health care for Camp Lejeune veterans who meet applicable criteria, including a 30-day service requirement. *See* 38 U.S.C. 1710(e)(1)(F), 38 CFR 17.400. This will help to avoid public confusion and inconsistent results, for example where some Camp Lejeune veterans would be eligible for a presumption for purposes of disability compensation, but not the statutory presumption for health care benefits.

2. Modality of Exposure to Contaminants

Comments from DAV and Legal Counsel for the Elderly stated that failure to consider periods of service shorter than 30 days ignores the likelihood of regular and repeated exposure to contaminants through multiple modalities. The commenters noted that the National Research Council (NRC) explored three major routes of exposure to contaminants: Inhalation, skin contact, and ingestion. The NRC's 2009 study noted that doses of contaminants from showering could provide inhalation and dermal exposures that are equivalent to ingesting two liters of water, as water temperature impacted the volatility of the contaminants. Accordingly, commenters argued that when taking into account multiple modalities of exposure, the exposure to contaminants could be much greater in a shorter time period than compared to 30 days of drinking the water. This comment was echoed by several individual commenters.

As noted in the proposed rule, the Technical Working Group's (TWG) assessment relied on a hazard evaluation model, focusing on the strength of the evidence that a chemical is capable of causing a given health condition. The TWG did not take into account estimated levels of contamination in the water during the period of contamination at Camp Lejeune or the estimated length or intensity of exposure. This is in part because contaimination levels and exposures were not well documented. For example, the 2009 NRC committee was ''not aware of any historical information that documents individual water-use patterns and behaviors of residents of base housing.'' Committee on Contaminated Drinking Water at Camp Lejeune; National Research Council, *Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects* 61 (National Academies Press, 2009). Accordingly, the TWG did not characterize the risk associated with potential alternative levels of exposure (to include various modalities of exposure) of those who served or resided at Camp Lejeune during the period of contamination.

It is also relevant to note that the scientific evidence was not analyzed by

VA for sufficiency to support an expert opinion in a legal proceeding regarding causation in any individual case. Therefore, VA intimates no conclusion regarding any individual veteran's development of a disease and its relationship to exposure to contaminated water at Camp Lejeune for any purpose beyond entitlement to disability benefits administered by VA.

In the notice of proposed rulemaking, VA acknowledged that the available scientific evidence does not provide data on levels of exposure associated with each condition and proposed to rely upon the 30-day service requirement contained in the provisions of the Camp Lejeune Act. In the absence of scientific evidence which supports establishment of an alternative service or exposure requirement, VA's determination favors consistency and parity with its own health care regulation and the statute stands. Congress understood the Camp Lejeune Act to mean that ''veterans deserve the presumptions of the service connection in the bill to ensure that they receive the benefits to which they are due,'' and did not specify that a different service requirement should exist for purposes of disability compensation. 158 Cong. Rec. H5430 (July 31, 2012) (statement by Rep. Dingell). Creation of a separate standard for the purposes of disability compensation would create inconsistency in the administration of benefits for Camp Lejeune veterans where the statute includes a clear service requirement for health care eligibility; inclusion of the 30-day requirement ensures consistency and parity in this regard with both the Camp Lejeune Act and VA's own regulations implementing the health care provisions of the act. For example, including a service requirement less than that in the Camp Lejeune Act could lead to the situation wherein a veteran is determined to be ineligible for VA health care on the grounds that he or she did not have the necessary 30 days of service at Camp Lejeune, but is then granted service connection on a presumptive basis based on the same service at Camp Lejuene upon filing a claim for compensation. A veteran in this situation could, via operation of this presumption, become eligible for VA health care based on their service connection rating, even though he or she would not have been eligible under the 30-day service requirement of the Camp Lejeune Act. This confusing result could raise a question as to whether VA had indirectly contravened a portion of the Camp Lejeune Act by virtue of a liberalizing evidentiary presumption meant for compensation claims.

One commenter expressed concern with the 30-day requirement because the individual had documentation stating that his or her length of stay at Camp Lejeune was four weeks (which would be 28 days if read strictly). The individual noted that Department of Defense documentation sometimes references weeks of training, rather than days of training and expressed concern with personal and administrative burden associated with documenting presence on base for a day or two before and/or after training. As stated above, VA is adopting a 30-day requirement to ensure consistency with the Camp Lejeune Act. In adjudicating individual claims, VA is required to assist claimants in obtaining evidence and to resolve reasonable doubt in claimants' favor.

Thus, while VA acknowledges and thanks the commenters for their input, VA is unable to make any changes based upon these comments at this time. However, VA will continue to review relevant information as it becomes available and will consider future amendments to the 30-day requirement as appropriate.

3. Decide Claims Through Tort Law

Another commenter felt that the statutory 30-day requirement lacked a medical basis and felt that veterans' claims should be handled through tort law rather than the disability claim process. VA notes that the 30-day requirement for health care benefits was established by Congress. Furthermore, the presumptions set forth in this rulemaking are for the purposes of administering VA disability compensation benefits only; VA expresses no view regarding the potential correlation between any given level or duration of exposure and the increased risk of disease and/or disability for any purpose beyond this rulemaking. Accordingly, VA takes no action based on this comment.

4. Eliminate 30-Day Requirement for Health Care

Another commenter stated that VA should not require 30 days of service at Camp Lejeune to establish entitlement to health care benefits. The service requirement to establish entitlement to health care is mandated by the Camp Lejeune Act. The Camp Lejeune Act is a statute, the provisions of which were enacted by Congress. VA lacks the legal authority to alter, amend, or otherwise change the provisions of a statute and therefore takes no action based on this comment. We discuss the difference in scope between the Camp Lejeune Act and this final rule in greater detail in section D.1, below.

5. Conduct Additional Studies on Exposure Requirements

A comment from VFW stated that VA should conduct additional studies to cover the impact of exposure on individuals who served less than 30 days, with the ultimate goal of reducing the 30-day exposure requirement. VA thanks VFW for its suggestion regarding conducting additional studies. However, this rulemaking pertains solely to establishing presumptions of service connection associated with exposure to contaminants in the water supply at Camp Lejeune; conducting scientific and/or medical studies is beyond the scope of this rulemaking. As such, VA makes no change to the final rule based on this comment.

6. Miscellaneous Alternative Exposure Requirement Comments

VA received several comments offering additional alternative minimum exposure requirements, with suggestions including a single day at Camp Lejeune and an increase to 90 days. While these comments offered alternative exposure criteria, they did not provide a rationale for the suggested alternative that was rooted in scientific, medical, or other rational basis.

As discussed above, the notice of proposed rulemaking acknowledged that the current science does not support a specific minimum exposure level for any of the conditions, as the available scientific and medical evidence focused on hazard models when studying the long-term health effects of the contaminants. Lacking such a scientific basis, VA relied upon the only source available in deciding to establish a 30-day exposure requirement: The Camp Lejeune Act. As VA acknowledged in the notice of proposed rulemaking, the Camp Lejeune Act does not provide a legal requirement for prescribing a 30-day service requirement for the purposes of disability compensation. However, the Camp Lejeune Act and VA's prior implementation of its provisions require 30 days of service at Camp Lejeune for a veteran to establish entitlement to health care. See 38 CFR 17.400. In light of the Camp Lejeune Act, VA's implementation of its provisions through 38 CFR 17.400, and the lack of an alternative exposure requirement supported by scientific, medical, or other rational evidence, VA determined that inclusion of the 30-day requirement in this rulemaking ensures consistency

and parity with both its health care regulations and the statute.

Without a rational basis to explain and support an alternative exposure requirement, VA's rulemaking would not comply with the statutory requirements of 38 U.S.C. 501 and therefore takes no action based on these comments. VA will continue to review relevant information as it becomes available and will consider future changes to the regulation as appropriate.

VA notes that nothing in the provisions of this rule prevents veterans without the requisite 30 days (consecutive or nonconsecutive) of service at Camp Lejeune from establishing service connection for any disease or disability on a direct basis. Direct service connection for any disease alleged to have been caused by the contaminants in the water supply at Camp Lejeune requires evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation.

B. Definition of Service at Camp Lejeune

VA received seven comments concerning the definition of *service at Camp Lejeune* for the purposes of establishing entitlement to disability benefits on a presumptive basis, as contained in proposed § 3.307(f)(7)(iii). These comments suggested that the rule make reference to specific locations within the borders of Camp Lejeune, some of which may be considered satellite camps/locations. One commenter noted that veterans may have lived in one of the specified satellite camps/locations while assigned to Camp Lejeune, or vice versa. Another commenter stated that listing specific satellite locations included within the definition of Camp Lejeune would avoid confusion for eligible veterans and minimize the risk of improper denials by claims processors who may not be aware of the satellite camps/locations. One commenter stated that the proposed rule did not include Marine Corps Air Station New River. Legal Counsel for the Elderly stated the presumption should extend to those who served in circumstances ''likely'' to have resulted in exposure to contaminants in the water supply at Camp Lejeune. This comment gave examples of those who served in training exercises or ships outside of Camp Lejeune but ''likely'' used water drawn from Camp Lejeune. An additional comment referenced Navy Amphibious Forces that docked at Camp Lejeune and most likely took on board fresh water from the Camp.

VA makes no change based on these comments. As stated in the proposed rule, VA broadly defined *service at Camp Lejeune* as any service within the borders of the entirety of the United States Marine Corps Base Camp Lejeune and Marine Corps Air Station New River, North Carolina, during the period beginning on August 1, 1953, and ending on December 31, 1987, as established by military orders or other official service department records. This definition is consistent with the Camp Lejeune Act and VA's prior implementation of the act, promulgated at 38 CFR 17.400. To ensure accurate and consistent application of the definition of *service at Camp Lejeune,* VA will administratively provide claims processors with all necessary factual and background information to process claims in accordance with this regulation.

Marine Corps Air Station (MCAS) New River, while located within the borders of the entirety of Camp Lejeune, falls under a separate command from Camp Lejeune itself. VA identified MCAS New River as a separate location as military orders or other official service department records may specifically denote service at or assignment to MCAS New River; failure to specify this location may result in improper denials of claims or create confusion for otherwise eligible veterans. VA notes that service at MCAS Cherry Point, which is geographically separate from Camp Lejeune (approximately 55 miles away), has a separate water source, and is under a separate command structure, does *not* meet the definition of *service at Camp Lejeune* for purposes of this rulemaking.

VA notes that the definition of *service at Camp Lejeune* relies on military orders or other official service department records to establish that an individual *had service* at Camp Lejeune for the purposes of entitlement to presumptive service connection based on exposure to contaminants in the water supply. As discussed in the proposed rule, the 2007 United States General Accounting Office (GAO) study found that the contaminated water supply systems served housing, administrative, and recreational facilities, as well as the base hospital at Camp Lejeune. See U.S. General Accounting Office, *Defense Health Care: Activities Related to Past Drinking Water Contamination at Marine Corps Base Camp Lejeune* (2007). Neither the GAO nor any other available study indicated that individuals who served aboard amphibious vessels were exposed to contaminants found in the water supply at Camp Lejeune. Without evidence in official service department records documenting official orders or assignment to serve, either in an individual capacity or as part of a larger unit, at Camp Lejeune, a claimant does not meet the evidentiary standard for presumptive service connection. As such, without military orders or other official service department records reflecting service at Camp Lejeune, veterans, former reservists or National Guard members who served aboard vessels that docked at Camp Lejeune during the period of contamination are not eligible for presumptive service connection under the provisions of this rule.

As stated in the proposed rule, veterans without the requisite 30 days (consecutive or nonconsecutive) of service at Camp Lejeune, including those who allege exposure aboard amphibious vessels without military orders or other official service department records reflecting assignment to serve at Camp Lejeune, may still establish service connection for any disease or disability on a direct basis. Direct service connection for any disease alleged to have been caused by the contaminants in the water supply at Camp Lejeune requires evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation.

C. Benefits for Former Reservists and National Guard Members

VA received five comments regarding benefits for former reservists and National Guard members. One commenter stated that VA should define what benefits are available to reservists under the rule, noting that the rule states reservists would be entitled to ''some'' benefits under the rulemaking. Similarly, another commenter stated that VA does not consider reservists and former National Guard members ''veterans'' unless they have a service-connected disability. Another commenter noted that reserve and National Guard status does not meet the requirements of 38 CFR 3.6, and urged VA to amend other regulations to eliminate any conflict for applying presumptions of disability to reserve and National Guard members. Finally, one commenter stated that the rule does not include reservists and asked for VA to amend the rulemaking to include reservists.

As stated in the proposed rule, basic eligibility for VA benefits requires that an individual be a ''veteran'' as that term is defined in 38 U.S.C. 101(2). Reserve duty during a period of active

duty for training or inactive duty for training generally does not qualify an individual as a ''veteran,'' because it does not constitute ''active military, naval, or air service,'' unless the person is disabled or dies during that period of service as prescribed by 38 U.S.C. 101(24)(B) and (C). However, under this rule, former reservists and National Guard members meeting the service criteria for presumptive service connection based on exposure to contaminants at Camp Lejeune have veteran status for the purpose of entitlement to service connection for the enumerated disabilities; there is no limitation of benefits to former reservists and National Guard members under this rule. VA makes no change based upon these comments.

Another commenter stated that VA's inclusion of former reservists and National Guard members in the rulemaking stretches Congressional intent with regards to the definition of ''veteran.'' The commenter also suggested that Congress should provide guidance on the definition of a veteran, and that VA is underestimating the financial impact of this rule. As explained in the proposed rule, although 38 U.S.C. 101(24) requires a period of active duty for training or inactive duty training ''during which the individual was disabled or died'' for this period to constitute active military, naval, or air service, this statute was enacted at a time when the latent effects of exposures to certain harmful chemicals were unrecognized. Further, the legislative history behind this statute does not specifically explain Congress' intent in requiring that the individual ''was disabled or died'' during the period of service in question. As section 101(24) serves a generally beneficial purpose to recognize certain reserve and National Guard service which results in disability or death as affording veteran status for the purposes of VA disability benefits, and in light of increased medical understanding of the possible latent effects of toxic exposure, VA feels it is reasonable to include former reservists and National Guard members with qualifying service under this rule. Accordingly, VA makes no change based upon this comment.

D. Comments Pertaining to Presumptive Disabilities

VA received several comments regarding the disabilities included in the proposed rulemaking. These comments fell into two basic categories: One group related to the general differences between the disabilities in the proposed rule and the health care provisions in the Camp Lejeune Act, while the other comments focused on individual disabilities.

1. Presumptive Disabilities Differ From the Camp Lejeune Act

VA received 42 comments, including from VVA, NOVA, and Legal Counsel for the Elderly, regarding the disabilities in our proposed rulemaking and the disabilities listed in the Camp Lejeune Act. The commenters noted that VA's proposed rulemaking contained fewer and different conditions than the Camp Lejeune Act, with several commenters urging VA to adopt the list of disabilities in the Camp Lejeune Act in its entirety, without change. One commenter stated that veterans who develop a condition listed in the health care provisions of the Camp Lejeune Act but not listed as a presumptive disability would be denied compensation benefits for conditions for which health care is being provided. For the reasons enumerated below, VA makes no change based on these comments.

As explained in the proposed rule, the Camp Lejeune Act provides medical care, but not compensation benefits, to veterans who served on active duty at Camp Lejeune for the 15 identified conditions ''notwithstanding that there is insufficient medical evidence to conclude that such illnesses or conditions are attributable to such service.'' VA's more recent review of scientific evidence was undertaken to determine the appropriateness of establishing presumptions of service connection for claimants who served at Camp Lejeune. As noted in the proposed rulemaking, this review included the analysis of several hazard evaluations on the chemicals of interest conducted by multiple bodies of scientific experts and was not an evaluation of the specific risks of exposure to contaminated water at Camp Lejeune. VA's review resulted in the recognition that liver cancer and Parkinson's disease, two diseases that were not included in the Camp Lejeune Act, are conditions for which there is strong evidence of a causal relationship and evidence that the condition may be caused by exposure to the contaminants. However, at this time, VA concludes that there is insufficient evidence to establish presumptions of service connection for the following diagnosed chronic disabilities in the Camp Lejeune Act: Esophageal cancer, lung cancer, breast cancer, neurobehavioral effects, and scleroderma. As noted in the notice of proposed rulemaking, none of the evidence reviewed concluded that there is a positive association between these conditions and the volatile organic compounds of interest. The exclusion of scleroderma is addressed separately in the next section.

Additionally, the health care provisions of the Camp Lejeune Act provide medical coverage for health effects that are not themselves diagnosed diseases or clearly associated with a specific diagnosed disease. To establish that disability arising years after service is associated with harmful exposure in service, the evidence generally must show that the disability results from a disease associated with the in-service exposure. Accordingly, in § 3.307, VA has established presumptions of service connection for specific diseases, as distinguished from general health effects that may result from specific diseases but are not themselves diseases. The available scientific evidence did not identify a specific or general diagnosis of disease associated with renal toxicity or hepatic steatosis, conditions which are included in the provisions of the Camp Lejeune Act.

Finally, the Camp Lejeune Act included health care for female infertility and miscarriage. However, as noted in the proposed rule, the NRC's 2009 report indicated that the occurrence of female infertility and miscarriage were limited to exposure concurrent with those health effects. As such, the inclusion of these conditions in the Camp Lejeune Act does not provide a basis at this time for presuming current health effects of this type to be associated with past exposure. Additionally, as stated in the proposed rule, these two conditions are not in and of themselves disabilities for which VA can provide disability compensation.

Accordingly, as noted by one commenter, an outcome of VA's review of the available scientific evidence, to include additional evidence that did not exist at the time the Camp Lejeune Act was passed, may result in situations where an individual receives VHA health care for a covered condition without an associated copayment under the Camp Lejeune Act, but is not eligible for presumptive service connection for disability compensation for that condition under this rulemaking. While these individuals may not be eligible for presumptive service connection under this rulemaking, they may be eligible for direct service connection for any disease alleged to have been caused by the contaminants in the water supply at Camp Lejeune, including a disease or disability covered under the Camp Lejeune Act. As noted earlier in section B, direct service connection requires

evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation. Conversely, it is similarly possible that a condition not exempted from copayment under the Camp Lejeune Act, such as liver cancer or Parkinson's disease, could be granted presumptive service connection pursuant to this final rule. We note that a grant of service connection for such a condition would exempt treatment associated with that condition from copayment requirements, as VA copayments do not apply to treatment of service connected disabilities. A grant of presumptive service connection could also create an alternative basis for enrollment in the VA health care system. See 38 CFR 17.36.

VA will continue to review relevant information as it becomes available and will consider future additions to the list of covered conditions as appropriate.

In addition to suggesting that VA should provide disability compensation for the conditions in the Camp Lejeune Act, one commenter suggested that, alternatively, VA should change the provisions of the Camp Lejeune Act to match the eight disabilities covered in the proposed rule. The Camp Lejeune Act is a statute, the provisions of which were enacted by Congress. VA lacks the legal authority to alter, amend, or otherwise change the provisions of a statute and therefore takes no action based on this comment.

2. Exclusion of Scleroderma as a Presumptive Disability

Eight commenters, including the Project on Government Oversight, Legal Counsel for the Elderly, and a member of Congress, specifically questioned VA's exclusion of scleroderma as a presumptive disability. These commenters noted that scleroderma was included in the health care provisions of the Camp Lejeune Act and suggested that VA specifically include this condition as a presumptive disability. Additionally, the comment from a member of Congress stated that there was modest causal evidence from the Agency for Toxic Substances and Disease Registry (ATSDR) and the economic impact of including scleroderma would be minimal, as the number of Camp Lejeune veterans suffering from this condition is small.

As explained in the proposed rule, due to the lack of new scientific/medical evidence (outside of the available evidence considered by the TWG) linking any of the contaminants found in the water supply with the development of scleroderma specifically, VA cannot create a presumption of service connection for Camp Lejeune veterans at this time. Though the available evidence has established a role for trichloroethylene (TCE) in the development of autoimmune diseases, the studies that specifically report on scleroderma include factors that introduce significant uncertainty into their results, to include small sample sizes and an unexplained gender effect. Although the science does not at this time support the addition of scleroderma to the list of covered diseases, VA will continue to monitor and review future studies as they become available and will consider future additions to the list of covered diseases as appropriate.

3. Inclusion of Neurobehavioral Effects and Parkinsonism

VA received eight comments regarding the issue of neurobehavioral effects and parkinsonism, including an organizational comment from the United Parkinson's Advocacy Council. Three commenters stated the presumptive disabilities should include neurobehavioral effects, with one commenter specifying inclusion of specific types of neurobehavioral effects. Another commenter suggested that VA include ''Parkinson-like'' symptoms as a presumptive disability under the general diagnosis of neurobehavioral effects. The third commenter asked if parkinsonism was included under the definition of Parkinson's disease. Another commenter stated that there is no way to definitively diagnose Parkinson's disease. The United Parkinson's Advocacy Council stated VA should include ''atypical parkinsonism'' in the rulemaking.

Parkinson's disease was included in the list of presumptive disabilities due to a recommendation made by the Institute of Medicine (IOM) in their 2015 report ''Review of VA Clinical Guidance for the Health Conditions Identified by the Camp Lejeune Legislation.'' The IOM noted that Parkinson's disease is a specific neurobehavioral effect that may be experienced by individuals exposed to the contaminants in the water supply at Camp Lejeune.

Parkinson's disease is medically distinguishable and separately diagnosable from a variety of parkinsonian syndromes, including drug-induced parkinsonism and neurodegenerative diseases, such as multiple systems atrophy, which have parkinsonian features combined with other abnormalities. Most notably, the pathologic findings in cases of parkinsonism show different patterns of brain injury than those noted in patients with Parkinson's disease. See Institute of Medicine of the National Academies, *Veterans and Agent Orange: Update 2012*, The National Academies Press (Washington, DC, 2014). The studies that have established a relationship between the contaminants in the water supply at Camp Lejeune and Parkinson's disease reported specifically on Parkinson's disease, not parkinsonism or other parkinsonian syndromes. At this time, the available evidence does not establish that parkinsonism and other manifestations of small fiber nerve damage are associated with exposure to the contaminants in the water supply at Camp Lejeune. Therefore, VA makes no change based on these comments.

4. Adult Leukemia

VA received 12 comments, including from the Project on Government Oversight and VFW, and one from a member of Congress, addressing the condition of adult leukemia. The commenters stated that VA should clarify the disabilities included in adult leukemia by changing the term to ''leukemia,'' ''adult leukemias,'' or by listing all sub-types of leukemia included in the definition of adult leukemia. A comment from a member of Congress specifically cited an ATSDR report, which noted all leukemia sub-types are associated with exposure to contaminants in the water supply at Camp Lejeune. The same member of Congress also stated the use of ''adult leukemia'' was unnecessary because all who qualify for this benefit are adults, as the rulemaking does not apply to dependents. Another commenter stated that VA should replace the term ''adult leukemia'' with ''chronic or acute forms of lymphocytic and myeloid leukemia'' to clarify what conditions are covered. VA disagrees and makes no change based on these comments.

The term ''adult leukemia'' clarifies that the types of leukemia covered under this rulemaking must have their onset in adulthood. This distinction between adult and non-adult leukemias is necessary, as the disability compensation provided by this rulemaking applies only to disabilities arising in veterans, reservists, or National Guard members as a result of their exposure to contaminants in the water supply at Camp Lejeune while serving under official military orders or other official assignment. As such, the presumptions of this rulemaking do not apply to veterans, reservists or National Guard members who develop leukemia

prior to qualifying service at Camp Lejeune.

The use of the term ''adult leukemia'' was not intended to restrict the types of leukemia covered by this rulemaking. No sub-type of leukemia was identified in the rulemaking in order to be inclusive to all types of leukemia, including the sub-types identified by commenters. VA notes that inclusion of specific sub-types included within this definition will lead to an incomplete list, potentially confusing veterans, reservists and National Guard members who have a qualifying disability, as well as claims processors.

5. Miscellaneous Disabilities

VA received 53 comments, including organizational comments from the Fort McClellan Veterans Stakeholders Group, which requested inclusion of miscellaneous conditions and disabilities, both specified and unspecified, that were not the subject of the proposed rulemaking, nor were they included in the provisions of the Camp Lejeune Act. These conditions include: Hodgkin's disease, diabetes mellitus, depression, sleep apnea, throat cancer, fibroid sarcoma, prostate cancer, colon cancer, brain cancer, mesothelioma, soft tissue sarcoma, gynecomastia, prolactemia, Crohn's disease, amyloidosis, hidradenitis suppurativa, immune system toxicity, gastrointestinal cancers, other unspecified immune system effects, unspecified neurologic disorders, unspecified skin conditions, unspecified endocrine disorders, unspecified cellular mutation, cancerous and non-cancerous urinary tract conditions, unspecified kidney effects, unspecified liver effects, unspecified endocrine effects, unspecified cardiovascular disorders, and unspecified cancers. Additionally some commenters stated that VA should include additional disabilities without specifying those additions. Two commenters stated that VA should consider all diseases and disabilities as associated with exposure to contaminants in the water supply at Camp Lejeune, noting that VA should bear the burden of proof as to why any disability is unrelated to exposure to contaminants at Camp Lejeune. Another commenter suggested inclusion of conditions not identified by scientific evidence. Finally, one commenter cited a decision by the Board of Veterans' Appeals (BVA) as sufficient evidence to support adding prostate cancer to the list of presumptive disabilities. The same commenter also stated VA should consider adding hepatitis C, noting a correlation between it and prostate cancer.

As stated in the proposed rule, VA undertook a deliberative scientific process to determine whether available scientific evidence was sufficient to support a presumption of service connection for any health condition as a result of exposure to the chemicals found in the drinking water at Camp Lejeune. This process involved an evaluation of comprehensive hazard studies conducted by several internationally respected expert bodies. VA also notes that BVA decisions are made on the facts, circumstances, and evidence of individual claims on a case-by-case basis; these cases do not set precedent. At this time, there is insufficient medical and scientific evidence to establish a presumption of service connection for any disability beyond the eight conditions included in the rulemaking; therefore, VA makes no change in response to these comments at this time.

VA relies heavily on studies of exposed populations in order to establish such an association, and will continue to monitor future studies, especially those conducted on the Camp Lejeune population, as they become available. VA will consider additions to the list of presumptive disabilities as appropriate, should future studies provide sufficient evidence for such a change.

As previously discussed, it is also relevant to note that the scientific evidence was not analyzed by VA for sufficiency to support an expert opinion in a legal proceeding regarding causation in any individual case. Therefore, VA intimates no conclusion regarding any individual veteran's development of a disease and its relationship to exposure to contaminated water at Camp Lejeune.

6. Kidney Cancer

One commenter asked why VA is not recognizing kidney cancer as a presumptive disability. As noted in the proposed rule under amended § 3.309(f), kidney cancer is one of the listed conditions VA recognizes as presumptively associated with exposure to contaminants in the water at Camp Lejeune. VA makes no change based upon this comment.

E. Effective Date

VA received 27 comments, including from the C–123 Veterans Association, VFW, and NOVA, concerning the effective date of the regulation. Comments included suggestions that this rule should be effective the date a claim was initially filed, even if prior to the effective date of the final rule, or on the date of onset or diagnosis of a covered illness. Other commenters stated the rule should be effective retroactively to the date an eligible veteran first served at Camp Lejeune. Some commenters stated that the rule excludes previously denied claims, and therefore VA should apply the provisions of the *Nehmer* v. *U.S. Department of Veterans Affairs* (*Nehmer*) court order to determine a retroactive effective date for awards. See *Nehmer* v. *U.S. Department of Veterans Affairs,* No. CV–86–6161 TEH (N.D. Cal.). One commenter suggested that the rule should be effective the date the proposed rule was published, as it should have been published as an interim final rule. Finally, one commenter asked if a ''pending'' claim includes the one-year period following notice of a denial as well as appeals before the BVA.

As stated in the proposed rule, this rule will apply to claims received by VA on or after the effective date of the final rule and to claims pending before VA on that date. Under 38 CFR 3.160(c), a claim that has not been finally adjudicated (which includes claims where a final and binding decision has been issued but the appeal period has not expired) is still considered a pending claim. The rule does not apply retroactively to claims that are finally adjudicated. VA must adhere to the provisions of its change of law regulation, 38 CFR 3.114, which states that where pension, compensation, dependency and indemnity compensation is awarded or increased pursuant to a liberalizing law, or a liberalizing VA issue approved by the Secretary or by the Secretary's direction, the effective date of such award or increase shall be fixed in accordance with the facts found, but shall not be earlier than the effective date of the act or administrative issue. See also 38 U.S.C. 5110(g).

This final regulation is based on the Secretary's broad authority under 38 U.S.C. 501(a) to ''prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws, including— . . . regulations with respect to the nature and extent of proof and evidence . . . in order to establish the right to benefits under such laws.'' This rulemaking authority does not explicitly afford the Secretary authority to assign retroactive effect to the regulations created thereunder, and retroactivity is heavily disfavored in the law. As explained in the proposed rule, a claimant whose claim was previously and finally denied may file a new claim to obtain a new determination of

entitlement under the final regulation. Finally, VA notes that the effective date provisions of the *Nehmer* court order apply only to claims based on exposure to herbicides in the Republic of Vietnam during the Vietnam era and are therefore inapplicable to this final rule.

The Administrative Procedures Act (APA) provides guidance as to when a rulemaking may be published as an interim final rule. Under the APA, a rulemaking may be published as an interim final rule if it is determined that notice and public comment ''are impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3)(B). As this rulemaking involves significant economic costs, the opportunity for prior review and comment was necessary and in accordance with the public interest. VA has acted expeditiously to consider these public comments and prepare a final rulemaking. Therefore, VA makes no changes based on these comments.

F. Date Range for Contamination

One commenter stated the date range for exposure should be extended without specifying exact dates. The commenter stated that contamination likely still existed even after the water supply met unspecified Environmental Protection Agency (EPA) standards. Similarly, VVA stated the contamination period should be extended until December 31, 2000, the last day of the year that the Navy removed contaminated soil and other items from the sites surrounding Camp Lejeune. Another commenter stated the background information in the proposed rule regarding contamination was incorrect; this commenter stated that contamination ended in 1987 and the initial contamination warnings were in 1980. Another commenter stated VA should expand the date range to include those who served from January 1, 1947, through July 31, 1953, without further elaboration.

As stated in the proposed rule, the Camp Lejeune Act specified a period of contamination from August 1, 1953, through December 31, 1987. This date range is likely based on some of the earliest assessments of the Camp Lejeune water supply noted in the NRC report. This period also represents the ATSDR's best estimate of the period of contamination at Camp Lejeune. In the absence of additional scientific evidence to support an expansion of the contamination period, VA makes no change based upon these comments at this time.

G. Additional Contaminants

VA received two comments regarding consideration of additional contaminants. One commenter stated that VA should include information about unspecified lead contamination during the 1990s. The commenter also requested inclusion of information contained in an unspecified 1997 study. Another commenter stated that VA's assessment of contaminants is incomplete, as it does not consider toxic compounds outside those noted in the rulemaking.

As stated in the proposed rule, VA is only addressing the contamination of the water supplies by the four chemicals of interest (*i.e.,* TCE, perchloroethylene (PCE), benzene, and vinyl chloride) that occurred between August 1, 1953, and December 31, 1987, as a result of on-base industrial activities and an off-base dry cleaning facility. Exposure events unrelated to the specified date range and sources of contamination are unrelated to the subject and scope of this rulemaking; therefore VA makes no change in response to this comment.

H. Additional Scientific or Medical Evidence

Two commenters stated that VA should reference additional, uncited studies, stating the rulemaking should consider the effects of exposure to solvent mixtures. One commenter stated VA should reference an unspecified study of the individuals who were actually exposed to contaminants in the water supply at Camp Lejeune. Another commenter, the Fort McClellan Veterans Stakeholders Group, without further elaboration, stated that VA uses the wrong method to evaluate toxic exposures. VA also received a comment stating that unspecified evidence exists to possibly support the addition of more disabilities. One commenter stated that the NRC did not perform a study, it merely reviewed available literature, and the 2009 NRC is flawed and outdated. This same commenter also stated that the description of the collaboration between ATSDR, VA's Camp Lejeune Science Liaison Team, and VA's Technical Workgroup (TWG) was incorrect. The commenter stated that the community was not directly involved in this collaboration. Another commenter stated it was unclear which ATSDR studies were considered in the rulemaking. Other commenters stated generally that inclusion or performance of additional studies could result in a larger list of presumptive disabilities. Finally, one commenter stated that a source with the Center for Disease Control stated it is impossible to determine the minimum level of exposure to a contaminant needed to result in negative health effects.

VA currently has no information at its disposal to define the specific hazardous exposure levels or combinations of exposure that any one individual received, which would determine exactly who in the veteran population might be at an increased risk of experiencing adverse health effects related to their service at Camp Lejeune. As explained in the proposed rule, the VA review consisted of a hazard evaluation for the four chemicals of interest: TCE, PCE, benzene and vinyl chloride, and focused on the effects of these individual contaminants without regard to specific exposure levels. Additionally, as explained in the rulemaking, VA reviewed evidence from several internationally recognized scientific authorities, including groups other than the NRC. Regarding the description of the process employed by ATSDR, VA notes that ATSDR is an external entity and, as such, is not subject to VA's control. VA also notes that the notice of proposed rulemaking contains a full list of scientific studies and reviews cited in the rulemaking in section E, ''Weight-of-Evidence Analyses Considered by the TWG.''

VA's rule is as inclusive as possible in covering the illnesses of veterans, former reservists and National Guard members exposed to contaminants in the water supply at Camp Lejeune based on the available scientific evidence, in the absence of specific exposure information. VA makes no change based on these comments.

I. Expedite Rulemaking

VA received 17 comments, including an organizational comment from VFW, urging VA to expedite the rulemaking, to include publication of a final rule under which benefits may be granted. VA must adhere to the requirements of the APA, which includes a period for public comment and review of the rulemaking. VA appreciates these comments and has taken the necessary steps to ensure this rule is finalized while conforming to the legal requirements of notice and comment rulemaking.

J. Benefits for Veterans Born at Camp Lejeune Without Service at Camp Lejeune

One commenter asked if the rule provides compensation for veterans who were born at Camp Lejeune but do not have qualifying active duty, reserve, or National Guard service at Camp Lejeune. VA is only authorized to pay disability compensation for disability

resulting from injury suffered or disease contracted in line of duty ''in the active military, naval, or air service''. 38 U.S.C. 1110, 1131. Thus, VA has no authority to pay compensation for disability arising from events prior to service entry. VA makes no change based upon this comment.

K. Standard of Evidence for Claims

One commenter stated that the proposed rulemaking would still require eligible veterans, former reservists and National Guard members to present a medical opinion in support of their claim for a presumptive disability. As stated in the proposed rulemaking, if a veteran, former reservist or National Guard member meets the stated requirements for service at Camp Lejeune, then the subsequent development of any of the eight listed disabilities is presumed to be related to the exposure to contaminants, in the absence of clear and convincing evidence to the contrary. These presumptions do not require any further evidence to support a claim, including a medical opinion. Therefore, VA makes no change based on this comment.

Another commenter stated that the proposed rule makes no reference for individual genetic predisposition to increased vulnerability to a specific toxin. The commenter stated this places an unrealistic burden of proof on an individual to prove that he or she suffers a disability due to exposure to toxins. VA has no information at its disposal to define the specific hazardous exposure any individual received, which could assist in determining who in the veteran population was or would be at an increased risk of suffering adverse health effects related to their service at Camp Lejeune. Furthermore, once the basic eligibility requirements of this rule are met (qualifying service and diagnosis of a listed disability), no further information, to include evidence of a genetic vulnerability to a specific toxin, is necessary. Therefore, VA makes no change based on this comment.

Two commenters asked if a medical opinion that served as the basis of a previous denial could serve as affirmative evidence to rebut the presumption created by this rule. The circumstances of individual claims are beyond the scope of this rulemaking and VA makes no change based upon this comment. However, VA notes that 38 CFR 3.307(d), which pertains to rebuttal of presumptive service connection, specifically requires consideration of all evidence of record when determining the issue of presumptive service connection. As noted above, a claimant whose claim was previously and finally denied may file a new claim to obtain a new determination of entitlement under the final regulation. All claims are adjudicated individually based upon the entire evidentiary record and in accordance with all applicable regulations.

Legal Counsel for the Elderly stated that VA should allow for a veteran's lay testimony to establish the occurrence of exposure to contaminants in the water supply at Camp Lejeune. VA will consider all evidence of record when deciding claims, including lay testimony. However, VA notes that current regulations provide very specific circumstances as to when a veteran's lay testimony is sufficient to establish an occurrence for the purposes of entitlement to disability benefits. For example, a veteran's lay testimony may be sufficient to establish the occurrence of an injury or event that occurred during combat, if that testimony is consistent with the circumstances, conditions, or hardships of that veteran's service, even where no official record of such incurrence exists. The purpose of this lay statement exception is to acknowledge certain circumstances where official records likely will not exist to establish a fact; in this example, it is highly unlikely that medical records will exist to document the occurrence of an injury at the time it occurred during combat. In the present rulemaking, establishing service at Camp Lejeune requires documentation of 30 days of service at Camp Lejeune by military orders or other official service department records. These documents are regularly and routinely issued by the military as a part of its normal duties in documenting personnel assignments and location and are a part of every servicemember's personnel file. As the evidence required to establish service at Camp Lejeune, and therefore satisfy the condition necessary to presume exposure to contaminants in the water supply, is readily available, VA makes no change based upon this comment.

Similarly, one commenter stated VA should provide a ''benefit of the doubt'' to anyone who served at Camp Lejeune in the 1980s. As stated in the rule, this presumption of service connection applies to any veteran, to include former reserve and National Guard members, who served at Camp Lejeune during the relevant time period. This presumption reduces the evidentiary burden required to establish entitlement to disability compensation for certain claims, as further explained in the notice of proposed rulemaking. VA makes no change based upon this comment.

L. Benefits for Family Members or Civilians

VA received 11 comments, including an organizational comment from the United Parkinson's Advocacy Council, stating that family members or civilians who were exposed to contaminants in the water supply at Camp Lejeune should receive disability compensation. VA notes that this rulemaking provides disability compensation for qualifying veterans, former reservists or National Guard members; benefits for family members or civilians are beyond the scope of the rulemaking and therefore VA will not respond to this comment. Additionally, VA notes that there is currently no statutory authority to provide benefits to the classes of people identified by the commenters.

M. General Support for the Rulemaking

VA received 56 comments, including from the C–123 Veterans Association, DAV, VFW, VVA, Project on Government Oversight, Reserve Officers Association, Marine Corps Reserve Association, United Parkinson's Advocacy Council, and Legal Counsel for the Elderly, expressing support for the rulemaking in general. Many of these comments, which were received from individuals as well as organizations in the veteran community, stated appreciation for VA's actions in establishing a presumption of exposure and service connection for veterans, reservists, and National Guard members exposed to contaminants in the water supply at Camp Lejeune. VA appreciates the time and effort expended by these commenters in reviewing the proposed rule and in submitting comments, as well as their support for this rulemaking.

N. Negative Comments

VA received five comments indicating opposition to the rulemaking. These comments expressed disagreement with the rulemaking process in general, and presumptive service connection in particular. VA's decision to create a presumption of exposure to contaminants in the water supply at Camp Lejeune and presumptive service connection for the listed disabilities was issued after the Secretary considered the available scientific evidence and recommendations, as explained in the notice of proposed rulemaking. This evidence demonstrated at least an association between the contaminants in the water supply at Camp Lejeune and the eight listed disabilities. This evidence is supported by published reports from multiple internationally-recognized authorities, and the

Secretary has determined this evidence provides a rational basis to issue regulations for presumptions of exposure and service connection. Accordingly, VA makes no change based on these comments.

O. Character of Discharge and Eligibility for Benefits

One commenter stated that individuals with an other than honorable discharge are excluded from eligibility under this rulemaking. This rulemaking amends 38 CFR 3.307 and 3.309; it does not affect the provisions of 38 CFR 3.12, which pertains to the character of discharge requirements for benefits eligibility. Therefore, this comment is outside the scope of the rulemaking and VA makes no change based on it.

P. Statements About Personal Claims

As stated previously, many commenters made general statements about their own experiences with one or more of the presumptive disabilities, non-presumptive disabilities, their personal disability claims, or their personal health care claims. Comments regarding situations involving the possible outcome of individual claims, or the medical or claims history presented by individual veterans are beyond the scope of this rulemaking. Claimants should contact their VA regional office for assistance with their individual claims.

Q. Other Comments Unrelated to or Outside the Scope of This Rulemaking

VA received 30 comments dealing with issues not directly related to the new presumption of exposure or the new presumptively service-connected diseases. Such comments covered a wide range of topics; examples of such comments appear below.

One commenter stated that VA needs to update the VA Schedule for Rating Disabilities, noting that the criteria used to evaluate the diseases covered under this rulemaking are subjective. Another commenter stated that VA should evaluate individuals who were previously denied as 100 percent disabled. One commenter stated that VA should provide a zero-percent evaluation for any veteran, reservist, or former National Guard member who served at Camp Lejeune during the qualifying period. Two commenters stated that VA should provide health care in addition to disability compensation for veterans, reservists, and former National Guard members contemplated under this rulemaking. Two commenters stated that the rule does not include a mechanism for notifying eligible veterans who may be unaware of their exposure to contaminants in the water supply at Camp Lejeune. Similarly, VFW stated VA should provide notification to claimants who were previously denied benefits. VFW also stated that VA should update the Catalog of Federal Domestic Assistance titles in the rulemaking to indicate the eligibility to additional benefits available to reservists and National Guard members as a result of the rulemaking. Another commenter urged VA to change the health care priority group level for reservists and National Guard members. Another comment stated that the same standards of evidence used to prosecute a corporation that harms an individual with toxic chemicals should be re-introduced in this rulemaking. Two commenters, including the Fort McClellan Veterans Stakeholders Group and the Project on Government Oversight, stated VA should pay benefits to veterans who served at Fort McClellan. Another commenter asked what effect this rulemaking has on the Camp Lejeune Act or House Resolution 3954—The Camp Lejeune Reservist Parity Act of 2015. One commenter stated the government uses members of the armed forces as guinea pigs for vaccines that have not been approved by the Food and Drug Administration. VA received one comment that stated this policy change does not protect the rights of veterans. Another commenter stated that the contamination is a violation of the 5th Amendment rights of those who were exposed and stated the base should be evacuated. Six commenters, including the Reserve Officers Association, requested that VA create or add their information to unspecified lists/registries. Another commenter stated that Parkinson's disease should have been specifically listed as a neurobehavioral effect. One commenter stated that VA should use available scientific evidence to ''dismantle'' the provisions of other exposure presumptions, such as benefits related to radiation exposure. The same commenter stated that the presumption of soundness does not apply to National Guard or reserve members who did not undergo physical examination during active duty. Finally, this commenter stated that VA should consider National Guard and reserve members as exposed to herbicides while serving in Canada. Another commenter asked if VA would provide compensation to private insurers for treatment of a covered disability. Without elaborating further, one commenter stated the proposal is too limited in scope and took too long to enact; a similar comment was received stating that the rule does not provide ''sufficient redress.'' Another commenter stated VA should cover the cost of in-vitro fertilization or adoption for veterans experiencing female infertility. One commenter, the Reserve Officers Association, urged Congress to enact additional legislation. A comment from VFW suggested VA study the combined effects of exposure to herbicides and contaminants in the water supply at Camp Lejeune. Another commenter stated that there is nothing in writing that pertains to the individuals who were stationed at Camp Lejeune. VA received a comment stating that VA should provide former Marines with the Purple Heart. One individual stated that qualifying individuals should receive a blanket settlement from the government.

VA does not respond to these comments because they are either unrelated to this rulemaking or beyond its scope.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may have an annual effect on the economy of $100 million or more and may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published from FY 2004 Through Fiscal Year to Date.''

Regulatory Flexibility Act

The Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). These amendments will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are exempt from the regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Congressional Review Act

Generally, under the Administrative Procedure Act, the required publication of a substantive rule shall be made not less than 30 days before its effective date. 5 U.S.C. 553(d). However, this regulatory action is a major rule under the Congressional Review Act, 5 U.S.C. 801–808, because it may result in an annual effect on the economy of $100 million or more. Therefore, in accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis. Provided Congress does not adopt a joint resolution of disapproval, this rule will become effective the later of the date occurring 60 days after the date on which Congress receives the report, or the date the rule is published in the **Federal Register**. 5 U.S.C. 801(a)(3)(A).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.109, Veterans Compensation for Service-Connected Disability; 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on November 16, 2016, for publication.

Dated: January 9, 2017.

Michael Shores,

Acting Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Veterans.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 3 as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

■ 1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 2. Amend § 3.307 by revising the section heading and paragraphs (a) introductory text and (a)(1), and adding paragraph (a)(7) to read as follows:

§ 3.307 Presumptive service connection for chronic, tropical, or prisoner-of-war related disease, disease associated with exposure to certain herbicide agents, or disease associated with exposure to contaminants in the water supply at Camp Lejeune; wartime and service on or after January 1, 1947.

(a) *General.* A chronic, tropical, or prisoner of war related disease, a disease associated with exposure to certain herbicide agents, or a disease associated with exposure to contaminants in the water supply at Camp Lejeune listed in § 3.309 will be considered to have been incurred in or aggravated by service under the circumstances outlined in this section even though there is no evidence of such disease during the period of service. No condition other than one listed in § 3.309(a) will be considered chronic.

(1) *Service.* The veteran must have served 90 days or more during a war period or after December 31, 1946. The requirement of 90 days' service means active, continuous service within or extending into or beyond a war period, or which began before and extended beyond December 31, 1946, or began after that date. Any period of service is sufficient for the purpose of establishing the presumptive service connection of a specified disease under the conditions listed in § 3.309(c) and (e). Any period of service is sufficient for the purpose of establishing the presumptive service connection of a specified disease under the conditions listed in § 3.309(f), as long as the period of service also satisfies the requirements to establish a presumption of exposure to contaminants in the water supply at Camp Lejeune under paragraph (a)(7)(iii) of this section.

* * * * *

(7) *Diseases associated with exposure to contaminants in the water supply at Camp Lejeune.* (i) For the purposes of this section, *contaminants in the water supply* means the volatile organic compounds trichloroethylene (TCE), perchloroethylene (PCE), benzene and vinyl chloride, that were in the on-base water-supply systems located at United States Marine Corps Base Camp Lejeune, during the period beginning on August 1, 1953, and ending on December 31, 1987.

(ii) The diseases listed in § 3.309(f) shall have become manifest to a degree of 10 percent or more at any time after service.

(iii) A veteran, or former reservist or member of the National Guard, who had no less than 30 days (consecutive or nonconsecutive) of service at Camp Lejeune during the period beginning on

August 1, 1953, and ending on December 31, 1987, shall be presumed to have been exposed during such service to the contaminants in the water supply, unless there is affirmative evidence to establish that the individual was not exposed to contaminants in the water supply during that service. The last date on which such a veteran, or former reservist or member of the National Guard, shall be presumed to have been exposed to contaminants in the water supply shall be the last date on which he or she served at Camp Lejeune during the period beginning on August 1, 1953, and ending on December 31, 1987. For purposes of this section, *service at Camp Lejeune* means any service within the borders of the entirety of the United States Marine Corps Base Camp Lejeune and Marine Corps Air Station New River, North Carolina, during the period beginning on August 1, 1953, and ending on December 31, 1987, as established by military orders or other official service department records.

(iv) Exposure described in paragraph (a)(7)(iii) of this section is an injury under 38 U.S.C. 101(24)(B) and (C). If an individual described in paragraph (a)(7)(iii) of this section develops a disease listed in § 3.309(f), VA will presume that the individual concerned became disabled during that service for purposes of establishing that the individual served in the active military, naval, or air service.

* * * * *

■ 3. Add § 3.309(f) to read as follows:

§ 3.309 Disease subject to presumptive service connection.

* * * * *

(f) *Disease associated with exposure to contaminants in the water supply at Camp Lejeune.* If a veteran, or former reservist or member of the National Guard, was exposed to contaminants in the water supply at Camp Lejeune during military service and the exposure meets the requirements of § 3.307(a)(7), the following diseases shall be service-connected even though there is no record of such disease during service, subject to the rebuttable presumption provisions of § 3.307(d).

(1) Kidney cancer.
(2) Liver cancer.
(3) Non-Hodgkin's lymphoma.
(4) Adult leukemia.
(5) Multiple myeloma.
(6) Parkinson's disease.
(7) Aplastic anemia and other myelodysplastic syndromes.
(8) Bladder cancer.

[FR Doc. 2017–00499 Filed 1–12–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0 and 1

[FCC 16–171]

Freedom of Information Act Improvement Act Implementation Order

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission amends its rules to update various sections implementing the Freedom of Information Act (FOIA) to reflect changes in the law made by the FOIA Improvement Act of 2016, to making conforming edits to reflect existing Commission FOIA practice, to streamline the Commission's FOIA procedures, and to provide for clerical corrections.

DATES: Effective February 13, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Yates, 202–418–0886 or TTY: 202–418–0484; *Ryan.Yates@fcc.gov.*

SUPPLEMENTARY INFORMATION:

1. This is a synopsis of the Federal Communication Commission's Order, FCC 16–171, released on December 15, 2016, amending Parts 0 and 1 of the Commission's rules to update sections implementing the FOIA. The complete text of the document is available on the Commission's Web site at *http://www.fcc.gov or at https://apps.fcc.gov/edocs_public/attachmatch/FCC-16-171A1.pdf.* It is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554.

2. By this Order, we amend Part 0 of the Commission's rules to update various sections implementing the Freedom of Information Act (FOIA). On June 30, 2016, the President signed into law the FOIA Improvement Act of 2016 (FOIA Improvement Act). The law went into effect July 1, 2016, and requires, inter alia, that agencies review their FOIA regulations and promulgate new rules in accordance with the substantive provisions of the law. These provisions included providing 90 days for requesters to file appeals of FOIA requests, ensuring that requesters are informed of avenues for FOIA dispute resolution, and providing for public posting of materials that are requested multiple times. The Commission has completed review of its FOIA regulations and in this Order adopts amendments to the rules, thus fulfilling the requirements of section 3(a) of the FOIA Improvement Act.

3. The amendments made by this Order can generally be grouped into two categories. First are rule amendments that are required by or flow directly from changes made by the FOIA Improvement Act. These include regulatory changes specifically mandated by the FOIA Improvement Act, as well as changes that are informed by the FOIA Improvement Act. Second are rule amendments designed to conform the rules to existing Commission FOIA practice, streamline FOIA procedures, and provide for clerical corrections. A number of years have passed since the Commission's FOIA regulations were last updated, and new technology, practices, and procedures have arisen since that time. We update the regulations to reflect the current state of the Commission's FOIA process.

4. The Commission's FOIA implementing rules are presently found at 47 CFR 0.441–0.470. The amended rules are set forth in the Appendix to this Order and are described in more detail below.

5. The following rule changes are either required by the text of the FOIA Improvement Act or are made in response to issues raised in the FOIA Improvement Act.

6. *Section 0.251—Authority Delegated.* Section 0.251 describes the authorities delegated to the General Counsel by the Commission. We add to the rule by delegating to the General Counsel the authority to act as the Chief FOIA Officer. The position of Chief FOIA Officer was created by the Open Government Act of 2007 and expanded upon by the FOIA Improvement Act.

7. *Section 0.441—General.* Section 0.441 sets forth general information related to the Commission's FOIA practice. We make two changes to this section that are required by the FOIA Improvement Act. First, we include a notice that FOIA requesters may seek the assistance of the FOIA Public Liaison or the Office of Government Information Services to assist in resolving disputes, along with the procedure for engaging such assistance. These changes are specifically required by the FOIA Improvement Act. Second, in light of the FOIA Improvement Act's emphasis on the duties of the Chief FOIA Officer, including new responsibilities to offer training to agency staff and to serve as the liaison with the National Archives and Records Administration's Office of Government Information Services and the Department of Justice's Office of

Information Policy, we clarify that the General Counsel serves as the Commission's Chief FOIA Officer and may exercise the responsibilities assigned to that position in the FOIA statute.

8. *Section 0.445—Publication, availability, and use of opinions, orders, policy statements, interpretations, administrative manuals, staff instructions, and frequently requested records.* Section 0.445 instructs the public how to access certain publicly available documents. This rule implements various statutory requirements concerning the public availability of these documents. We amend the rule to make electronically available records that have been or are likely to be the subject of multiple FOIA requests, pursuant to the FOIA Improvement Act.

9. *Section 0.457—Records not routinely available for public inspection.* Section 0.457 addresses some of the types of records that are routinely withheld from public inspection. We change the introductory paragraph to the section to articulate the reasonably foreseeable harm standard codified in the FOIA Improvement Act. We also amend section 0.457(e) to reflect changes brought about by the FOIA Improvement Act eliminating the deliberative process privilege of FOIA Exemption 5 for records more than 25 years old.

10. *Section 0.461—Requests for inspection of materials not routinely available for public inspection.* Section 0.461 sets forth the rules for filing requests to view records that are not routinely available to the public. These rules govern the majority of requests under the FOIA. We extend the amount of time for requesters to file FOIA appeals (called applications for review under Commission practice) from 30 days to 90 days, consistent with the requirements of the FOIA Improvement Act. We will also make a conforming edit to section 1.115(d) of our rules.

11. *Section 0.470—Assessment of fees.* Section 0.470 sets out the three fee categories of FOIA requests and the rules regarding fee waivers. Consistent with the FOIA Improvement Act, we make modifications to make clear that the agency may not charge otherwise applicable search and duplication fees when it fails to meet the notice requirements and time limits under the FOIA, unless more than 5,000 pages are necessary to respond to a single request or exceptional circumstances apply.

12. The following rule changes are not specifically required by the FOIA Improvement Act. Instead, we adopt these rules changes to conform the rules to existing Commission FOIA practice, streamline FOIA procedures, and provide for clerical corrections.

13. *Section 0.251—Authority Delegated.* Section 0.251 describes the authorities delegated to the General Counsel by the Commission. We grant to the General Counsel the authority to dismiss FOIA applications for review that are untimely, repetitious, or fail to articulate specific grounds for review. By giving the General Counsel this authority, procedurally defective requests can be dealt with efficiently and expediently without compromising substantive appeal rights, consistent with other regulations.

14. *Section 0.441—General.* Section 0.441 sets forth general information related to the Commission's FOIA practice. We make two clerical changes to this rule. First, we amend this section to remove facsimile as a method of contacting the Commission regarding FOIA requests. Second, we remove a reference to the Commission's copy contractor, as the Commission no longer employs a copy contractor.

15. *Section 0.442—Disclosure to other Federal government agencies of information submitted to the Commission in confidence.* Section 0.442 applies to the sharing of confidential third-party information with other Federal agencies. We make no changes to this section.

16. *Section 0.445—Publication, availability, and use of opinions, orders, policy statements, interpretations, administrative manuals, staff instructions, and frequently requested records.* Section 0.445 instructs the public how to access certain publicly available documents. This rule implements various statutory requirements concerning the public availability of these documents. To reflect current Commission practice, we eliminate a reference to records being held by the Office of Media Relations. We also include a reference to the availability of records on the Electronic Document Management System (EDOCS) and through the Commission's Web site. Lastly, we remove a reference to the Commission's copy contractor, as the Commission no longer employs a copy contractor.

17. *Section 0.451—Inspection of records: Generally.* Section 0.451 provides an introduction to the broad category of records that are or are not available to the public, along with specifying where in the rules the procedures for requesting those records can be found. We modify section 0.451(b)(4) (previously numbered section 0.451(b)(5)) to reflect current Commission practice, which permits the release of certain non-internal documents without requiring the filing of a FOIA request. This will facilitate the bureaus' and offices' sharing of non-internal documents without the need for a formal FOIA request. We also amend the rules to simplify the language used and consolidate related subsections.

18. *Section 0.453—Public reference rooms.* Section 0.453 currently provides a listing of records routinely available in the Commission's public reference room. It derives from a time that various bureaus and offices of the Commission had individual reference rooms containing paper records for public access. These locations no longer exist, having been supplanted by one central Reference Information Center and the Commission's Web site. We amend the rule to add references to the resources available on the Commission's Web site. It is often simpler and more efficient for members of the public to access this information on the Commission's Web site rather than traveling to the Commission to inspect the records in person. Also, we delete the list of types of documents available in the reference room, and instead provide that a regularly updated list of records will be posted to the Commission's electronic reading room. Using an online list, as opposed to a list set forth in the Code of Federal Regulations, will give staff more flexibility to add to the list of routinely available records, consistent with the FOIA Improvement Act's emphasis on proactive release of records. It will also ensure that the posted list accurately reflects the current routinely available records. Lastly, we include additional information about the types of records available through the Commission's Electronic Comment Filing System (ECFS).

19. *Section 0.455—Other locations at which records may be inspected.* Section 0.455 listed the various bureaus and offices of the Commission at which certain other types of records could be inspected. We delete this section in its entirety. As with section 0.453, we conclude it is more efficient to specify these records on a regularly updated online list rather than on a list in the Code of Federal Regulations.

20. *Section 0.457—Records not routinely available for public inspection.* Section 0.457 articulates some of the types of records that are routinely withheld from public inspection. We update section 0.457(b)(2) in conformance with the Supreme Court's holding in *Milner* v. *Department of the Navy,* reading the plain language of FOIA Exemption 2. Consistent with existing Commission

practice, we remove several outdated or inapplicable references to types of records that are generally withheld. We add a reference to withholding of some copyrighted materials, in accordance with Department of Justice guidance. Also, we make several minor clerical changes to the rules.

21. *Section 0.458—Nonpublic information.* Section 0.458 contains the rules for persons who come into possession of nonpublic information as the result of an inadvertent or unauthorized release. We make no changes to this section.

22. *Section 0.459—Requests that materials or information submitted to the Commission be withheld from public inspection.* Section 0.459 applies to third-party requests for confidential treatment of information given to the Commission. We make no changes to this section.

23. *Section 0.460—Requests for inspection of records which are routinely available to the public.* Section 0.460 provides the rules for access to records which are routinely already available to the public. We streamline the process for requesting such records by removing the requirement that initial requests be specifically labeled and include the requester's mailing address, phone number, and email address in order to be considered valid. Instead, we provide that Commission staff may contact the requester if this information becomes necessary. We replace references to the copy contractor and instead direct parties to the Commission's Reference Information Center. We delete section 0.460(i), which provided that records inspected in person be available for seven days. Given the limited number of persons who seek to inspect records in person, this limitation is unnecessary. We also make several minor clerical changes to improve accuracy and readability.

24. *Section 0.461—Requests for inspection of materials not routinely available for public inspection.* Section 0.461 sets forth the rules for filing requests to view records that are not routinely available to the public. These rules govern the majority of requests under the FOIA. Consistent with section 0.460, we remove the requirement that requests be specifically labeled and include the requester's mailing address, phone number, and email address in order to be considered valid.

25. We also amend subsection (d)(1) to remove the use of facsimile or email to file FOIA requests; instead, requesters are directed to submit their requests either via the postal mail or through the Commission's FOIAonline portal. In section 0.461(d)(2), we clarify that the responsibility to sign FOIA response letters may be delegated to staff of the bureau or office that is the custodian of the records. We amend the provisions of section 0.461(e)(1) concerning date stamping of incoming initial requests to reflect the current procedure as implemented through FOIAonline. In section 0.461(e)(2)(i)(B)(1), we modify the situations in which the processing time may be tolled pending the outcome of a fee matter, explicitly providing that the time for processing a FOIA request will be tolled in cases where the amount of fees authorized is less than the estimated cost for completing the production. This is consistent with existing practice. We update section 0.461(e)(3) to reflect the new methods for FOIA requesters to check on the status of their requests. We also provide for consultation with other agencies regarding records in which other agencies have equities in the Commission's decision concerning the disposition of a FOIA request for those records.

26. In section 0.461(f)(4)–(5), we update the language regarding the use of discretionary authority and segregation of records, to conform it to existing Commission practice. We modify section 0.461(g)(2) to clarify how records will be provided if a requester is unwilling to provide for an extension of time necessary to complete the production. Similar to our rules for FOIA fee waivers and confidentiality requests, in section 0.461(h)(2), we note that merely claiming that a request should be expedited is insufficient to warrant consideration. We also delete section 0.461(n), which provided that records inspected in person be available for only seven days. Given the limited number of persons who seek to inspect records in person, this limitation is unnecessary.

27. We also make modifications to our FOIA appeals rules in section 0.461(i)–(j). Consistent with section 1.7 of the Commission's rules, appeals are considered filed upon receipt. We also note the availability of the *FOIA-Appeal@fcc.gov* email inbox. Lastly, we take additional steps to limit repetitious or deficient FOIA appeals. Petitions for reconsideration will not be entertained after full Commission decisions on FOIA Applications for Review. Such an approach is more consistent with review process in the FOIA, beginning with an initial agency decision, followed by review of that decision by the head of the agency, and finally appeal to the district court.

28. *Section 0.463—Disclosure of Commission records and information in legal proceedings in which the Commission is a non-party.* Section 0.463 covers the Commission's procedures for responding to *Touhy* requests. We make no changes to this section.

29. *Section 0.465—Request for copies of materials which are available, or made available, for public inspection.* Section 0.465 specifies the rules for obtaining physical copies of documents. As the Commission does not currently employ a copy contractor, we replace references to the copy contractor and instead direct requesters to the Reference Information Center. We update the types of other media referred to in section 0.465(c)(2) to reflect current technology. We also make other minor adjustments to the language of the section to improve accuracy and readability.

30. *Section 0.466—Definitions.* We make no changes to section 0.466, which sets forth definitions applicable to sections 0.467–0.468.

31. *Section 0.467—Search and review fees.* Section 0.467 explains what types of fees a requester might be charged in responding to a FOIA request. We delete section 0.467(h), which provided that records inspected in person be available for seven days, and additional fees may be charged if the records are requested again after that seven day period. Given the limited number of persons who seek to inspect records in person, this rule is unnecessary.

32. *Section 0.468—Interest.* Section 0.468 specifies how interest will be calculated for unpaid FOIA fees. We make no changes to this section.

33. *Section 0.469—Advance payments.* Section 0.469 states the circumstances where the Commission may require advance payment of estimated fees. We make no changes to this section.

34. *Section 0.470—Assessment of fees.* Section 0.470 sets out the three fee categories of FOIA requests and the rules regarding fee waivers. We make minor clerical changes to sections 0.470(a)–(b), ensuring consistent use of the term ''duplication'' or ''duplicating,'' the terms used in the FOIA. In section 0.470(c), we remove a requirement that FOIA requesters include an explanation and certification when requesting a fee status other than commercial. As a matter of practice, the Commission does not require this. If not evident from the face of the request, staff may require the requester to provide additional information regarding his or her fee status. We delete the last sentence from section 0.470(d), as it only pertains to in person inspection of records, which, as noted above, is uncommon. Lastly, to improve

consistency with the FOIA and in line with current Commission practice, we modify section 0.470(f) to provide that fees will not be charged if the cost of collecting and processing the fees are greater than the actual amount of fees to be recovered.

35. We have determined that the changes we adopt here are general statements of policy, interpretive rules, or rules of agency organization, procedure, or practice, and are therefore exempt from the notice and comment requirements of the Administrative Procedure Act.

36. Section 603 of the Regulatory Flexibility Act, as amended, requires a regulatory flexibility analysis in notice and comment rulemaking proceedings. As we are adopting these rules without notice and comment, no regulatory flexibility analysis is required. This document does not contain any new proposed information collection(s) subject to the Paperwork Reduction Act of 1995. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002. The Commission will not send a copy of this Order pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not ''substantially affect the rights or obligations of non-agency parties.''

List of Subjects

47 CFR Part 0

Classified information, Freedom of information, Government publications, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements.

47 CFR Part 1

Administrative practice and procedure, Government employees, Lawyers.

Federal Comunications Commission.

Katura Howard,

Federal Register Liaison Officer, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications amends 47 CFR parts 0 and 1 as follows:

PART 0—COMMISSION ORGANIZATION

■ 1. The authority citation for part 0 continues to read as follows:

Authority: Sec. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155, 225, unless otherwise noted.

■ 2. Amend § 0.251 by adding paragraph (j) to read as follows:

§ 0.251 Authority delegated.

* * * * *

(j) The General Counsel is delegated authority to act as the Commission's Chief FOIA Officer, as specified in 5 U.S.C. 552(j). In this role, the General Counsel is delegated authority to dismiss FOIA applications for review that are untimely, repetitious, or fail to articulate specific grounds for review.

* * * * *

■ 3. Revise § 0.441 to read as follows:

§ 0.441 General.

(a) Any person desiring to obtain information from the Commission may do so by contacting the Consumer and Governmental Affairs Bureau (CGB). Requests for information and general inquiries may be submitted by:

(1) Internet at *http://www.fcc.gov/consumer-governmental-affairs* or *http://www.fcc.gov/foia.*

(2) Telephone at 1–888–CALL–FCC (1–888–225–5322).

(3) TDD/TDY at 1–888–TELL–FCC (1–888–835–5322).

(4) Correspondence to: Consumer and Governmental Affairs Bureau, 445 12th Street SW., Washington, DC 20554.

(5) Visiting the Reference Information Center of the Consumer and Governmental Affairs Bureau at Room CY–A257 of the Commission's main office at 445 12th Street SW., Washington, DC 20554.

(b) The Commission's FOIA Public Liaison is available to assist any person requesting information from the Commission in resolving any concerns related to a Freedom of Information Act request. Requesters may contact the FOIA Public Liaison to seek assistance on resolving disputes related to FOIA requests. See *http://www.fcc.gov/foia/.*

(c) The Office of Government Information Services is available to provide mediation services to help resolve disputes between FOIA requesters and Federal agencies. FOIA requesters may contact the Office of Government Information Services directly to seek its assistance. See *http://ogis.archives.gov/.*

(d) The General Counsel shall, subject to the authority of the Chairman, exercise the responsibilities of the Chief FOIA Officer specified in 5 U.S.C. 552(j).

■ 4. Revise § 0.445 to read as follows:

§ 0.445 Publication, availability, and use of opinions, orders, policy statements, interpretations, administrative manuals, staff instructions, and frequently requested records.

(a) Adjudicatory opinions and orders of the Commission, or its staff acting on delegated authority, are mailed or delivered by electronic means to the parties, and as part of the record, are available for inspection in accordance with § 0.453.

(b) Documents adopted by the Commission or a member of its staff on delegated authority and released through the Office of Media Relations are published in the FCC Record. Older materials of this nature are available in the FCC Reports. In the event that such older materials are not published in the FCC Reports, reference should be made to the **Federal Register** or Pike and Fischer Communications Regulation.

(c) All rulemaking documents or summaries thereof are published in the **Federal Register** and are available on the Commission's Web site. The complete text of the Commission decision also is released by the Commission and is available for inspection and copying during normal business hours in the Reference Information Center, via the Electronic Document Management System (EDOCS), or as otherwise specified in the rulemaking document published in the **Federal Register**.

(d) Formal policy statements and interpretations designed to have general applicability are published on the Commission's Web site and in the **Federal Register**, the FCC Record, FCC Reports, or Pike and Fischer Communications Regulation. Commission decisions and other Commission documents not entitled formal policy statements or interpretations may contain substantive interpretations and statements regarding policy, and these are published as part of the document in the FCC Record, FCC Reports or Pike and Fischer Communications Regulation. General statements regarding policy and interpretations furnished to individuals, in correspondence or otherwise, are not ordinarily published.

(e) Copies of all records that have been released to any person under § 0.461 and that because of the nature of their subject matter, the Commission determines have become or are likely to become the subject of subsequent requests for substantially the same records, or that have been requested three or more times, are made available in electronic format.

(f) If the documents described in paragraphs (a) through (d) of this section are published in the **Federal Register**, the FCC Record, FCC Reports, or Pike and Fischer Communications Regulation, they are indexed, and they may be relied upon, used or cited as precedent by the Commission or private parties in any manner. If they are not so published, they may not be relied upon, used or cited as precedent, except against persons who have actual notice of the document in question or by such persons against the Commission. No person is expected to comply with any requirement or policy of the Commission unless he or she has actual notice of that requirement or policy or a document stating it has been published as provided in this paragraph. Nothing in this paragraph, however, shall be construed as precluding a reference to a recent document that is pending publication.

(g) Subparts A and B of this part describe the functions of the staff and list the matters on which authority has been delegated to the staff. All general instructions to the staff and limitations upon its authority are set forth in those subparts or in decisions of the Commission published in the **Federal Register**. Instructions to the staff in particular matters or cases are privileged and/or protected and are not published or made available for public inspection.

(h) To the extent required to prevent a clearly unwarranted invasion of personal privacy, or to prevent disclosure of information required or authorized to be withheld by another statute, the Commission may delete identifying details or confidential information when it makes available or publishes any document described in this section. The justification for any such deletion will be fully explained in a preamble to the document.

■ 5. Revise § 0.451 to read as follows:

§ 0.451 Inspection of records: Generally.

(a) *Records which are routinely available for public inspection.* Section 0.453 specifies those Commission records which are routinely available for public inspection and where those records may be inspected. Procedures governing requests for inspection of such records are set out in § 0.460.

(b) *Records which are not routinely available for public inspection.* Records which are not specified in § 0.453 are not routinely available for public inspection. Such records fall into three categories.

(1) The first category consists of categories of records listed in § 0.457, and of particular records withheld from public inspection under § 0.459. The Commission has determined that there is a statutory basis for withholding these records from public inspection. In some cases, the Commission is prohibited from permitting the inspection of records. This category also includes records that are the property of another agency that the Commission has no authority to release for inspection. In still other cases, the Commission is authorized, for reason of policy, to withhold records from inspection, but is not required to do so. As applicable, procedures governing demands by competent authority for inspection of these records are set forth in § 0.463.

(2) The second category consists of records that are not specified in § 0.453 or § 0.457 and have not been withheld from inspection under § 0.459. In some cases, these records have not been identified for listing. In other cases an individualized determination is required. Procedures governing requests for inspection of these records are set forth in § 0.461. Procedures governing demands by competent authority for inspection of these records are set forth in § 0.463.

(3) The third category consists of material previously released consistent with the agency's rules that the agency determines is not likely to become the subject of a subsequent FOIA request or otherwise likely to be of broader public interest.

(4) Except as provided in § 0.461 and § 0.463, or pursuant to § 19.735–203 of this chapter, no officer or employee of the Commission shall permit the inspection of records which are not routinely available for public inspection under § 0.453, or disclose information contained therein. This provision does not restrict the inspection or disclosure of records described in § 0.453(b)(3).

(c) *Copies.* Section 0.465 applies to requests for copies of Commission records which are routinely available for public inspection under § 0.453 and those which are made available for inspection under § 0.461. Sections 0.467 and 0.465(c)(3) apply to requests for certified copies of Commission records.

(d) *Search and copying fees.* Section 0.465(c)(2) prescribes the per page fee for copying records made available for inspection under § 0.460 or § 0.461. Section 0.466 prescribes fees to cover the expense of searching for and reviewing records made available for inspection under § 0.460 or § 0.461. Review of initial fee determinations under § 0.467 through § 0.470 and initial fee reduction or waiver determinations under § 0.470(e) may be sought under § 0.461(j).

■ 6. Revise § 0.453 to read as follows:

§ 0.453 Public reference rooms.

The Commission's main Web site at *http://www.fcc.gov* and its electronic reading room at *http://www.fcc.gov/general/freedom-information-act-electronic-reading-room* host the Commission's online public reference room. The Commission also maintains the FCC Reference Information Center as its public reference room at its offices in Washington, DC.

(a) The Reference Information Center maintains files containing the record of all docketed cases, petitions for rule making and related papers. A file is maintained for each docketed hearing case and for each docketed rule making proceeding. Cards summarizing the history of such cases for the years before 1984 are available for inspection. Information summarizing the history of such cases for the years from 1984 through present is available online on the Electronic Comment Filing System (ECFS). ECFS serves as the repository for official filings in the FCC's docketed proceedings from 1992 to the present. The public can use ECFS to retrieve any document in the system, including selected pre-1992 documents.

(b) The Commission will maintain a regularly updated listing of other routinely available records in its electronic reading room at *http://www.fcc.gov/general/freedom-information-act-electronic-reading-room*.

§ 0.455 [Removed]

■ 7. Remove § 0.455.

■ 8. Revise § 0.457 to read as follows:

§ 0.457 Records not routinely available for public inspection.

The records listed in this section are not routinely available for public inspection pursuant to 5 U.S.C. 552(b). The records are listed in this section by category, according to the statutory basis for withholding those records from inspection; under each category, if appropriate, the underlying policy considerations affecting the withholding and disclosure of records in that category are briefly outlined. The Commission will entertain requests from members of the public under § 0.461 for permission to inspect particular records withheld from inspection under the provisions of this section, and will weigh the policy considerations favoring non-disclosure against the reasons cited for permitting inspection in the light of the facts of the particular case. In making such requests, there may be more than one basis for withholding particular records from inspection. The Commission will permit inspection of records unless

Commission staff reasonably foresees that disclosure would harm an interest protected by the exemptions described in 5 U.S.C. 552(b) or where disclosure is prohibited by law. The listing of records by category is not intended to imply the contrary but is solely for the information and assistance of persons making such requests. Requests to inspect or copy the transcripts, recordings or minutes of closed agency meetings will be considered under § 0.607 rather than under the provisions of this section.

(a) Materials that are specifically authorized under criteria established by Executive Order (E.O.) to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive Order, 5 U.S.C. 552(b)(1).

(1) Classified materials and information will not be made available for public inspection, including materials classified under E.O. 10450, ''Security Requirements for Government Employees''; E.O. 10501, as amended, ''Safeguarding Official Information in the Interests of the Defense of the United States''; and E.O. 13526, ''Classified National Security Information,'' or any other executive order concerning the classification of records. *See also* 47 U.S.C. 154(j).

(2) Materials referred to another Federal agency for classification will not be disclosed while such a determination is pending.

(b) Materials that are related solely to the internal personnel rules and practices of the Commission, 5 U.S.C. 552(b)(2).

(c) Materials that are specifically exempted from disclosure by statute (other than the Government in the Sunshine Act, 5 U.S.C. 552b, provided that such statute either requires that the materials be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of materials to be withheld), 5 U.S.C. 552(b)(3). The Commission is authorized under the following statutory provisions to withhold materials from public inspection.

(1) Section 4(j) of the Communications Act, 47 U.S.C. 154(j), provides, in part, that, ''The Commission is authorized to withhold publication of records or proceedings containing secret information affecting the national defense.'' Pursuant to that provision, it has been determined that the following materials should be withheld from public inspection (*see also* paragraph (a) of this section):

(i) Maps showing the exact location of submarine cables.

(ii) Minutes of Commission actions on classified matters.

(iii) Maps of nation-wide point-to-point microwave networks.

(2) Under section 213 of the Communications Act, 47 U.S.C. 213(f), the Commission is authorized to order, with the reasons therefor, that records and data pertaining to the valuation of the property of common carriers and furnished to the Commission by the carriers pursuant to the provisions of that section, shall not be available for public inspection. If such an order has been issued, the data and records will be withheld from public inspection, except under the provisions of § 0.461. Normally, however, such data and information is available for inspection.

(3) Under section 412 of the Communications Act, 47 U.S.C. 412, the Commission may withhold from public inspection certain contracts, agreements and arrangements between common carriers relating to foreign wire or radio communication. Any person may file a petition requesting that such materials be withheld from public inspection. To support such action, the petition must show that the contract, agreement or arrangement relates to foreign wire or radio communications; that its publication would place American communication companies at a disadvantage in meeting the competition of foreign communication companies; and that the public interest would be served by keeping its terms confidential. If the Commission orders that such materials be kept confidential, they will be made available for inspection only under the provisions of § 0.461.

(4) Section 605 of the Communications Act, 47 U.S.C. 605(a), provides, in part, that, ''no person not being authorized by the sender shall intercept any communication [by wire or radio] and divulge or publish the existence, contents, substance, purport, effect, or meaning of such intercepted communications to any person.'' In executing its responsibilities, the Commission regularly monitors radio transmissions. Except as required for the enforcement of the communications laws, treaties and the provisions of this chapter, or as authorized in sec. 605, the Commission is prohibited from divulging information obtained in the course of these monitoring activities; and such information, and materials relating thereto, will not be made available for public inspection.

(5) The Trade Secrets Act, 18 U.S.C. 1905, prohibits the unauthorized disclosure of certain confidential information. *See* paragraph (d) of this section and § 19.735–203 of this chapter.

(d) *Trade secrets and commercial or financial information obtained from any person and privileged or confidential—categories of materials not routinely available for public inspection, 5 U.S.C. 552(b)(4) and 18 U.S.C. 1905.* (1) The materials listed in this paragraph have been accepted, or are being accepted, by the Commission on a confidential basis pursuant to 5 U.S.C. 552(b)(4). To the extent indicated in each case, the materials are not routinely available for public inspection. If the protection afforded is sufficient, it is unnecessary for persons submitting such materials to submit therewith a request for non-disclosure pursuant to § 0.459. A persuasive showing as to the reasons for inspection will be required in requests submitted under § 0.461 for inspection of such materials.

(i) Financial reports submitted by radio or television licensees.

(ii) Applications for equipment authorizations (type acceptance, type approval, certification, or advance approval of subscription television systems), and materials relating to such applications, are not routinely available for public inspection prior to the effective date of the authorization. The effective date of the authorization will, upon request, be deferred to a date no earlier than that specified by the applicant. Following the effective date of the authorization, the application and related materials (including technical specifications and test measurements) will be made available for inspection upon request (*see* § 0.460). Portions of applications for equipment certification of scanning receivers and related materials will not be made available for inspection.

(iii) Information submitted in connection with audits, investigations and examination of records pursuant to 47 U.S.C. 220.

(iv) Programming contracts between programmers and multichannel video programming distributors.

(v) The rates, terms and conditions in any agreement between a U.S. carrier and a foreign carrier that govern the settlement of U.S.-international traffic, including the method for allocating return traffic, except as otherwise specified by the Commission by order or by the International Bureau under delegated authority. *See, e.g., International Settlements Policy Reform,* IB Docket Nos. 11–80, 05–254, 09–10, RM–11322, Report and Order, FCC 12–145 (rel. Nov. 29, 2012).

(vi) Outage reports filed under part 4 of this chapter.

(vii) The following records, relating to coordination of satellite systems pursuant to procedures codified in the International Telecommunication Union (ITU) Radio Regulations:

(A) Records of communications between the Commission and the ITU related to the international coordination process, and

(B) Documents prepared in connection with coordination, notification, and recording of frequency assignments and Plan modifications, including but not limited to minutes of meetings, supporting exhibits, supporting correspondence, and documents and correspondence prepared in connection with operator-to-operator arrangements.

(viii) Information submitted with a 911 reliability certification pursuant to 47 CFR 12.4 that consists of descriptions and documentation of alternative measures to mitigate the risks of nonconformance with certification elements, information detailing specific corrective actions taken with respect to certification elements, or supplemental information requested by the Commission with respect to such certification.

(ix) Confidential Broadcaster Information, as defined in § 1.2206(d) of this chapter, submitted by a broadcast television licensee in a broadcast television spectrum reverse auction conducted under section 6403 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96) (the ''Spectrum Act''), or in the application to participate in such a reverse auction, is not routinely available for public inspection until the reassignments and reallocations under section 6403(b)(1)(B) of the Spectrum Act become effective or until two years after public notice that the reverse auction is complete and that no such reassignments and reallocations shall become effective. In the event that reassignments and reallocations under section 6403(b)(1)(B) of the Spectrum Act become effective, Confidential Broadcaster Information pertaining to any unsuccessful reverse auction bid or pertaining to any unsuccessful application to participate in such a reverse auction will not be routinely available for public inspection until two years after the effective date.

(x) Copyrighted materials the release of which would have a substantial adverse effect on the copyright holder's potential market, except to the extent such a release can be considered fair use.

Note to paragraph (d)(1): The content of the communications described in paragraph (d)(1)(vii)(A) of this section is in some circumstances separately available through the ITU's publication process, or through records available in connection with the Commission's licensing procedures.

(2) Unless the materials to be submitted are listed in paragraph (d)(1) of this section and the protection thereby afforded is adequate, any person who submits materials which he or she wishes withheld from public inspection under 5 U.S.C. 552(b)(4) must submit a request for non-disclosure pursuant to § 0.459. If it is shown in the request that the materials contain trade secrets or privileged or confidential commercial, financial or technical data, the materials will not be made routinely available for inspection; and a persuasive showing as to the reasons for inspection will be required in requests for inspection submitted under § 0.461. In the absence of a request for non-disclosure, the Commission may, in the unusual instance, determine on its own motion that the materials should not be routinely available for public inspection.

(e) *Interagency and intra-agency memoranda or letters, 5 U.S.C. 552(b)(5).* Interagency and intra-agency memoranda or letters and the work papers of members of the Commission or its staff will not be made available for public inspection, except in accordance with the procedures set forth in § 0.461. Normally such papers are privileged and not available to private parties through the discovery process, because their disclosure would tend to restrain the commitment of ideas to writing, would tend to inhibit communication among Government personnel, and would, in some cases, involve premature disclosure of their contents. The Commission will not use this deliberative process exemption to withhold records created 25 years or more before the date on which the request was received.

(f) *Personnel, medical and other files whose disclosure would constitute a clearly unwarranted invasion of personal privacy, 5 U.S.C. 552(b)(6).* Under E.O. 12107, the Commission maintains an Official Personnel Folder for each of its employees. Such folders are under the jurisdiction and control, and are a part of the records, of the U.S. Office of Personnel Management. Except as provided in the rules of the Office of Personnel Management (5 CFR 293.311), such folders will not be made available for public inspection by the Commission. In addition, other records of the Commission containing private, personal or financial information will be withheld from public inspection.

(g) *Under 5 U.S.C. 552(b)(7), records compiled for law enforcement purposes, to the extent that production of such records:*

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person of a right to fair trial or an impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source;

(5) Would disclose investigative techniques or procedures or would disclose investigative guidelines if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

■ 9. Revise § 0.460 to read as follows:

§ 0.460 Requests for inspection of records which are routinely available for public inspection.

(a) Section 0.453 specifies those Commission records which are routinely available for public inspection and the places at which those records may be inspected. Subject to the limitations set out in this section, a person who wants to inspect such records need only appear at the Reference Information Center and ask to see the records. Many records also are available on the Commission's Web site, *http://www.fcc.gov* and the Commission's electronic reading room, *http://www.fcc.gov/general/freedom-information-act-electronic-reading-room.* Commission documents are generally published in the FCC Record, and many of these documents or summaries thereof are also published in the **Federal Register**.

(b) A person who wishes to inspect the records must appear at the specified location during the office hours of the Commission and must inspect the records at that location. (Procedures governing requests for copies are set out in § 0.465.) However, arrangements may be made in advance, by telephone or by correspondence, to make the records available for inspection on a particular date, and there are many circumstances in which such advance arrangements will save inconvenience. If the request is for a large number of documents, for example, a delay in collecting them is predictable. Current records may be in use by the staff when the request is made. Older records may have been forwarded to another location for storage.

(c) The records in question must be reasonably described by the person

requesting them to permit their location by staff personnel. The information needed to locate the records will vary, depending on the records requested. Advice concerning the kind of information needed to locate particular records will be furnished in advance upon request. Members of the public will not be given access to the area in which records are kept and will not be permitted to search the files.

(d) If it appears that there will be an appreciable delay in locating or producing the records (as where a large number of documents is the subject of a single request or where an extended search for a document appears to be necessary), the requester may be directed to submit or confirm the request in writing in appropriate circumstances.

(e)(1) Written requests for records routinely available for public inspection under § 0.453 shall be directed to the Commission's Reference Information Center pursuant to the procedures set forth in § 0.465. Requests shall set out all information known to the person making the request which would be helpful in identifying and locating the document, including the date range of the records sought, if applicable. Upon request by Commission staff, the requester shall provide his or her street address, phone number (if any), and email address (if any). Written requests shall, in addition, specify the maximum search fee the person making the request is prepared to pay (*see* § 0.467).

(2) Written requests shall be delivered or mailed directly to the Commission's Reference Information Center (*see* § 0.465(a)).

(f) When a written request is received by the Reference Information Center, it will be date-stamped.

(g) All requests limited to records listed in § 0.453 will be granted, subject to paragraph (j) of this section.

(h) The records will be produced for inspection at the earliest possible time.

(i) Records shall be inspected within 7 days after notice is given that they have been located and are available for inspection. After that period, they will be returned to storage and additional charges may be imposed for again producing them.

(j) In addition to the other requirements of this section, the following provisions apply to the reports filed with the Commission pursuant to 5 CFR parts 2634 and 3902.

(1) Such reports shall not be obtained or used:

(i) For any unlawful purpose;

(ii) For any commercial purpose, other than by news and communications media for dissemination to the general public;

(iii) For determining or establishing the credit rating of any individual; or

(iv) For use, directly or indirectly, in the solicitation of money for any political, charitable, or other purpose.

(2) Such reports may not be made available to any person nor may any copy thereof be provided to any person except upon a written application by such person stating:

(i) That person's name, occupation and address;

(ii) The name and address of any other person or organization on whose behalf the inspection or copying is requested; and

(iii) That such person is aware of the prohibitions on the obtaining or use of the report. Further, any such application for inspection shall be made available to the public throughout the period during which the report itself is made available to the public.

■ 10. Revise § 0.461 to read as follows:

§ 0.461 Requests for inspection of materials not routinely available for public inspection.

Any person desiring to inspect Commission records that are not specified in § 0.453 shall file a request for inspection meeting the requirements of this section. The FOIA Public Liaison is available to assist persons seeking records under this section. *See* § 0.441(a).

(a)(1) Records include:

(i) Any information that would be an agency record subject to the requirements of the Freedom of Information Act when maintained by the Commission in any format, including an electronic format; and

(ii) Any information maintained for the Commission by an entity under Government contract.

(2) The records in question must be reasonably described by the person requesting them to permit personnel to locate them with a reasonable amount of effort. Whenever possible, a request should include specific information about each record sought, such as the title or name, author, recipient, and subject matter of the record. Requests must also specify the date or time period for the records sought. The custodian of records sought may contact the requester to obtain further information about the records sought to assist in locating them.

(3) The person requesting records under this section may specify the form or format of the records to be produced provided that the records may be made readily reproducible in the requested form or format.

(b)(1) Requests shall reasonably describe, for each document requested (*see* § 0.461(a)(1)), all information known to the person making the request that would be helpful in identifying and locating the document, including the date range of the records sought, if applicable, and the persons/offices to be searched, if known. Upon request by Commission staff, the requester shall provide his or her street address, phone number (if any), and email address (if any).

(2) The request shall, in addition, specify the maximum search fee the person making the request is prepared to pay or a request for waiver or reduction of fees if the requester is eligible (*see* § 0.470(e)). By filing a FOIA request, the requester agrees to pay all applicable fees charged under § 0.467, unless the person making the request seeks a waiver of fees (*see* § 0.470(e)), in which case the Commission will rule on the waiver request before proceeding with the search.

(c) If the records are of the kinds listed in § 0.457 or if they have been withheld from inspection under § 0.459, the request shall, in addition, contain a statement of the reasons for inspection and the facts in support thereof. In the case of other materials, no such statement need accompany the request, but the custodian of the records may require the submission of such a statement if he or she determines that the materials in question may lawfully be withheld from inspection.

(d)(1) Requests shall be

(i) Filed electronically though the Internet at *http://foiaonline.regulations.gov/;* or

(ii) Delivered or mailed to the Managing Director, Attn: FOIA Request, FCC, 445 12th Street SW., Room 1–A836, Washington, DC 20554.

(2) For purposes of this section, the custodian of the records is the Chief of the Bureau or Office where the records are located. The Chief of the Bureau or Office may designate an appropriate person to act on a FOIA request. The Chief of the Bureau or Office may also designate an appropriate person to sign the response to any FOIA request. *See* § 0.461(m).

(3) If the request is for materials submitted to the Commission by third parties and not open to routine public inspection under § 0.457(d), § 0.459, or another Commission rule or order, or if a request for confidentiality is pending pursuant to § 0.459, or if the custodian of records has reason to believe that the information may contain confidential commercial information, one copy of the request will be provided by the custodian of the records (*see* paragraph

(e) of this section) to the person who originally submitted the materials to the Commission. If there are many persons who originally submitted the records and are entitled to notice under this paragraph, the custodian of records may use a public notice to notify the submitters of the request for inspection. The submitter or submitters will be given ten calendar days to respond to the FOIA request. *See* § 0.459(d)(1). If a submitter has any objection to disclosure, he or she is required to submit a detailed written statement specifying all grounds for withholding any portion of the information (*see* § 0.459). This response shall be served on the party seeking to inspect the records. The requester may submit a reply within ten calendar days unless a different period is specified by the custodian of records. The reply shall be served on all parties that filed a response. In the event that a submitter fails to respond within the time specified, the submitter will be considered to have no objection to disclosure of the information.

Note to paragraph (d)(3): Under the ex parte rules, § 1.1206(a)(7) of this chapter, a proceeding involving a FOIA request is a permit-but-disclose proceeding, but is subject to the special service rules in this paragraph. We also note that while the FOIA request itself is a permit-but-disclose proceeding, a pleading in a FOIA proceeding may also constitute a presentation in another proceeding if it addresses the merits of that proceeding.

(e)(1) When the request is received by the Managing Director, it will be assigned to the Freedom of Information Act (FOIA) Control Office, where it will be entered into the FOIAonline system. The request will be reviewed and, if it is determined that the request meets all the requirements of a proper FOIA request, will be designated as perfected. A FOIA request is then considered properly received. This will occur no later than ten calendar days after the request is first received by the agency.

(2)(i) Except for the purpose of making a determination regarding expedited processing under paragraph (h) of this section, the time for processing a request for inspection of records will be tolled

(A) While the custodian of records seeks reasonable clarification of the request;

(B) Until clarification with the requester of issues regarding fee assessment occurs, including:

(*1*) Where the amount of fees authorized is less than the estimated cost for completing the production;

(*2*) Following the denial of a fee waiver, unless the requester had provided a written statement agreeing to pay the fees if the fee waiver was denied;

(*3*) Where advance payment is required pursuant to § 0.469 and has not been made.

(ii) Only one Commission request for information shall be deemed to toll the time for processing a request for inspection of records under paragraph (e)(2)(i)(A) of this section. Such request must be made no later than ten calendar days after a request is properly received by the custodian of records under paragraph (e)(1) of this section.

(3) The FOIA Control Office will send an acknowledgement to the requester notifying the requester of the control number assigned to the request, the due date of the response, and the telephone contact number (202–418–0440) to be used by the requester to obtain the status of the request. Requesters may also obtain the status of an FOIA request via email at *foia-public-liaison@fcc.gov* or by viewing their request at *http://foiaonline.regulations.gov/.*

(4) Multiple FOIA requests by the same or different FOIA requesters may be consolidated for disposition. *See also* § 0.470(b)(2).

(f) Requests for inspection of records will be acted on as follows by the custodian of the records.

(1) If the Commission is prohibited from disclosing the records in question, the request for inspection will be denied with a statement setting forth the specific grounds for denial.

(2)(i) If records in the possession of the Commission are the property of another agency, the request will be referred to that agency and the person who submitted the request will be so advised, with the reasons for referral.

(ii) If it is determined that the FOIA request seeks only records of another agency or department, the FOIA requester will be so informed by the FOIA Control Officer and will be directed to the correct agency or department.

(iii) If the records in the possession of the Commission involve the equities of another agency, the Commission will consult with that agency prior to releasing the records.

(3) If it is determined that the Commission does not have authority to withhold the records from public inspection, the request will be granted.

(4) If it is determined that the Commission has authority to withhold the records from public inspection, the considerations favoring disclosure and non-disclosure will be weighed in light of the facts presented, and the Commission may, at its discretion, grant the request in full or in part, or deny the request.

(5) If there is a statutory basis for withholding part of a document from inspection, to the extent that portion is reasonably segregable, that part will be deleted and the remainder will be made available for inspection. Unless doing so would harm an interest protected by an applicable exemption, records disclosed in part shall be marked or annotated, if technically feasible, to show the amount of information deleted, the location of the information deleted, and the exemption under which the deletion is made.

(6) In locating and recovering records responsive to an FOIA request, only those records within the Commission's possession and control as of the date a request is perfected shall be considered.

(g)(1) The custodian of the records will make every effort to act on the request within twenty business days after it is received and perfected by the FOIA Control Office. However, if a request for clarification has been made under paragraph (e)(2)(i)(A) of this section or an issue is outstanding regarding the payment of fees for processing the FOIA request is pending under paragraph (e)(2)(i)(B) of this section, the counting of time will start upon resolution of these requests. If it is not possible to locate the records and to determine whether they should be made available for inspection within twenty business days, the custodian may, upon timely notice to the requester, extend the time for action by up to ten business days, in any of the following circumstances:

(i) It is necessary to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request.

(ii) It is necessary to search for, collect and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) It is necessary to consult with another agency having a substantial interest in the determination of the request, or among two or more components of the Commission having substantial subject matter interest therein.

(2) The custodian of the records will notify the requester in writing of any extension of time exercised pursuant to paragraph (g) of this section. The custodian of the records may also call the requester to extend the time provided a subsequent written confirmation is provided. If it is not possible to locate the records and make the determination within the extended

period, the person or persons who made the request will be provided an opportunity to limit the scope of the request so that it may be processed within the extended time limit, or an opportunity to arrange an alternative time frame for processing the request or a modified request, and asked to consent to an extension or further extension. If the requester agrees to an extension, the custodian of the records will confirm the agreement in a letter or email specifying the length of the agreed-upon extension. If he or she does not agree to an extension, the request will be denied, on the grounds that the custodian has not been able to locate the records and/or to make the determination within the period for a ruling mandated by the Freedom of Information Act, 5 U.S.C. 552. In that event, the custodian will provide the requester with the records, if any, that could be located and produced within the allotted time. The requester may file an application for review by the Commission.

(3) If the custodian of the records grants a request for inspection of records submitted to the Commission in confidence under § 0.457(d), § 0.459, or some other Commission rule or order, the custodian of the records will give the submitter written notice of the decision and of the submitter's right to seek review pursuant to paragraph (i) of this section.

(h)(1) Requesters who seek expedited processing of FOIA requests shall submit such requests, along with their FOIA requests, to the Managing Director, as described in paragraph (d) of this section.

(2) Expedited processing shall be granted to a requester demonstrating a compelling need that is certified by the requester to be true and correct to the best of his or her knowledge and belief. Simply stating that the request should be expedited is not a sufficient basis to obtain expedited processing.

(3) For purposes of this section, *compelling need* means—

(i) That failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) With respect to a request made by a person primarily engaged in disseminating information, there is an urgency to inform the public concerning actual or alleged Federal Government activity.

(4)(i) Notice of the determination whether to grant expedited processing shall be provided to the requester by the custodian of records within ten calendar days after receipt of the request by the FOIA Control Office. Once the determination has been made to grant expedited processing, the custodian shall process the FOIA request as soon as practicable.

(ii) If a request for expedited processing is denied, the person seeking expedited processing may file an application for review within five business days after the date of the written denial. The application for review shall be delivered or mailed to the General Counsel. (For general procedures relating to applications for review, *see* § 1.115 of this chapter.) The Commission shall act expeditiously on the application for review, and shall notify the custodian of records and the requester of the disposition of such an application for review.

(i)(1) If a request for inspection of records submitted to the Commission in confidence under § 0.457(d), § 0.459, or another Commission rule or order is granted in whole or in part, an application for review may be filed by the person who submitted the records to the Commission, by a third party owner of the records or by a person with a personal privacy interest in the records, or by the person who filed the request for inspection of records within the ten business days after the date of the written ruling. The application for review shall be filed within ten business days after the date of the written ruling, shall be delivered or mailed to the General Counsel, or sent via email to *FOIA-Appeal@fcc.gov,* and shall be served on the person who filed the request for inspection of records and any other parties to the proceeding. The person who filed the request for inspection of records may respond to the application for review within ten business days after it is filed.

(2) The first day to be counted in computing the time period for filing the application for review is the day after the date of the written ruling. An application for review is considered filed when it is received by the Commission. If an application for review is not filed within this period, the records will be produced for inspection.

(3) If an application for review is denied, the person filing the application for review will be notified in writing and advised of his or her rights. A denial of an application for review is not subject to a petition for reconsideration under § 1.106 of this chapter.

(4) If an application for review filed by the person who submitted, owns, or has a personal privacy interest in the records to the Commission is denied, or if the records are made available on review which were not initially made available, the person will be afforded ten business days from the date of the written ruling in which to move for a judicial stay of the Commission's action. The first day to be counted in computing the time period for seeking a judicial stay is the day after the date of the written ruling. If a motion for stay is not made within this period, the records will be produced for inspection.

(j) Except as provided in paragraph (i) of this section, an application for review of an initial action on a request for inspection of records, a fee determination (*see* § 0.467 through § 0.470), or a fee reduction or waiver decision (*see* § 0.470(e)) may be filed only by the person who made the request. The application shall be filed within 90 calendar days after the date of the written ruling by the custodian of records. An application for review is considered filed when it is received by the Commission. The application shall be delivered or mailed to the General Counsel, or sent via email to *FOIA-Appeal@fcc.gov.* If the proceeding involves records subject to confidential treatment under § 0.457 or § 0.459, or involves a person with an interest as described in § 0.461(i), the application for review shall be served on such persons. That person may file a response within 14 calendar days after the application for review is filed. If the records are made available for review, the person who submitted them to the Commission will be afforded 14 calendar days after the date of the written ruling to seek a judicial stay. *See* paragraph (i) of this section. The first day to be counted in computing the time period for filing the application for review or seeking a judicial stay is the day after the date of the written ruling.

Note to paragraphs (i) and (j): The General Counsel may review applications for review with the custodian of records and attempt to informally resolve outstanding issues with the consent of the requester. For general procedures relating to applications for review, see § 1.115 of this chapter.

(k)(1)(i) The Commission will make every effort to act on an application for review of an action on a request for inspection of records within twenty business days after it is filed. In the following circumstances and to the extent time has not been extended under paragraphs (g)(1)(i), (ii), or (iii) of this section, the Commission may extend the time for acting on the application for review up to ten business days. (The total period of extensions taken under this paragraph and under paragraph (g) of this section without the consent of the person who

submitted the request shall not exceed ten business days.):

(A) It is necessary to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(B) It is necessary to search for, collect and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(C) It is necessary to consult with another agency having a substantial interest in the determination of the request or among two or more components of the Commission having substantial subject matter interest therein.

(ii) If these circumstances are not present, the person who made the request may be asked to consent to an extension or further extension. If the requester or person who made the request agrees to an extension, the General Counsel will confirm the agreement in a letter specifying the length of the agreed-upon extension. If the requestor or person who made the request does not agree to an extension, the Commission will continue to search for and/or assess the records and will advise the person who made the request of further developments; but that person may file a complaint in an appropriate United States district court.

(2) The Commission may at its discretion or upon request consolidate for consideration related applications for review filed under paragraph (i) or (j) of this section.

(l)(1) Subject to the application for review and judicial stay provisions of paragraphs (i) and (j) of this section, if the request is granted, the records will be produced for inspection at the earliest possible time.

(2) If a request for inspection of records becomes the subject of an action for judicial review before the custodian of records has acted on the request, or before the Commission has acted on an application for review, the Commission may continue to consider the request for production of records.

(m) Staff orders and letters ruling on requests for inspection are signed by the official (or officials) who give final approval of their contents. Decisions of the Commission ruling on applications for review will set forth the names of the Commissioners participating in the decision.

■ 11. Revise § 0.465 to read as follows:

§ 0.465 Request for copies of materials which are available, or made available, for public inspection.

(a) The Commission may award a contract to a commercial duplication firm to make copies of Commission records and offer them for sale to the public. In addition to the charge for copying, the contractor may charge a search fee for locating and retrieving the requested documents from the Commission's files.

Note to paragraph (a): The name, address, telephone number, and schedule of fees for the current copy contractor, if any, are published at the time of contract award of renewal in a public notice and periodically thereafter. Current information is available at *http://www.fcc.gov/foia* and *http://www.fcc.gov/consumer-governmental-affairs.* Questions regarding this information should be directed to the Reference Information Center of the Consumer and Governmental Affairs Bureau at 202–418–0270.

(b)(1) Records routinely available for public inspection under § 0.453 are available to the public through the Commission's Reference Information Center. Section 0.461 does not apply to such records.

(2) Audio or video recordings or transcripts of Commission proceedings are available to the public through the Commission's Reference Information Center. In some cases, only some of these formats may be available.

(c)(1) Contractual arrangements which have been entered into with commercial firms, as described in this section, do not in any way limit the right of the public to inspect Commission records or to retrieve whatever information may be desired. Coin-operated and debit card copy machines are available for use by the public.

(2) The Commission has reserved the right to make copies of its records for its own use or for the use of other agencies of the U.S. Government. When it serves the regulatory or financial interests of the U.S. Government, the Commission will make and furnish copies of its records free of charge. In other circumstances, however, if it should be necessary for the Commission to make and furnish copies of its records for the use of others, the fee for this service shall be ten cents ($0.10) per page or $5 per computer disk in addition to charges for staff time as provided in § 0.467. For copies prepared with other media, such as thumb drives or other portable electronic storage, the charge will be the actual direct cost including operator time. Requests for copying should be accompanied by a statement specifying the maximum copying fee the person making the request is prepared to pay. If the Commission estimates that copying charges are likely to exceed the greater of $25 or the amount which the requester has indicated that he/she is prepared to pay, then it shall notify the requester of the estimated amount of fees. Such a notice shall offer the requester the opportunity to confer with Commission personnel with the object of revising or clarifying the request.

Note to paragraph (c)(2): The criterion considered in acting on a waiver request is whether ''waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.'' 5 U.S.C. 552(a)(4)(A). A request for a waiver or reduction of fees will be decided by the General Counsel as set forth in § 0.470(e).

(3) *Certified documents.* Copies of documents which are available or made available, for inspection under §§ 0.451 through 0.465, will be prepared and certified, under seal, by the Secretary or his or her designee. Requests shall be in writing, specifying the exact documents, the number of copies desired, and the date on which they will be required. The request shall allow a reasonable time for the preparation and certification of copies. The fee for preparing copies shall be the same as that charged by the Commission as described in paragraph (c)(2) of this section. The fee for certification shall be $10 for each document.

(d)(1) Computer maintained databases produced by the Commission and routinely available to the public (*see* § 0.453) may be obtained from the FCC's Web site at *http://www.fcc.gov* or if unavailable on the Commission's Web site, from the Reference Information Center.

(2) Copies of computer generated data stored as paper printouts or electronic media and available to the public may also be obtained from the Commission's Reference Information Center (*see* paragraph (a) of this section).

(3) Copies of computer source programs and associated documentation produced by the Commission and available to the public may be obtained from the Office of the Managing Director.

(e) This section does not apply to records available on the Commission's Web site, *http://www.fcc.gov,* or printed publications which may be purchased from the Superintendent of Documents or private firms (*see* §§ 0.411 through 0.420), nor does it apply to application forms or information bulletins, which are prepared for the use and information of the public and are available upon request (*see* §§ 0.421 and 0.423) or on the Commission's Web site, *http://www.fcc.gov/formpage.html.*

■ 12. Revise § 0.467 to read as follows:

§ 0.467 Search and review fees.

(a)(1) Subject to the provisions of this section, an hourly fee shall be charged for recovery of the full, allowable direct costs of searching for and reviewing records requested under § 0.460 or § 0.461, unless such fees are reduced or waived pursuant to § 0.470. The fee is based on the pay grade level of the FCC's employee(s) who conduct(s) the search or review, or the actual hourly rate of FCC contractors or other non-FCC personnel who conduct a search.

Note to paragraph (a)(1): The fees for FCC employees will be modified periodically to correspond with modifications in the rate of pay approved by Congress and any such modifications will be announced by public notice and will be posted on the Commission's Web site, *http://www.fcc.gov/foia/#feeschedule.*

(2) The fees specified in paragraph (a)(1) of this section are computed at Step 5 of each grade level based on the General Schedule or the hourly rate of non-FCC personnel, including in addition twenty percent for personnel benefits. Search and review fees will be assessed in ¼ hour increments.

(b) Search fees may be assessed for time spent searching, even if the Commission fails to locate responsive records or if any records located are determined to be exempt from disclosure.

(c) The Commission shall charge only for the initial review, *i.e.,* the review undertaken initially when the Commission analyzes the applicability of a specific exemption to a particular record. The Commission shall not charge for review at the appeal level of an exemption already applied. However, records or portions of records withheld in full under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs of such a subsequent review, under these circumstances, are properly assessable.

(d) The fee charged will not exceed an amount based on the time typically required to locate records of the kind requested.

(e)(1) If the Commission estimates that search charges are likely to exceed the greater of $25 or the amount which the requester indicated he/she is prepared to pay, then it shall notify the requester of the estimated amount of fees. Such a notice shall offer the requester the opportunity to confer with Commission personnel with the object of revising or clarifying the request. *See* § 0.465(c)(2) and § 0.470(d).

(2) The time for processing a request for inspection shall be tolled while conferring with the requester about his or her willingness to pay the fees required to process the request. *See* § 0.461(e).

(f) When the search has been completed, the custodian of the records will give notice of the charges incurred to the person who made the request.

(g) The fee shall be paid to the Financial Management Division, Office of Managing Director, or as otherwise directed by the Commission.

■ 13. Revise § 0.470 to read as follows:

§ 0.470 Assessment of fees.

(a)(1) *Commercial use requesters.* (i) When the Commission receives a request for documents for commercial use, it will assess charges that recover the full direct cost of searching for, reviewing and duplicating the records sought pursuant to § 0.466 and § 0.467.

(ii) Commercial use requesters shall not be assessed search fees if the Commission fails to comply with the time limits under § 0.461(g), except as provided in paragraph (a)(1)(iii) of this section.

(iii) Commercial requesters may still be assessed search fees when the Commission fails to comply with the time limits under § 0.461(g) if the Commission determines that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, so long as the Commission has provided a timely written notice to the requester and has discussed with the requester (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request. Additionally, if a court has determined that exceptional circumstances exist, a failure to comply with a time limit under § 0.461(g) will be excused for the length of time provided by the court order.

(2) *Educational and non-commercial scientific institution requesters and requesters who are representatives of the news media.* (i) The Commission shall provide documents to requesters in these categories for the cost of duplication only, pursuant to § 0.465 above, excluding duplication charges for the first 100 pages, provided however, that requesters who are representatives of the news media shall be entitled to a reduced assessment of charges only when the request is for the purpose of distributing information.

(ii) Educational requesters or requesters who are representatives of the news media shall not be assessed fees for the cost of duplication if the Commission fails to comply with the time limits under § 0.461(g), except as provided in paragraph (a)(2)(iii) of this section.

(iii) Educational requesters or requesters who are representatives of the news media may still be assessed duplication fees when the Commission fails to comply with the time limits under § 0.461(g) if the Commission determines that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, so long as the Commission has provided a timely written notice to the requester and has discussed with the requester (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request. Additionally, if a court has determined that exceptional circumstances exist, a failure to comply with a time limit under § 0.461(g) will be excused for the length of time provided by the court order.

(3) *All other requesters.* (i) The Commission shall charge requesters who do not fit into any of the categories above fees which cover the full, reasonable direct cost of searching for and duplicating records that are responsive to the request, pursuant to § 0.465 and § 0.467, except that the first 100 pages of duplication and the first two hours of search time shall be furnished without charge.

(ii) All other requesters shall not be assessed search fees if the Commission fails to comply with the time limits under § 0.461(g), except as provided in paragraph (a)(3)(iii) of this section.

(iii) All other requesters may still be assessed search fees when the Commission fails to comply with the time limits under § 0.461(g) if the Commission determines that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, so long as the Commission has provided a timely written notice to the requester and has discussed with the requester (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request. Additionally, if a court has determined that exceptional circumstances exist, a failure to comply with a time limit under § 0.461(g) will be excused for the length of time provided by the court order.

(b)(1) The 100 page restriction on assessment of duplication fees in paragraphs (a)(2) and (3) of this section refers to 100 paper copies of a standard size, which will normally be 8½″ x 11″ or 11″ x 14″.

(2) When the agency reasonably believes that a requester or group of requesters is attempting to segregate a request into a series of separate individual requests for the purpose of evading the assessment of fees, the

agency will aggregate any such requests and assess charges accordingly.

(c) When a requester believes he or she is entitled to a waiver pursuant to paragraph (e) of this section, the requester must include, in his or her original FOIA request, a statement explaining with specificity, the reasons demonstrating that he or she qualifies for a fee waiver. Included in this statement should be a certification that the information will not be used to further the commercial interests of the requester.

(d) If the Commission reasonably believes that a commercial interest exists, based on the information provided pursuant to paragraph (c) of this section, the requester shall be so notified and given an additional ten business days to provide further information to justify receiving a reduced fee. *See* § 0.467(e)(2).

(e)(1) Copying, search and review charges shall be waived or reduced by the General Counsel when ''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.'' 5 U.S.C. 552(a)(4)(A)(iii). Simply repeating the fee waiver language of section 552(a)(4)(A)(iii) is not a sufficient basis to obtain a fee waiver.

(2) The criteria used to determine whether disclosure is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government include:

(i) Whether the subject of the requested records concerns the operations or activities of the government;

(ii) Whether the disclosure is likely to contribute to an understanding of government operations or activities; and

(iii) Whether disclosure of the requested information will contribute to public understanding as opposed to the individual understanding of the requester or a narrow segment of interested persons.

(3) The criteria used to determine whether disclosure is primarily in the commercial interest of the requester include:

(i) Whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so

(ii) Whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester.

(4) This request for fee reduction or waiver must accompany the initial request for records and will be decided under the same procedures used for record requests.

(5) If no fees or de minimis fees would result from processing a FOIA request and a fee waiver or reduction has been sought, the General Counsel will not reach a determination on the waiver or reduction request.

(f) Whenever Commission staff determines that the total fee calculated under this section likely is less than the cost to collect and process the fee, no fee will be charged.

(g) Review of initial fee determinations under § 0.467 through § 0.470 and initial fee reduction or waiver determinations under paragraph (e) of this section may be sought under § 0.461(j).

PART 1—PRACTICE AND PROCEDURE

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

Authority: 15 U.S.C. 79 *et seq.*; 47 U.S.C. 151, 154(i), 154(j), 155, 157, 160, 201, 225, 227, 303, 309, 310, 332, 1403, 1404, 1451, 1452, and 1455.

■ 15. Amend § 1.115 by revising paragraph (d) to read as follows:

§ 1.115 Application for review of action taken pursuant to delegated authority.

* * * * *

(d) Except as provided in paragraph (e) of this section and in § 0.461(j) of this chapter, the application for review and any supplemental thereto shall be filed within 30 days of public notice of such action, as that date is defined in § 1.4(b). Opposition to the application shall be filed within 15 days after the application for review is filed. Except as provided in paragraph (e)(3) of this section, replies to oppositions shall be filed within 10 days after the opposition is filed and shall be limited to matters raised in the opposition.

* * * * *

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Proposed Rules

Federal Register
Vol. 82, No. 9
Friday, January 13, 2017

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 65

[Doc. No. AMS–LPS–16–0014]

Addition of Mandatory Country of Origin Labeling Requirements for Venison

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) proposes to amend the country of origin labeling (COOL) regulation to add muscle cuts of venison and ground venison to mandatory COOL requirements. AMS is issuing this proposed rule to conform to amendments to the Agricultural Marketing Act of 1946 (Act) as mandated by the Agricultural Act of 2014 (2014 Farm Bill), that added muscle cuts of venison and ground venison to the list of covered commodities subject to mandatory COOL.

DATES: Submit comments on or before March 14, 2017. Pursuant to the Paperwork Reduction Act, comments on the recordkeeping burden that would result from this proposal must be received by March 14, 2017.

ADDRESSES: All comments should reference the docket number AMS–LPS–16–0014; the date of submission; and the page number of this issue of the **Federal Register**. Comments may also be submitted to: Julie Henderson, Director, COOL Division; Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture (USDA); Room 2614–S, STOP 0216; 1400 Independence Avenue SW., Washington, DC 20250–0216. AMS will make the comments available for public inspection at the above address during regular business hours or via the Internet at *www.regulations.gov.*

Pursuant to the Paperwork Reduction Act (PRA), send comments regarding the accuracy of the burden estimate, ways to minimize burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information to the above address. Comments concerning the information collection under PRA also should be sent to the Desk Office for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Please be advised that all comments submitted in response to this proposed rule will be included in the record without change and will be made available to the public on the Internet at *www.regulations.gov.* The identity, including any personal information provided, of the individuals or entities submitting the comments will be made public.

FOR FURTHER INFORMATION CONTACT: Julie Henderson, Director, COOL Division; Livestock, Poultry, and Seed Program, Agricultural Marketing Service, USDA; Room 2614–S, STOP 0216; 1400 Independence Avenue SW., Washington, DC 20250–0216; telephone (202) 720–4486; or email *COOL@ ams.usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13563

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is not intended to have a retroactive effect. The Act prohibits states or political subdivisions of a state to impose any requirement that is in addition to, or inconsistent with, any requirement of the Act. There are no civil justice implications associated with this proposed rule.

Executive Order 13132

This proposed rule has been reviewed under Executive Order 13132, Federalism. This Order directs agencies to construe, in regulations and otherwise, a Federal statute to preempt state law only where the statute contains an express preemption provision. No federalism implications are associated with this proposed rule.

With regard to consultation with states, as directed by Executive Order 13132, AMS previously consulted with the states that have country of origin labeling programs. Currently, AMS has cooperative agreements with 47 states to assist in the enforcement of the COOL program and has communications with all 50 states on a regular basis.

Background and Proposed Revisions

AMS is proposing to add venison and ground venison to the list of covered commodities subject to mandatory COOL regulation in conformance to section 12104(b) of the Agricultural Act of 2014 (2014 Farm Bill) (Pub. L. 113–79). Retailers and suppliers would subsequently be required to keep records and provide their customers notification of the country of origin of muscle cuts and ground venison that they sell. Individuals that supply venison, whether directly to retailers or indirectly through other participants in the marketing chain, would be required to establish and maintain country of origin information for venison and supply this information to retailers. As a result, producers, handlers, manufacturers, wholesalers, importers, and retailers of venison would be affected.

This proposed rule would amend the country of origin labeling regulations (7 CFR part 65). AMS proposes to add definitions for *cervidae* (§ 65.117), *ground venison* (§ 65.178), and *venison* (§ 65.270). The proposed rule would amend definitions for *covered commodity* (§ 65.135(a)(1) and (2)), *production step* (§ 65.230), *raised* (§ 65.235), *slaughter* (§ 65.250), and *United States country of origin* (§ 65.260(a)) by adding references to venison. AMS proposes to amend *country of origin notification*

(§ 65.300(h)) to add references to ground venison, and *responsibilities of suppliers* (§ 65.500(b)(1)) to include references to venison and cervidae.

Additional administrative changes are necessary to reflect the withdrawal of beef and pork commodities from the COOL regulations as published in the **Federal Register** on March 2, 2016 (81 FR 10761). Therefore, AMS is proposing to amend *production step* (§ 65.230), *raised* (§ 65.235), and *United States country of origin* (§ 65.260) by removing references to *beef* and *pork* from these definitions.

AMS is seeking comments on the aforementioned definitions and requirements. AMS also invites comments concerning potential economic and other effects of this proposed rule.

Initial Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Administrator of AMS has considered the economic effect of this action on small entities and has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

Venison Industry

In general, the supply chain for venison and ground venison consists of: Producers (ranchers); slaughterhouses, processors, importers, wholesalers, and distributors (intermediary firms); and retailers. Under this proposed rule, all entities in the supply chain would be affected. Because the venison industry is very small at all levels of the supply chain, the overall impact of this proposed rule would be insignificant. According to the 2014 North American Deer Farmers Association's Venison Council, most venison is sold to restaurants, which are not subject to COOL requirements.

The proposed rule would impose recordkeeping requirements on venison producers and intermediary firms selling venison destined for retail channels. Individual retailers selling venison would also be subject to point of sale labeling and recordkeeping requirements. Each participant in the venison supply chain would bear recordkeeping costs as well as costs associated with modifications to their business practices.

Producers

USDA's National Agricultural Statistics Service (NASS) estimated that, in 2012, there were 4,042 deer farms and 1,199 elk farms, totaling 5,241 venison farms, in the U.S. This is a decrease from 7,571 in 2007. Of the venison producers identified in a Texas A&M University 2007 study,[1] 32 percent of survey respondents were breeding and hunting operations and 7 percent were hunting-only operations. Moreover, the trophy-hunting segment of the venison industry represents the primary end market for the breeding stock industry. Breeding and hunting and hunting-only operations are not considered to be producers of venison for consumption that are subject to COOL. Relying on the NASS and Texas A&M data, AMS assumes that 60 percent of the ranches, or 3,144 producers, raise animals for meat consumption. Virtually all venison-producing operations that would be subject to the amended COOL regulations are small businesses under the criteria established by the Small Business Administration (SBA) [13 CFR 121.201]. SBA defines small agricultural producers as those having annual receipts of less than $750,000.

While AMS believes that venison producers already maintain birth and raising records on each animal (which may include ear tagging, radio frequency identification devices, and other related means of identification on either an animal or a lot basis) as a normal part of business operations and animal husbandry practices, venison producers may use an affidavit to proclaim where the animals they produce are born and raised, not by individual but for the whole herd. Two factors drive the cost to venison producers to comply with this proposed rule: The time to create the initial affidavit and the time to administer and maintain the affidavit annually. AMS estimates it will take each venison producer 15 minutes (0.25 hours) to create and sign the initial affidavit used to substantiate country of origin claims and carry out the purposes of this regulation. If producers sign an affidavit of country of origin on all animals in the herd, the affidavit will suffice to achieve the purposes of this regulation even if some of the venison produced ultimately is not sold to retail establishments covered by the regulation.

For venison producers, it is assumed that the added work needed to generate an affidavit from an existing recordkeeping system for country of origin is primarily a bookkeeping task. This task may be performed by an independent bookkeeper, or in the case of operations that perform their own bookkeeping, an individual with equivalent skills. The Bureau of Labor Statistics (BLS) publishes wage rates for bookkeepers, accounting, and auditing clerks. In estimating recordkeeping costs, May 2015 wage rates and benefits published by BLS from the National Compensation Survey are used. It is assumed that this wage rate represents the cost for venison producers to hire an independent bookkeeper. In the case of venison producers who currently perform their own bookkeeping, it is assumed that this wage rate represents the opportunity cost of the producers' time for performing these tasks. The May 2015 wage rate is estimated at $23.23 per hour. For this analysis, an additional 33 percent is added to the wage rate to account for total benefits, which include Social Security, unemployment insurance, workers compensation, etc. resulting in $30.90 per hour. Recordkeeping time for venison producers to generate and sign a producer affidavit is estimated at 15 minutes (0.25 hours) per operation. This 0.25 hours multiplied by 3,144 producers at a cost of $30.90 per hour results in approximately $24,287 to generate affidavits to substantiate country of origin claims. Annual maintenance is estimated to take 5 minutes (0.083 hours) for each of the 3,144 operations at a cost of $30.90 per hour for total annual costs of $8,063. Therefore, the total cost estimates for producers are $32,351, or approximately $10.29 per firm.

Intermediary Firms

Any establishment that supplies retailers with venison or ground venison would be required to provide country of origin information to retailers. This includes importers, slaughterhouses, processors, wholesalers, and distributors.

From 2011 to 2015, USDA's Foreign Agricultural Service (FAS) reported venison imports of 21.78 million pounds valued at $79.3 million. For those years, the average annual venison imports were 4.356 million pounds valued at $15.86 million, or $3.64 per pound. During this period, the United States saw a dramatic increase in venison imports, with virtually all of it originating from New Zealand. For an imported venison covered commodity, the importer of record must ensure that

[1] Anderson, D.P., Frosch, B.J., and Outlaw, J.L. Economic Impact of the United States Cervid Farming Industry. APFC Research Report 07–4, August 2007. Agricultural & Food Policy Center. Texas A&M University: College Station, TX.

records provide clear product tracking from the port of entry into the U.S. to the immediate subsequent recipient. In addition, the records must accurately reflect the country of origin in relevant U.S. Customs and Border Protection entry documents and information systems. Regulated firms must maintain records to verify the accuracy of COOL declarations for a period of one year from the date of the transaction (purchase or sale of animals for slaughter, or venison meat at each point in the supply chain). AMS expects that importers already maintain records mandated by other Federal Statutes (*e.g.,* Bioterrorism Act of 2002; Tariff Act of 1930) that would be sufficient to verify compliance with COOL.

Of intermediaries potentially affected by the proposed rule, SBA classifies as small those manufacturing firms with less than 500 employees and wholesalers with less than 100 employees. Therefore, approximately 93 percent of the general-line grocery wholesalers are small businesses. According to NASS' 2012 Economic Census, there were a total of 2,162 meat and meat products specialty wholesaler firms. Of these, 2,043 firms had less than 100 employees, meaning approximately 95 percent of meat wholesalers are small firms. That same Census reported that 2,354 out of 2,629 (90 percent) livestock processing and slaughtering firms were in operation and classified as small businesses. USDA's Food Safety Inspection Service (FSIS) reported that 577 FSIS-inspected establishments (22 percent) in the U.S. process (*i.e.,* slaughter and process or process-only) non-amenable species, which include venison.

Intermediaries are generally assumed to have prior experience with COOL compliance and are expected to have lower costs needed to meet the requirements of this proposed rule than they did when COOL was first implemented. Wholesalers would incur recordkeeping costs, costs associated with supplying country of origin information to retailers, costs associated with segmenting products by country of origin, and additional handling costs. Given that venison is such a small percentage of proteins on the market, it is estimated that few intermediaries handle venison meat for sale to retail.

Since virtually all intermediary firms are assumed to already have a recordkeeping system in place for other COOL covered commodities, it is estimated that one (1) hour will be required to add venison to the design at a cost of $45 per firm. The initial recordkeeping costs are estimated by using the Label Cost Model developed for the Food and Drug Administration (FDA) by RTI International for including additional country of origin information to a livestock processor's records ($33.75 per hour with an additional 33 percent added to cover benefit costs for a total of $45.00 per hour). While the cost will be higher for some firms and lower for others, it is believed that $45 per hour represents a reasonable estimate of average cost for all firms. Based on this calculation, it is estimated that the initial recordkeeping costs for the 577 firms specializing in livestock processing and slaughtering of non-amenable species will be approximately $25,965. Intermediaries such as handlers, processors, importers and wholesalers (except livestock processing and slaughtering) are considered to already have sufficient recordkeeping and documentation systems in place to convey COOL information for venison products. Thus, no recordkeeping, set-up, and maintenance burden is estimated for these entities.

Maintenance activities will include inputting, tracking, and storing country of origin for venison. Since this is mostly an administrative task, the cost is estimated by using the May 2015 BLS wage rate from the National Compensation Survey for administrative support occupations ($17.40 per hour with an additional 33 percent added to cover benefit costs for a total of $23.14 per hour). This occupation category includes stock and inventory clerks and record clerks. Annual maintenance for venison processing and slaughter facilities is estimated to take 5 minutes (0.083 hours) at a cost of $23.14 per hour, for a total annual cost of $1,108. Total initial and maintenance costs for 577 livestock processing firms are estimated to be $27,073, or $46.92 per firm.

Retailers

According to the definition of *retailer* under the Perishable Agricultural Commodities Act of 1930, the number of retailers that would be affected by this proposed rule is considerably smaller than the total number of retailers nationwide. There are 4,504 retail firms subject to mandatory COOL regulations. An estimated 88 percent (3,964 out of 4,504) of retail firms are considered small businesses.

Only a small percentage of the producers identified by the previously mentioned Texas A&M University 2007 study actually sell venison and an even smaller percentage sell venison products to retail stores subject to COOL. Venison meat is available through some specialty grocers and national chains that focus on 'natural' meats. USDA's Economic Research Service supermarket sales data for venison and elk meat show that a total of 350,404 pounds were sold in supermarkets (the regulated retail firms subject to COOL) during the 5-year period from 2008 through 2012, or an average of 70,081 pounds per year. Average annual retail sales of venison are less than 2 percent of annual venison imports (70,000 divided by 4.4M pounds) without even accounting for domestic production. Most venison meat is consumed in restaurants, which are not subject to COOL requirements.

The number of retailers selling venison is a small subset of the COOL-regulated retailer population. Retailers choosing to carry venison products would accrue additional recordkeeping costs associated with supplying country of origin information to consumers as well as additional handling costs. USDA estimates that 3 percent of retailers (135 firms out of 4,504 retailers in the U.S.) will carry venison. AMS estimates that 88 percent of these retailers will be small businesses, consistent with the overall retailer population.

It is estimated that each of the 135 retail firms will require one (1) hour to add venison to existing data management systems. The initial recordkeeping costs for retailers are estimated by using the same Label Cost Model developed for FDA by RTI International for including additional country of origin information to a retailer's records. It is assumed that limited information, such as one-color redesign of a paper document, will be sufficient to comply with the rule's recordkeeping requirements (total salary and benefit costs of $45.00 per hour). Based on one hour per firm at $45 per hour and 135 firms, initial recordkeeping costs at retail are estimated to be approximately $6,075. The yearly storing and maintenance cost for retailers is estimated by using the May 2015 BLS wage rate from the National Compensation Survey for administrative support occupations ($23.14 for wages plus benefits per hour). Annual maintenance for retail firms is estimated to take 30 minutes (0.5 hours) on average for 135 retail firms, because only a small subset, about 3 percent, of the 4,504 retailers will sell venison, at a cost of $23.14 per hour for total annual maintenance costs of $1,562. Total initial and maintenance costs for 135 retailers are estimated to be $7,637.

Accordingly, the Administrator of AMS has conducted this Initial Regulatory Flexibility Analysis and has determined that this proposed rule will not have a significant economic impact

on a substantial number of small entities. However, AMS invites comments concerning potential effects of this proposed rule.

AMS has considered any significant alternatives to this proposal that accomplish the statutory objectives and minimize the significant economic impact of the proposal on small entities. AMS does not believe there are other Federal rules that may duplicate, overlap, or conflict with the proposed rule. The effect of this proposed rule would be limited to a small number of firms that produce, process, and market venison. The only effective means of achieving the results mandated by the 2014 Farm Bill is through this proposed regulatory action.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection to add venison as a COOL covered commodity. The overall total burden for initial set-up, annual storage, and maintenance to comply with reporting and recordkeeping requirements for 3,856 recordkeepers is estimated to be 1,873 hours. OMB previously approved information collection requirements associated with all other COOL covered commodities and regulated firms and assigned OMB control number 0581–0250. This proposed rule would increase the overall reporting and recordkeeping burden due to the anticipated increase in number of respondents from the venison industry. Therefore, a NEW information collection is required to carry out the requirements of this proposed rule. AMS intends to merge this new information collection, upon OMB approval, into the approved 0581–0250 collection.

Below, AMS has described and estimated the annual burden, *i.e.,* the amount of time and cost of labor, for entities to prepare and maintain information to participate in this proposed mandatory labeling program. AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes. As with all mandatory regulatory programs, recordkeeping burdens are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. The Act, as amended, provides authority for this action.

Title: Mandatory Country of Origin Labeling Requirements for Venison Meat.

OMB Number: 0581–NEW.

Type of Request: This is a NEW collection.

Abstract: The information collection requirements are essential to carry out this rule.

COOL provisions of the Act require retailers and suppliers of COOL covered commodities to verify the accuracy of COOL claims. Only records maintained in the course of the normal conduct of the business are required to serve as verification. This proposed rule would add this recordkeeping requirement for producers, intermediaries, and retailers of venison meat. This public reporting burden is necessary to ensure conveyance and accuracy of country of origin and method of production declarations relied upon at the point of sale at retail. The public reporting burden also assures that all parties involved in supplying venison and ground venison meat to retail stores maintain and convey accurate information as required.

AMS believes that typical venison ranching operations have already developed much of the necessary recordkeeping (for example, birth, health, feeding records, and other documentation used to manage and identify the flock or herd) through normal animal husbandry and business practices. Furthermore, producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims. Therefore, the estimated incremental costs for venison producers to supplement existing records with country of origin information will be relatively small per firm. Examples of initial or start-up costs would be any additional recordkeeping burden to record the required country of origin information and transfer this information to handlers, processors, wholesalers, or retailers via records used in the normal course of business.

Table 1 displays the estimated annual costs associated for venison producers, intermediaries, and retailers. This public reporting burden is necessary to ensure conveyance and accuracy of country of origin and method of production declarations relied upon at the point of sale at retail. The public reporting burden also assures that all parties involved in supplying covered commodities to retail stores maintain and convey accurate information as required.

TABLE 1—ESTIMATED INITIAL SET-UP AND ESTIMATED ANNUAL STORAGE MAINTENANCE COSTS ASSOCIATED WITH PAPERWORK BURDEN

Initial & set-up costs (incurred one time only)	Firms	Initial costs
Venison Producers	3,144	$24,287
Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering)	0	0
Livestock Processing & Slaughtering (non-amenable species)	577	25,965
Retailers	135	6,075
Total Initial & Set-Up Costs	3,856	56,327
Annual Storing & Maintenance Costs (yearly maintenance cost burden)	**Firms**	**Maintenance costs**
Venison Producers	3,144	8,063
Handlers, Processors, Importers & Wholesalers (except livestock processing & slaughtering)	0	0
Livestock Processing & Slaughtering (non-amenable species)	577	1,108
Retailers	135	1,562
Total Annual Storing & Maintenance Costs	3,856	10,694
Total Estimated Set-Up and Annual Maintenance Costs		67,061

The request for approval of the new information collection is as follows:

Estimate of Burden: Public reporting burden for initial set-up, recordkeeping, storage, and maintenance is estimated to average 14 minutes (0.24 hours) per response from all respondents (venison producers, livestock processers and slaughterers, and retailers).

Initial Set-Up Burden

Respondents: Producers, processors, slaughterhouses, handlers, wholesalers, importers, and retailers of venison and ground venison meat.

Estimated Number of Respondents: 3,856.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 3,856.

Estimated Total Annual Burden on Respondents: 1,498 hours.

Annual Storage Maintenance Burden

Respondents: Producers, processors, slaughterhouses, handlers, wholesalers, importers, and retailers of venison and ground venison meat.

Estimated Number of Respondents: 3,856.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 3,856.

Estimated Total Annual Burden on Respondents: 376 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of AMS, including whether the information will have practical utility; (2) the accuracy of AMS' estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. A 60-day period is provided to comment on the information collection burden. Comments should reference OMB No. 0581–NEW and be sent to Julie Henderson, Director, COOL Division; Livestock, Poultry, and Seed Program, Agricultural Marketing Service, USDA; Room 2614–S, STOP 0216; 1400 Independence Avenue SW., Washington, DC 20250–0216; telephone (202) 720–4486; or email *COOL@ ams.usda.gov.* All comments received will be available for public inspection. All responses to this proposed rule will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Comments concerning the information collection under PRA should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects in 7 CFR Part 65

Agricultural commodities, Food labeling, Meat and meat products, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, AMS proposes to amend 7 CFR part 65 as follows:

PART 65—COUNTRY OF ORIGIN LABELING OF LAMB, CHICKEN, GOAT, AND VENISON MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADEMIA NUTS, PECANS, PEANUTS, AND GINSENG

■ 1. The authority citation for 7 CFR part 65 continues to read as follows:

Authority: 7 U.S.C. 1621 *et seq.*

■ 2. Revise the part heading of 7 CFR part 65 as set forth above.

■ 3. Add § 65.117 to read as follows:

§ 65.117 Cervidae.

Cervidae means any one of the various species that are raised for the production of venison meat, such as whitetail deer, elk, fallow deer, axis deer, sika, red deer (maral), musk deer, rusa deer, antelope, nilgai, pronghorn, reindeer, and caribou.

■ 4. Amend § 65.135 by revising paragraphs (a)(1) and (2) to read as follows:

§ 65.135 Covered commodity.

(a) * * *

(1) Muscle cuts of lamb, chicken, goat, and venison;

(2) Ground lamb, ground chicken, ground goat, and ground venison;

* * * * *

■ 5. Add § 65.178 to read as follows:

§ 65.178 Ground Venison.

Ground venison means comminuted venison of skeletal origin that is produced in conformance with all applicable Food Safety and Inspection Service labeling guidelines.

■ 6. Revise § 65.230 to read as follows:

§ 65.230 Production step.

Production step means, in the case of lamb, chicken, goat, and venison, born, raised, or slaughtered.

■ 7. Revise § 65.235 to read as follows:

§ 65.235 Raised.

Raised means, in the case of lamb, chicken, goat, and venison, the period of time from birth until slaughter or in the case of animals imported for immediate slaughter as defined in § 65.180, the period of time from birth until date of entry into the United States.

■ 8. Revise § 65.250 to read as follows:

§ 65.250 Slaughter.

Slaughter means the point in which a livestock animal (including chicken and cervidae) is prepared into meat products (covered commodities) for human consumption. For purposes of labeling under this part, the word *harvested* may be used in lieu of slaughtered.

■ 9. Amend § 65.260 by revising paragraph (a) to read as follows:

§ 65.260 United States country of origin.

* * * * *

(a) Lamb, chicken, goat, and venison:

* * * * *

■ 10. Add § 65.270 to read as follows:

§ 65.270 Venison.

Venison means meat produced from animals in the cervidae family.

■ 11. Amend § 65.300 by revising paragraph (h) to read as follows:

§ 65.300 Country of origin notification.

* * * * *

(h) *Labeling Ground Lamb, Ground Goat, Ground Chicken, and Ground Venison.* The declaration for ground lamb, ground goat, ground chicken, and ground venison covered commodities shall list all countries of origin contained therein or that may be reasonably contained therein. In determining what is considered reasonable, when a raw material from a specific origin is not in a processor's inventory for more than 60 days, that country shall no longer be included as a possible country of origin.

* * * * *

■ 12. Amend § 65.500 by revising paragraph (b)(1) to read as follows:

§ 65.500 Recordkeeping requirements.

* * * * *

(b) * * * (1) Any person engaged in the business of supplying a covered commodity to a retailer, whether directly or indirectly, must make available information to the buyer about the country(ies) of origin of the covered commodity. This information may be provided either on the product itself, on

the master shipping container, or in a document that accompanies the product through retail sale. In addition, the supplier of a covered commodity that is responsible for initiating a country(ies) of origin claim, which in the case of lamb, chicken, goat, and venison is the slaughter facility, must possess records that are necessary to substantiate that claim for a period of 1 year from the date of the transaction. For that purpose, packers that slaughter animals that are tagged with an 840 Animal Identification Number device without the presence of any additional accompanying marking (*i.e.,* ''CAN'' or ''M'') may use that information as a basis for a U.S. origin claim. Packers that slaughter animals that are part of another country's recognized official system (*e.g.* Canadian official system, Mexico official system) may also rely on the presence of an official ear tag or other approved device on which to base their origin claims. In the case of cervidae, producer affidavits shall also be considered acceptable records that suppliers may utilize to initiate origin claims, provided it is made by someone having first-hand knowledge of the origin of the covered commodity and identifies the covered commodity unique to the transaction.

* * * * *

Dated: January 9, 2017.

Bruce Summners,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2017–00588 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1260

[No. AMS–LPS–16–0071]

Beef Promotion and Research; Reapportionment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would adjust representation on the Cattlemen's Beef Promotion and Research Board (Board), established under the Beef Promotion and Research Act of 1985 (Act), to reflect changes in domestic cattle inventories since January 1, 2013, as well as changes in levels of imported cattle, beef, and beef products that have occurred since December 31, 2012, which were the cut-off dates for data used by the Agricultural Marketing Service (AMS) when the Board was last reapportioned in July 2014. These adjustments are required by the Beef Promotion and Research Order (Order) and, if adopted, would result in a decrease in Board membership from 100 to 99, effective with the U.S. Department of Agriculture's (USDA) appointments for terms beginning early in the year 2018.

DATES: Submit comments on or before March 14, 2017.

ADDRESSES: Comments should be posted online at *www.regulations.gov*. Comments received will be posted without change, including any personal information provided. All comments should reference the docket number AMS–LPS–16–0071, the date of submission, and the page number of this issue of the **Federal Register**. Comments may also be sent to Mike Dinkel, Agricultural Marketing Specialist; Research and Promotion Division; Livestock, Poultry, and Seed Program, AMS, USDA; Room 2610–S, STOP 0249, 1400 Independence Avenue SW., Washington, DC 20250–0249; or via fax to (202) 720–1125. Comments will be made available for public inspection at the above address during regular business hours or via the Internet at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mike Dinkel, Research and Promotion Division, at (301) 352–7497; fax (202) 720–1125; or by email at *Michael.Dinkel@ams.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13563

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act prohibits states or political subdivisions of a state to impose any requirement that is in addition to, or inconsistent with, any requirement of the Act. There are no civil justice implications associated with this proposed rule.

Regulatory Flexibility Act and Paperwork Reduction Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) [5 U.S.C. 601–612], the Administrator of AMS has considered the economic effect of this action on small entities and has determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

In the February 2013 publication of ''Farms, Land in Farms, and Livestock Operations,'' USDA's National Agricultural Statistics Service (NASS) estimated that the number of operations in the United States with cattle in 2012 totaled approximately 915,000, down from 950,000 in 2009. There are approximately 270 importers who import beef or edible beef products into the United States and 198 importers who import live cattle into the United States. It is estimated that the majority of those operations subject to the Order are considered small businesses under the criteria established by the Small Business Administration (SBA) [13 CFR 121.201]. SBA generally defines small agricultural service firms as those having annual receipts of $7.5 million or less, and small agricultural producers are generally defined as those having annual receipts of less than $750,000.

The proposed rule imposes no new burden on the industry. It only adjusts representation on the Board to reflect changes in domestic cattle inventory, as well as in cattle and beef imports. The adjustments are required by the Order and would result in a decrease in Board membership from 100 to 99.

AMS is committed to complying with the E-Government Act of 2002 to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes.

USDA has not identified any relevant federal rules that duplicate, overlap, or conflict with this rule.

Background and Proposed Action

The Board was initially appointed on August 4, 1986, pursuant to the provisions of the Act [7 U.S.C. 2901–2911] and the Order issued thereunder. Domestic representation on the Board is

based on cattle inventory numbers, while importer representation is based on the conversion of the volume of imported cattle, beef, and beef products into live animal equivalencies.

Reapportionment

Section 1260.141(b) of the Order provides that the Board shall be composed of cattle producers and importers appointed by the Secretary of Agriculture from nominations submitted by certified producer and importer organizations. A producer may only be nominated to represent the State or unit in which that producer is a resident.

Section 1260.141(c) of the Order provides that at least every 3 years, but not more than every 2 years, the Board shall review the geographic distribution of cattle inventories throughout the United States and the volume of imported cattle, beef, and beef products and, if warranted, shall reapportion units and/or modify the number of Board members from units in order to reflect the geographic distribution of cattle production volume in the United States and the volume of cattle, beef, or beef products imported into the United States.

Section 1260.141(d) of the Order authorizes the Board to recommend to the Secretary modifications to the number of cattle per unit necessary for representation on the Board.

Section 1260.141(e)(1) provides that each geographic unit or State that includes a total cattle inventory equal to or greater than 500,000 head of cattle shall be entitled to one representative on the Board. Section 1260.141(e)(2) provides that States that do not have total cattle inventories equal to or greater than 500,000 head shall be grouped, to the extent practicable, into geographically-contiguous units, each of which have a combined total inventory of not less than 500,000 head. Such grouped units are entitled to at least one representative on the Board. Each unit is entitled to an additional Board member for each additional 1 million head of cattle within the unit, as provided in § 1260.141(e)(4). Further, as provided in § 1260.141(e)(3), importers are represented by a single unit, with their number of Board members based on a conversion of the total volume of imported cattle, beef, or beef products into live animal equivalencies.

The initial Board appointed in 1986 was composed of 113 members. Reapportionment, based on a 3-year average of cattle inventory numbers and import data, reduced the Board to 111 members in 1990 and to 107 members in 1993 before the Board was increased back to 111 members in 1996. The Board decreased to 110 members in 1999, 108 members in 2001, and 104 members in 2005; increased to 106 members in 2009; decreased to 103 members in 2011; and decreased to 100 members in 2013. This proposal would amend § 1260.141(a) by increasing the importers from 6 to 7 members, decreasing the State of Virginia from 2 members to 1 member and decreasing the State of Texas from 13 to 12 members. Overall, if adopted, it would decrease the number of Board members from 100 to 99, with appointments for terms effective early in 2018.

The currently proposed, updated Board representation by States or geographic units is based on an average of the January 1, 2011, 2012, and 2013 inventory of cattle in the various States as reported by NASS. The proposed importer representation would be based on a combined total average of the 2011, 2012, and 2013 live cattle imports as published by USDA's Foreign Agricultural Service and the average of the 2011, 2012, and 2013 live animal equivalents for imported beef and beef products.

In considering reapportionment, the Board reviewed cattle inventories on the date January 1 in 2014, 2015, and 2016, as well as cattle, beef, and beef product import data for the period of January 1, 2013, to December 31, 2015. The Board recommended that a 3-year average of cattle inventories and import numbers should be continued. The Board determined that an average of the January 1, 2014, 2015, and 2016 cattle inventory numbers would best reflect the number of cattle in each state or unit since publication of the last reapportionment rule published in 2014 [79 FR 46961]. The Board reviewed data published by the USDA's Economic Research Service to determine proper importer representation. The Board recommended the use of the average of a combined total of the 2013, 2014, and 2015 cattle import data and the average of the 2013, 2014, and 2015 live animal equivalents for imported beef products. The method used to calculate the total number of live animal equivalents was the same as that used in the previous reapportionment of the Board. The live animal equivalent weight was changed in 2006 from 509 pounds to 592 pounds [71 FR 47074].

The Board's recommended reapportionment plan, if adopted, would decrease the number of representatives on the Board from 100 to 99. From the Board's analysis of USDA cattle inventories and import equivalencies, Virginia would lose one Board seat and Texas would lose one Board seat. The importers would gain one Board seat.

The States and units affected by the reapportionment plan and the current and proposed member representation per unit are as follows:

State/unit	Current representation	Revised representation
Virginia	2	1
Texas	13	12
Importers	6	7

The Board reapportionment as proposed by this rulemaking would take effect, if adopted, with appointments to fill positions early in the year 2018.

A 60-day comment period is provided to allow interested persons to respond to this proposal. Thirty days is deemed appropriate to facilitate the adjustment of the representation on the Board, which is required by the Order at least every 3 years but not more than every 2 years, and to allow for the annual nomination and appointment process for Board appointments that will be effective early in 2018.

List of Subjects in 7 CFR Part 1260

Administrative practice and procedure, Advertising, Agricultural research, Imports, Meat and meat products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS proposes to amend 7 CFR part 1260 as follows:

PART 1260—BEEF PROMOTION AND RESEARCH

■ 1. The authority citation for 7 CFR part 1260 continues to read as follows:

Authority: 7 U.S.C. 2901–2911 and 7 U.S.C. 7401.

■ 2. Revise § 1260.141 paragraph (a) and the table immediately following to read as follows:

§ 1260.141 Membership of Board.

(a) Beginning with the 2017 Board nominations and the associated appointments effective early in the year 2018, the United States shall be divided into 37 geographical units and 1 unit representing importers, for a total of 38 units. The number of Board members from each unit shall be as follows:

CATTLE AND CALVES [1]

State/unit	(1,000 head)	Directors
1. Arizona	900	1
2. Arkansas	1,660	2
3. Colorado	2,600	3
4. Florida	1,680	2
5. Idaho	2,307	2
6. Illinois	1,143	1
7. Indiana	873	1
8. Iowa	3,867	4
9. Kansas	5,983	6
10. Kentucky	2,110	2
11. Louisiana	787	1
12. Michigan	1,133	1
13. Minnesota	2,347	2
14. Mississippi	923	1
15. Missouri	3,983	4
16. Montana	2,567	3
17. Nebraska	6,317	6
18. New Mexico	1,340	1
19. New York	1,450	1
20. North Carolina	803	1
21. North Dakota	1,697	2
22. Ohio	1,243	1
23. Oklahoma	4,567	5
24. Oregon	1,300	1
25. Pennsylvania	1,580	2
26. South Dakota	3,783	4
27. Tennessee	1,770	2
28. Texas	11,500	12
29. Utah	807	1
30. Virginia	1,487	1
31. Wisconsin	3,467	3
32. Wyoming	1,293	1
33. Northwest		1
Alaska	10	
Hawaii	135	
Washington	1,137	
Total	1,282	
34. Northeast		1
Connecticut	48	
Delaware	16	
Maine	84	
Massachusetts	38	
New Hampshire	32	
New Jersey	28	
Rhode Island	5	
Vermont	260	
Total	511	
35. Mid-Atlantic		1
Maryland	186	
West Virginia	382	
Total	567	
36. Southeast		3
Alabama	1,240	
Georgia	1,057	
South Carolina	337	
Total	2,633	
37. Southwest		6
California	5,183	
Nevada	442	
Total	5,625	
38. Importers [2]	6,949	7

[1] 2014, 2015, and 2016 average of January 1 cattle inventory data.
[2] 2013, 2014, and 2015 average of annual import data.

* * * * *

Dated: January 9, 2017.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2017–00587 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Office of Procurement and Property Management

7 CFR Part 3201

RIN 0599–AA24

Designation of Product Categories for Federal Procurement

AGENCY: Office of Procurement and Property Management, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Agriculture (USDA) is proposing to amend the Guidelines for Designating Biobased Products for Federal Procurement (Guidelines) to add 12 sections that will designate 12 product categories composed of intermediate ingredient and feedstock materials within which biobased products would be afforded procurement preference by Federal agencies and their contractors. USDA is also proposing minimum biobased contents for each of these product categories.

DATES: USDA will accept public comments on this proposed rule until March 14, 2017.

ADDRESSES: You may submit comments by any of the following methods. All submissions received must include the agency name and Regulatory Information Number (RIN). The RIN for this rulemaking is 0599–AA24. Also, please identify submittals as pertaining to the ''Proposed Designation of Product Categories.''

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: biopreferred_support@amecfw.com.* Include RIN number 0599–AA24 and ''Proposed Designation of Product Categories'' on the subject line. Please include your name and address in your message.
- *Mail/commercial/hand delivery:* Mail or deliver your comments to: Marie Wheat, USDA, Office of Procurement and Property Management, Room 361, Reporters Building, 300 7th St. SW., Washington, DC 20024.
- Persons with disabilities who require alternative means for communication for regulatory information (Braille, large print, audiotape, etc.) should contact the USDA TARGET Center at (202) 720–2600 (voice) and (202) 690–0942 (TTY).

FOR FURTHER INFORMATION CONTACT: Marie Wheat, USDA, Office of Procurement and Property Management, Room 361, Reporters Building, 300 7th St. SW., Washington, DC 20024; email: *biopreferred_support@amecfw.com;* phone (202) 239–4502. Information regarding the Federal preferred procurement program (one initiative of the BioPreferred Program) is available on the Internet at *http://www.biopreferred.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Authority
II. Background
III. Summary of Today's Proposed Rule
IV. Designation of Product Categories, Minimum Biobased Contents, and Time Frame
  A. Background
  B. Product Categories and Minimum Biobased Contents Proposed for Designation
  C. Compliance Date for Procurement Preference and Incorporation Into Specifications
V. Where can agencies get more information on these USDA-designated product categories?
VI. Regulatory Information
  A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  B. Regulatory Flexibility Act (RFA)
  C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights
  D. Executive Order 12988: Civil Justice Reform
  E. Executive Order 13132: Federalism
  F. Unfunded Mandates Reform Act of 1995
  G. Executive Order 12372: Intergovernmental Review of Federal Programs
  H. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  I. Paperwork Reduction Act
  J. E-Government Act

I. Authority

The designation of these product categories is proposed under the authority of section 9002 of the Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), as amended by the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill), and further amended by the Agricultural Act of 2014 (the 2014 Farm Bill), 7 U.S.C. 8102. (Section 9002 of the 2002 Farm Bill, as amended by the 2008 and the 2014 Farm Bills, is referred to in this document as ''section 9002''.)

II. Background

Section 9002 provides for the preferred procurement of biobased products by Federal procuring agencies and is referred to hereafter in this **Federal Register** notice as the ''Federal preferred procurement program.'' Under the provisions specified in the ''Guidelines for Designating Biobased Products for Federal Procurement'' (7 CFR part 3201) (Guidelines), the USDA BioPreferred Program ''designates'' product categories to which the preferred procurement requirements apply by listing them in subpart B of 7 CFR part 3201.

The term ''product category'' is used as a generic term in the designation process to mean a grouping of specific products that perform a similar function. As originally finalized, the Guidelines included provisions for the designation of product categories that were composed of finished, consumer products such as mobile equipment hydraulic fluids, penetrating lubricants, or hand cleaners and sanitizers.

The 2008 and 2014 Farm Bills directed USDA to expand the scope of the Guidelines to include the designation of product categories composed of intermediate ingredients and feedstock materials. Specifically, the 2008 Farm Bill stated that USDA shall ''designate those intermediate ingredients and feedstocks that are or can be used to produce items that will be subject'' to the Federal preferred procurement program. The term ''intermediate ingredient and feedstock'' is defined in the Farm Bill as ''a material or compound made in whole or in significant part from biological products, including renewable agricultural materials (including plant, animal, and marine materials) or forestry materials, that are subsequently used to make a more complex compound or product.'' The term ''intermediates'' is used in the titles of the product categories being proposed for designation today to distinguish these proposed categories from the finished, consumer products previously designated by USDA. Additionally, in section 9001 of the 2014 Farm Bill, the term ''renewable chemical'' is defined as ''a monomer, polymer, plastic, formulated product, or chemical substance produced from renewable biomass.'' Thus, most products that are described as ''renewable chemicals'' will be eligible for the Federal preferred procurement program because they meet the definition of one or more of the intermediate product categories included in today's proposed rule.

For example, the chemical substance known as citric acid, if biobased, may be considered as a renewable chemical and an intermediate ingredient for finished products in the cleaning, personal care, or textiles industries. Thus, biobased citric acid could be categorized in one or all of the following intermediate product categories that are proposed for designation today: Intermediates—Chemicals, Intermediates—Textile Processing Materials, Intermediates—Cleaner Components, or Intermediates—Personal Care Product Components. Additionally, the chemical substance known as oleic acid may be considered as a renewable chemical and an intermediate ingredient for finished products in the cleaning, personal care, or lubricant industries. Therefore, oleic acid could be categorized in one or all of the following intermediate product categories that are proposed for designation today: Intermediates—Chemicals, Intermediates—Lubricant Components, Intermediates—Cleaner Components, or Intermediates—Personal Care Product Components. These examples show that the intermediate product categories being proposed today may accommodate a variety of renewable chemical substances.

Although the Federal government does not typically purchase large quantities of intermediate ingredients and feedstock materials, designating such materials represents a means to identify and include finished products made from such designated materials in the Federal preferred procurement program. In the August 1, 2014 **Federal Register** (79 FR 44641), USDA finalized amendments to the Guidelines establishing procedures for designating intermediate ingredient or feedstock categories. Today's proposed rule follows the established procedures for designating intermediate ingredient product categories. Soon, USDA will propose designating product categories comprised of finished products made from intermediate ingredients that may be categorized within the product categories proposed for designation in today's rule. Therefore, USDA requests manufacturers and members of the public to submit technical information related to the designation of such finished product categories to *biopreferred_support@amecfw.com.* Specific technical information to submit includes the following: A finished product category name, descriptions of finished products that belong in this product category, how these finished products are used, any special features of these finished products, estimated or tested biobased contents for each finished product, applicable performance standards that the finished products meet, and which intermediate ingredient and feedstock categories are used to make these finished products. Such information will be valuable in supporting the selection of product categories for designation but will be evaluated independently from today's proposed rule. Please refer to Section IV.B. of today's proposed rule for further details on the information required to designate product categories for Federal procurement preference.

Once USDA designates a product category, procuring agencies are required, with some exceptions, to purchase biobased products within these designated product categories where the purchase price of the procurement product exceeds $10,000 or where the quantity of such products or the functionally equivalent products purchased over the preceding fiscal year equaled $10,000 or more. Procuring agencies must procure biobased products within each product category unless they determine that products within a product category are not reasonably available within a reasonable period of time, fail to meet the reasonable performance standards of the procuring agencies, or are available only at an unreasonable price. As stated in the Guidelines, biobased products that are merely incidental to Federal funding are excluded from the Federal preferred procurement program; that is, the requirements to purchase biobased products do not apply to such purchases if they are unrelated to or incidental to the purpose of the Federal contract. For example, if a janitorial service company purchases cleaning supplies to be used in the performance of a Federal contract, the cleaning supplies would be subject to the authority of the Federal preferred procurement program. However, cleaning supplies purchased to maintain the offices from which the janitorial service company manages the Federal contract would be incidental to the performance of the contract and, as such, would not be subject to the authority of the Federal preferred procurement program. In implementing the Federal preferred procurement program for biobased products, procuring agencies should follow their procurement rules and Office of Federal Procurement Policy guidance on buying non-biobased products when biobased products exist and should document exceptions taken for price, performance, and availability. The definition of ''procuring agency'' in section 9002 includes both Federal agencies and ''a person that is a party to a contract with any Federal agency, with respect to work performed under such a contract.'' Thus, Federal contractors, as well as Federal agencies, are expressly subject to the procurement preference provisions of section 9002.

USDA recognizes that the performance needs for a given application are important criteria in making procurement decisions. USDA is not requiring procuring agencies to limit their choices to biobased products that are categorized within the product categories proposed for designation in this proposed rule. Rather, the effect of the designation of the product categories is to require procuring agencies to determine their performance needs, determine whether there are qualified biobased products that are categorized within the designated product categories that meet the reasonable performance standards for those needs, and purchase such qualified biobased products to the maximum extent practicable as required by section 9002.

Section 9002(a)(3)(B) requires USDA to provide information to procuring agencies on the availability, relative price, and performance of such products and to recommend, where appropriate, the minimum level of biobased content to be contained in the procured products.

Subcategorization. Most of the product categories USDA has designated for Federal preferred procurement cover a wide range of products. For some product categories, there are subgroups of products that meet different requirements, uses and/or different performance specifications. For example, within the product category ''hand cleaners and sanitizers,'' products that are used in medical offices may be required to meet performance specifications for sanitizing, while other products that are intended for general purpose hand washing may not need to meet these specifications. Where such subgroups exist, USDA intends to create subcategories. Thus, for example, for the product category ''hand cleaners and sanitizers,'' USDA determined that it was reasonable to create a ''hand cleaner'' subcategory and a ''hand sanitizer'' subcategory. Sanitizing specifications are applicable to the latter subcategory, but not the former. In sum, USDA looks at the products within each product category to evaluate whether there are groups of products within the category that have unique characteristics or that meet different performance specifications and, if USDA finds these types of differences within a given product category, it intends to create subcategories with the

minimum biobased content based on the tested products within the subcategory.

For some product categories, however, USDA may not have sufficient information at the time of proposal to create subcategories. For example, USDA may know that there are different performance specifications that metal cleaners and corrosion remover products are required to meet, but it may have information on only one type of metal cleaner and corrosion remover product. In such instances, USDA may either designate the product category without creating subcategories (*i.e.,* defer the creation of subcategories) or designate one subcategory and defer designation of other subcategories within the product category until additional information is obtained. Once USDA has received sufficient additional information to justify the designation of a subcategory, the subcategory will be designated through the proposed and final rulemaking process.

USDA has not created subcategories for any of the product categories being proposed for designation in today's rule. USDA requests public comment, along with supporting data, on the need to create subcategories within any of the proposed product categories. If public comments are received that support the creation of subcategories, USDA will consider the supporting data and may create subcategories in the final rule.

Minimum Biobased Contents. The minimum biobased contents being proposed in this rule are based on products for which USDA has biobased content test data. USDA obtains biobased content data in conjunction with product manufacturer's applications for certification to use the USDA Certified Biobased Product label. Products that are certified to display the label must undergo biobased content testing by an independent, third party testing lab using ASTM D6866, ''Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis''. These test data become part of the BioPreferred Program database and their use in setting the minimum biobased content for designated product categories results in a more efficient process for both the Program and manufacturers of products within the product categories.

As a result of public comments received on the first designated product categories rulemaking proposal, USDA decided to account for the slight imprecision in the analytical method used to determine biobased content of products when establishing the minimum biobased content. Thus, rather than establishing the minimum biobased content for a product category at the tested biobased content of the product selected as the basis for the minimum value, USDA is establishing the minimum biobased content for each product category at a level three (3) percentage points lower than the tested value. USDA believes that this adjustment is appropriate to account for the expected variations in analytical results. USDA encourages procuring agencies to seek products with the highest biobased content that is practicable in all of the proposed designated product categories.

In addition to considering the biobased content test data for each product category, USDA also considers other factors including product performance information. USDA evaluates this information to determine whether some products that may have a lower biobased content also have unique performance or applicability attributes that would justify setting the minimum biobased content at a level that would include these products. For example, a lubricant product that has a lower biobased content than others within a product category but is formulated to perform over a wider temperature range than the other products may be more desirable to Federal agencies. Thus, it would be beneficial to set the minimum biobased content for the product category at a level that would include the product with superior performance features.

USDA also considers the overall range of the tested biobased contents within a product category, groupings of similar values, and breaks (significant gaps between two groups of values) in the biobased content test data array. For example, in a previously proposed product category, the biobased contents of 7 tested products ranged from 17 to 100 percent, as follows: 17, 41, 78, 79, 94, 98, and 100 percent. Because this is a very wide range, and because there is a significant gap in the data between the 41 percent biobased product and the 78 percent biobased product, USDA reviewed the product literature to determine whether subcategories could be created within this product category. USDA found that the available product information did not justify creating a subcategory based on the 17 percent product or the 41 percent biobased content product. Further, USDA did not find any performance claims that would justify setting the minimum biobased content based on either the 17 percent or the 41 percent biobased content products. Thus, USDA set the minimum biobased content for this product category at 75 percent, based on the product with a tested biobased content of 78 percent. USDA believes that this evaluation process allows it to establish minimum biobased contents based on a broad set of factors to assist the Federal procurement community in its decisions to purchase biobased products.

USDA makes every effort to obtain biobased content test data on multiple products within each product category. For most designated product categories, USDA has biobased content test data on more than one product within the category. However, in some cases, USDA has been able to obtain biobased content data for only a single product within a designated product category. As USDA obtains additional data on the biobased contents of products within these designated product categories or their subcategories, USDA will evaluate whether the minimum biobased content for a designated product category or subcategory will be revised.

Overlap with EPA's Comprehensive Procurement Guideline program for recovered content products under the Resource Conservation and Recovery Act (RCRA) Section 6002. Some of the products that are within biobased product categories designated for Federal preferred procurement under this program may also be within categories the Environmental Protection Agency (EPA) has designated under the EPA's Comprehensive Procurement Guideline (CPG) for products containing recovered (or recycled) materials. Because today's proposed rule would designate intermediate ingredient product categories rather than categories of finished, consumer-use products, USDA does not believe that there is a direct overlap between these categories and CPG categories. However, if such an overlap situation is discovered, USDA is asking manufacturers of qualifying biobased products to make additional product and performance information available to Federal agencies conducting market research to assist them in determining whether the biobased products in question are, or are not, the same products for the same uses as the recovered content products. Manufacturers are asked to provide information highlighting the sustainable features of their biobased products and to indicate the various suggested uses of their product and the performance standards against which a particular product has been tested. In addition, depending on the type of biobased product, manufacturers are being asked to provide other types of information, such as whether the product contains fossil energy-based components (including petroleum, coal, and natural gas) and whether the product contains

recovered materials. Federal agencies also may review available information on a product's biobased content. Federal agencies may then use this information to make purchasing decisions based on the sustainability features of the products.

Where a biobased product is used for the same purposes and to meet the same Federal agency performance requirements as an EPA-designated recovered content product, the Federal agency must purchase the recovered content product. For example, if a biobased hydraulic fluid is to be used as a fluid in hydraulic systems and because ''lubricating oils containing re-refined oil'' has already been designated by EPA for that purpose, then the Federal agency must purchase the EPA-designated recovered content product, ''lubricating oils containing re-refined oil.'' If, on the other hand, the biobased hydraulic fluid is to be used to address a Federal agency's certain environmental or health performance requirements that the EPA-designated recovered content product would not meet, then the biobased product should be given preference, subject to reasonable price, availability, and performance considerations.

Federal Government Purchase of Sustainable Products. The Federal government's sustainable purchasing program includes the following three mandatory preference programs for designated products: The BioPreferred Program, the EPA's Comprehensive Procurement Guideline for products containing recovered materials, and the Environmentally Preferable Purchasing program. The Office of the Chief Sustainability Officer (OCSO) and the Office of Management and Budget (OMB) encourage agencies to implement these components comprehensively when purchasing products and services.

Procuring agencies should note that not all biobased products are ''environmentally preferable.'' For example, unless cleaning products contain no or reduced levels of metals and toxic or hazardous constituents, they can be harmful to aquatic life, the environment, and/or workers. Household cleaning products that are formulated to be disinfectants are required, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), to be registered with EPA (unless they are formulated with exempt ingredients) and must meet specific labeling requirements warning of the potential risks associated with misuse of such products. When purchasing environmentally preferable cleaning products, many Federal agencies specify that products must meet Green Seal standards for institutional cleaning products or that the products have been reformulated in accordance with recommendations from the EPA's Safer Choice Program (previously known as the ''Design for the Environment'' (DfE) program). Both the Green Seal standards and the Safer Choice program identify chemicals of concern in cleaning products. These include zinc and other metals, formaldehyde, ammonia, alkyl phenol ethoxylates, ethylene glycol, and volatile organic compounds. In addition, both require that cleaning products have neutral pH.

In contrast, some biobased products may be environmentally preferable to some products that meet Green Seal standards for institutional cleaning products or that have been reformulated in accordance with EPA's Safer Choice program. To fully compare products, one must look at the ''cradle-to-grave'' impacts of the manufacture, use, and disposal of products. USDA has been unable to perform the analyses necessary to determine the ''cradle-to-grave'' impacts of products within the product categories being proposed for designation because of resource constraints.

One consideration of a product's impact on the environment is whether (and to what degree) it introduces new, fossil carbon into the atmosphere. Fossil carbon is derived from non-renewable sources (typically fossil fuels such as coal and oil), whereas renewable biomass carbon is derived from renewable sources (biomass). Qualifying biobased products offer the user the opportunity to manage his or her impact on the carbon cycle and reduce the introduction of new fossil carbon into the atmosphere.

Other Federal Preferred Procurement Programs. Federal procurement officials should also note that many biobased products may be available for purchase by Federal agencies through the AbilityOne Program (formerly known as the Javits-Wagner-O'Day (JWOD) program). Under this program, members of organizations including the National Industries for the Blind (NIB) and SourceAmerica (formerly known as the National Industries for the Severely Handicapped) offer products and services for preferred procurement by Federal agencies. A search of the AbilityOne Program's online catalog (*www.abilityone.gov*) indicated that the types of intermediate ingredient product categories being proposed for designation in today's proposed rule are not available through the AbilityOne Program. USDA notes, however, that if such materials are offered at some point in the future, their procurement through the AbilityOne Program would further the objectives of both the AbilityOne Program and the Federal preferred procurement program.

Outreach. To augment its own research, USDA consults with industry and Federal stakeholders to the Federal preferred procurement program during the development of the rulemaking packages for the designation of product categories. USDA consults with stakeholders to gather information used in determining the order of product category designation and in identifying: Manufacturers producing and marketing products that are categorized within a product category proposed for designation; performance standards used by Federal agencies evaluating products to be procured; and warranty information used by manufacturers of end user equipment and other products with regard to biobased products.

III. Summary of Today's Proposed Rule

USDA is proposing to designate the following product categories for Federal preferred procurement: Intermediates—Plastic Resins; Intermediates—Chemicals; Intermediates—Paint and Coating Components; Intermediates—Textile Processing Materials; Intermediates—Foams; Intermediates—Fibers and Fabrics; Intermediates—Lubricant Components; Intermediates—Binders; Intermediates—Cleaner Components; Intermediates—Personal Care Product Components; Intermediates—Oils, Fats, and Waxes; and Intermediates—Rubber Materials. In addition, USDA is proposing a minimum biobased content for each of these product categories and subcategories. Lastly, USDA is proposing a date by which Federal agencies must incorporate these designated product categories into their procurement specifications (see Section IV.E).

USDA is working with manufacturers and vendors to make all relevant product and manufacturer contact information available on the BioPreferred Program's Web site. Steps USDA has implemented, or will implement, include: Making direct contact with submitting companies through email and phone conversations to encourage completion of product listing; coordinating outreach efforts with intermediate material producers to encourage participation of their customer base; conducting targeted outreach with industry and commodity groups to educate stakeholders on the importance of providing complete product information; participating in industry conferences and meetings to educate companies on program benefits

and requirements; and communicating the potential for expanded markets beyond the Federal government, to include State and local governments, as well as the general public markets. Section V provides instructions to agencies on how to obtain this information on products within these product categories through the BioPreferred Program's Web site: *http://www.biopreferred.gov.*

Comments. USDA invites public comment on the proposed designation of these intermediate ingredient product categories, including the definition, proposed minimum biobased content, and any of the relevant analyses performed during their selection. In addition, USDA invites comments and information in the following areas:

1. We have attempted to identify relevant and appropriate performance standards and other relevant measures of performance for each of the proposed product categories. If you know of other such standards or relevant measures of performance for any of the proposed product categories, USDA requests that you submit information identifying such standards and measures, including their name (and other identifying information as necessary), identifying who is using the standard/measure, and describing the circumstances under which the product is being used.

2. Many biobased products within the product categories being proposed for designation will have positive environmental and human health attributes. USDA is seeking comments on such attributes in order to provide additional information on the BioPreferred Program's Web site. This information will then be available to Federal procuring agencies and will assist them in making informed sustainable procurement decisions. When possible, please provide appropriate documentation to support the environmental and human health attributes you describe.

3. Some product categories being proposed for designation today have wide ranges of tested biobased contents. For the reasons discussed later in this preamble, USDA is proposing a minimum biobased content for these product categories that would allow most of the tested products to be eligible for Federal preferred procurement. USDA welcomes comments on the appropriateness of the proposed minimum biobased contents for these product categories and whether there are potential subcategories within the product categories that should be considered.

4. Today's proposed rule is expected to have both positive and negative impacts on individual businesses, including small businesses. USDA anticipates that the biobased Federal preferred procurement program will provide additional opportunities for businesses and manufacturers to begin supplying products under the proposed designated biobased product categories to Federal agencies and their contractors. However, other businesses and manufacturers that supply only non-qualifying products and do not offer biobased alternatives may experience a decrease in demand from Federal agencies and their contractors. Because USDA has been unable to determine the number of businesses, including small businesses, which may be adversely affected by today's proposed rule USDA requests comment on how many small entities may be affected by this rule and on the nature and extent of that effect.

All comments should be submitted as directed in the **ADDRESSES** section above.

5. As stated in Section II of today's proposed rule, USDA will soon propose designating product categories comprised of finished products made from intermediate ingredients that may be categorized within the product categories proposed for designation in today's rule. Therefore, USDA requests manufacturers and members of the public to submit technical information related to the designation of such finished product categories to *biopreferred_support@amecfw.com.* Specific technical information to submit includes the following: A finished product category name, descriptions of finished products that belong in this product category, how these finished products are used, any special features of these finished products, estimated or tested biobased contents for each finished product, applicable performance standards that the finished products meet, and which intermediate ingredient and feedstock categories are used to make these finished products. Such information will be valuable in supporting the selection of product categories for designation but will be evaluated independently from today's proposed rule. Please refer to Section IV.B. of today's proposed rule for further details on the information required to designate product categories for Federal procurement preference.

IV. Designation of Product Categories, Minimum Biobased Contents, and Time Frame

A. Background

When designating product categories for Federal preferred procurement, section 9002 requires USDA to consider: (1) The availability of biobased products within the product categories and (2) the economic and technological feasibility of using those products.

In considering a product's availability, USDA uses several sources of information. The primary source of information for the product categories being proposed for designation is USDA's database of manufacturers and products that have been certified to display the USDA Certified Biobased Product label. In addition, USDA performs Internet searches, contacts trade associations and commodity groups, and contacts manufacturers and vendors to identify those with biobased products within product categories being considered for designation. USDA uses the results of these same searches to determine if a product category is generally available.

In considering a product category's economic and technological feasibility, USDA examines evidence pointing to the general commercial use of a product and its life-cycle cost and performance characteristics. This information is obtained from the sources used to assess a product's availability. Commercial use, in turn, is evidenced by any manufacturer and vendor information on the availability, relative prices, and performance of their products as well as by evidence of a product being purchased by a procuring agency or other entity, where available. In sum, USDA considers a product category economically and technologically feasible for purposes of designation if products within that product category are being offered and used in the marketplace.

As discussed earlier, USDA has implemented, or will implement, several steps intended to educate the manufacturers and other stakeholders on the benefits of this program and the need to make relevant information, including manufacturer contact information, available to procurement officials via the BioPreferred Program Web site. Additional information on specific products within the product categories proposed for designation may also be obtained directly from the manufacturers of the products. USDA has also provided information on the BioPreferred Program Web site for manufacturers and vendors who wish to position their businesses as biobased product vendors to the Federal Government. This information can be accessed by clicking on the ''Selling Biobased'' tab on the left side of the home page of the BioPreferred Program's Web site.

USDA recognizes that information related to the functional performance of biobased products is a primary factor in making the decision to purchase these products. USDA is gathering information on industry standard test methods and performance standards that manufacturers are using to evaluate the functional performance of their products. (Test methods are procedures used to provide information on a certain attribute of a product. For example, a test method might determine how many bacteria are killed. Performance standards identify the level at which a product must perform in order for it to be ''acceptable'' to the entity that set the performance standard. For example, a performance standard might require that a certain percentage (*e.g.,* 95 percent) of bacteria must be killed through the use of the product.) The primary sources of information on these test methods and performance standards are manufacturers of biobased products within these product categories. Additional test methods and performance standards are also identified during meetings of the interagency council and during the review process for each proposed rule. We have listed, under the detailed discussion of each product category proposed for designation (presented in Section IV.B), the functional performance test methods, performance standards, product certifications, and other measures of performance associated with the functional aspects of products identified during the development of this **Federal Register** notice for these product categories.

While this process identifies many of the relevant test methods and standards, USDA recognizes that those identified herein do not represent all of the methods and standards that may be applicable for a product category or for any individual product within the category. As noted earlier in this preamble, USDA is requesting identification of other relevant performance standards and measures of performance. As the program becomes fully implemented, these and other additional relevant performance standards will be available on the BioPreferred Program's Web site.

To propose a product category for designation, USDA must have sufficient information on a sufficient number of products within the category to be able to assess its availability and its economic and technological feasibility. For some product categories, there may be numerous products available. For others, there may be very few products currently available. Given the infancy of the market for some product categories, it is expected that categories with only a single product will be identified.

Further, given that the intent of section 9002 is largely to stimulate the production of new biobased products and to energize emerging markets for those products, USDA has determined it is appropriate to designate a product category or subcategory for Federal preferred procurement even when there is only a single product with a single supplier. Similarly, the documented availability and benefits of even a very small percentage of all products that may exist within a product category are also considered sufficient to support designation.

Exemptions. Products that are exempt from the biobased procurement preference are military equipment, defined as any product or system designed or procured for combat or combat-related missions, and spacecraft systems and launch support equipment. However, USDA points out that it is not the intent of these exemptions to imply that biobased products are inferior to non-biobased products and agencies are encouraged to purchase biobased products wherever performance, availability and reasonable price indicates that such purchases are justified.

Although each product category in today's proposed rule would be exempt from the procurement preference requirement when used in spacecraft systems or launch support application or in military equipment used in combat and combat-related applications, this exemption does not extend to contractors performing work other than direct maintenance and support of the spacecraft or launch support equipment or combat or combat-related missions. For example, if a contractor is applying a paint remover product as a step in refurbishing office furniture on a military base, the paint remover the contractor purchases should be a qualifying biobased paint remover. The exemption does apply, however, if the product being purchased by the contractor is for use in combat or combat-related missions or for use in space or launch applications. After reviewing the regulatory requirement and the relevant contract, where contractors have any questions on the exemption, they should contact the cognizant contracting officer.

B. Product Categories and Minimum Biobased Contents Proposed for Designation

In today's proposed rule, USDA is proposing to designate the following product categories for the Federal preferred procurement program: Intermediates—Plastic Resins; Intermediates—Chemicals; Intermediates—Paint and Coating Components; Intermediates—Textile Processing Materials; Intermediates—Foams; Intermediates—Fibers and Fabrics; Intermediates—Lubricant Components; Intermediates—Binders; Intermediates—Cleaner Components; Intermediates—Personal Care Product Components; Intermediates—Oils, Fats, and Waxes; and Intermediates—Rubber Materials.

USDA has determined that each of these product categories meets the necessary statutory requirements—namely, that they are being produced with biobased materials and that their procurement by procuring agencies will carry out the following objectives of section 9002:

- To increase demand for biobased products, which would in turn increase demand for agricultural commodities that can serve as feedstocks for the production of biobased products;
- To spur development of the industrial base through value-added agricultural processing and manufacturing in rural communities; and
- To enhance the Nation's energy security by substituting biobased products for products derived from imported oil and natural gas.

Further, USDA anticipates that the designation of these intermediate ingredient product categories will facilitate the designation of the many categories of finished consumer products that are made from these biobased intermediate ingredients. This designation of finished products made from designated ingredients was one key addition to Section 9002 made by the 2008 Farm Bill.

In addition, because of the participation by the manufacturers of these products in the voluntary labeling initiative, USDA has sufficient information on these product categories to determine their availability and to conduct the requisite analyses to determine their biobased content and their economic and technological feasibility.

The proposed designated product categories are discussed in the following sections.

1. Intermediates—Plastic Resins (Minimum Biobased Content 22 Percent)

Intermediates—Plastic Resins are materials that are typically viscous liquids with the ability to harden permanently and may exist in liquid or solid (powder or pellets) states. Intermediates—Plastic Resins may be

used in a variety of finished products neat, consisting of a single resin, or as a homogeneous blend of two or more neat resins, or composite, containing two or more distinct materials such as fiber-reinforced resins. Additionally, Intermediates—Plastic Resins may be used in finished products as additives such as plasticizers, pigments, thermal stability agents, or impact modifiers.

USDA identified 62 manufacturers and suppliers of 150 biobased Intermediates—Plastic Resins. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Plastic Resins, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 150 biobased Intermediates—Plastic Resins range in biobased content from 25 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Plastic Resins. Thus, the proposed minimum biobased content for this product category is 22 percent, based on the products with a tested biobased content of 25 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, some of these manufacturers and suppliers identified nine test methods (as shown below) used in evaluating products within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test methods identified by the manufacturers and suppliers include:

- ASTM D256; Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics,
- ASTM D638; Standard Test Method for Tensile Properties of Plastics,
- ASTM D790; Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials,
- ASTM D882; Standard Test Method for Tensile Properties of Thin Plastic Sheeting,
- ASTM D6400; Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,
- ASTM D6868; Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities,
- BPI Certification; Compostable in Municipal and Industrial Composting Facilities
- ISO 9001; Quality Management Systems—Requirements, and
- Vinçotte; OK COMPOST.

USDA has been unable to obtain data on the amount of Intermediates—Plastic Resins purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics has been collected on 150 Intermediates—Plastic Resins and may be found on the BioPreferred Program's Web site.

2. Intermediates—Chemicals (Minimum Biobased Content: 22 Percent)

Intermediates—Chemicals are those used as reactants for organic synthesis reactions rather than for their functional properties in a chemical mixture; those used as building block chemicals and secondary chemicals such as glycerol, succinic acid, propanediol, and monomers such as lactic acid and propylene; those used for specific functional properties during manufacturing of other products such as pH regulators, flocculants, precipitants, neutralizing agents, emulsifiers, detergents, wetting agents, foaming agents, or dispersants; those that are added to end-use products for their specific functional properties including solvents for thinning and drying applications but excluding solvents used for cleaning; and those used for dyes, pigments, and scents including flavorings for non-food products such as lip balm.

USDA identified 27 manufacturers and suppliers of 70 biobased Intermediates—Chemicals. These 27 manufacturers and suppliers do not necessarily include all manufacturers and suppliers of Intermediates—Chemicals, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 70 biobased Intermediates—Chemicals range in biobased content from 25 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Chemicals. Thus, the proposed minimum biobased content for this product category is 22 percent, based on the products with a tested biobased content of 25 percent.

Relevant product information supplied by these manufacturers and suppliers indicates that these products are being used commercially. However, these 27 manufacturers and suppliers did not identify any applicable performance standards, test methods, or other industry measures of performance against which these products have been tested. USDA points out that the lack of identified performance standards is not relevant to the designation of a product category for Federal preferred procurement because it is not one of the criteria section 9002 requires USDA to consider in order to designate a product category for Federal preferred procurement. If and when performance standards, test methods, and other relevant measures of performance are identified for this product category, USDA will provide such information on the BioPreferred Program's Web site.

USDA has been unable to obtain data on the amount of Intermediates—Chemicals purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these 70 Intermediate—Chemicals products and is available on the BioPreferred Program's Web site.

3. Intermediates—Paint and Coating Components (Minimum Biobased Content 22 Percent)

Intermediates—Paint and Coating Components are ingredients used to formulate finished waterborne or solvent borne paint and coating products. Examples of Intermediates—Paint and Coating Components include binders, pigments thickeners, curing agents, modifiers, alkyd latex resins, polyols, reactive oligomers, or reactive diluents.

USDA identified 13 manufacturers and suppliers of 51 biobased Intermediates—Paint and Coating Components. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased

Intermediates—Paint and Coating Components, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 51 biobased Intermediates—Paint and Coating Components range in biobased content from 25 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Paint and Coating Components. Thus, the proposed minimum biobased content for this product category is 22 percent, based on the products with a tested biobased content of 25 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. However, these manufacturers and suppliers did not identify any applicable performance standards, test methods, or other industry measures of performance against which these products have been tested. USDA points out that the lack of identified performance standards is not relevant to the designation of a product category for Federal preferred procurement because it is not one of the criteria section 9002 requires USDA to consider in order to designate a product category for Federal preferred procurement. If and when performance standards, test methods, and other relevant measures of performance are identified for this product category, USDA will provide such information on the BioPreferred Program's Web site.

USDA has been unable to obtain data on the amount of Intermediates—Paint and Coating Components purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics has been collected on these 51 Intermediates—Paint and Coating Components and may be found on the BioPreferred Program's Web site.

4. Intermediates—Textile Processing Materials (Minimum Biobased Content 22 Percent)

Intermediates—Textile Processing Materials are used to treat or finish textiles for the purposes of altering textile characteristics such as color, fading, wrinkle resistance, texture, or moisture management.

USDA identified four manufacturers and suppliers of 24 biobased Intermediates—Textile Processing Materials. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Textile Processing Materials, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 24 biobased Intermediates—Textile Processing Materials range in biobased content from 25 percent to 98 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Textile Processing Materials. Thus, the proposed minimum biobased content for this product category is 22 percent, based on the products with a tested biobased content of 25 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. However, these manufacturers and suppliers did not identify any applicable performance standards, test methods, or other industry measures of performance against which these products have been tested. USDA points out that the lack of identified performance standards is not relevant to the designation of a product category for Federal preferred procurement because it is not one of the criteria section 9002 requires USDA to consider in order to designate a product category for Federal preferred procurement. If and when performance standards, test methods, and other relevant measures of performance are identified for this product category, USDA will provide such information on the BioPreferred Program's Web site.

USDA has been unable to obtain data on the amount of Intermediates—Textile Processing Materials purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these 24 Intermediates—Textile Processing Materials and may be found on the BioPreferred Program's Web site.

5. Intermediates—Foams (Minimum Biobased Content 22 Percent)

Intermediates—Foams are dry polymer foams used for non-construction purposes, such as cushions for furniture.

USDA identified seven manufacturers and suppliers of eight biobased Intermediates—Foams. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Foams, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These eight biobased Intermediates—Foams were each measured by ASTM D6866 to have 25, 30, 30, 33, 33, 40, 53, and 53 percent biobased contents. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Foams. Thus, the proposed minimum biobased content for this product category is 22 percent, based on the product with a tested biobased content of 25 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, some of these manufacturers and suppliers identified three test methods (as shown below) used in evaluating products within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test methods identified by the manufacturers and suppliers include:

- ASTM D97; Standard Test Method for Pour Point of Petroleum Products,
- ASTM D6868; Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities, and
- California Technical Bulletin 117; Requirements, Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used In Upholstered Furniture.

USDA has been unable to obtain data on the amount of Intermediates—Foams purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for

designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these eight Intermediates—Foams and may be found on the BioPreferred Program's Web site.

6. Intermediates—Fibers and Fabrics (Minimum Biobased Content 25 Percent)

Intermediates—Fibers and Fabrics encompasses plant and animal fibers, fibers made from plant-derived polymers that are not yet formed into more complex products such as carpet or fabrics, fabrics made from natural fibers, fabrics made from synthetic fibers, or fabrics made from a blend of the two. These materials are used to manufacture finished products such as clothing, upholstery, or drapes.

USDA identified 16 manufacturers and suppliers of 48 biobased Intermediates—Fibers and Fabrics. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Fibers and Fabrics, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 48 biobased Intermediates—Fibers and Fabrics range in biobased content from 28 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Fibers and Fabrics. Thus, the proposed minimum biobased content for this product category is 25 percent, based on the product with a tested biobased content of 28 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, some of these manufacturers and suppliers identified seven test methods (as shown below) used in evaluating products within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test methods identified by the manufacturers and suppliers include:

- AATCC 79; Absorbency of Textiles,
- AATCC 197; Vertical Wicking of Textiles,
- AATCC 198; Horizontal Wicking of Textiles,
- ACT Physical Properties Performance Guidelines,
- ASTM D737; Standard Test Method for Air Permeability of Textile Fabrics,
- ASTM D6868; Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities, and
- Oeko-Tex Standard 100; Tests for Harmful Substances in Textiles.

USDA has been unable to obtain data on the amount of Intermediates—Fibers and Fabrics purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on 48 Intermediates—Fibers and Fabrics and may be found on the BioPreferred Program's Web site.

7. Intermediates—Lubricant Components (Minimum Biobased Content 44 Percent)

Intermediates—Lubricant Components are ingredients that used specifically to formulate finished lubricant products. Examples of Intermediates—Lubricant Components include base oils, base fluids, additives, or friction modifiers.

USDA identified nine manufacturers and suppliers of 35 biobased Intermediates—Lubricant Components. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Lubricant Components, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 35 biobased Intermediates—Lubricant Components range in biobased content from 47 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Lubricants. Thus, the proposed minimum biobased content for this product category is 44 percent, based on the products with a tested biobased content of 47 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, one of these manufacturers and suppliers identified one test method used in evaluating products within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test method identified by the manufacturer and supplier is NSF H1 Nonfood Compound Product Registration Program.

USDA has been unable to obtain data on the amount of Intermediates—Lubricant Components purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these 35 Intermediates—Lubricant Components and may be found on the BioPreferred Program's Web site.

8. Intermediates—Binders (Minimum Biobased Content 47 Percent)

Intermediates—Binders are materials used to provide cohesiveness throughout an entire finished product. The product category does not include adhesives and glues that are finished products used to attach the surfaces of two or more distinct and separate components to one another.

USDA identified one manufacturer and supplier of one biobased Intermediates—Binders. This manufacturer and supplier is not expected to be the only manufacturer and supplier of biobased Intermediates—Binders, merely the only one that was identified through the USDA Certified Biobased Products in the BioPreferred Program's database. The biobased content of this Intermediates—Binders product is 50 percent, as measured by ASTM D6866. As discussed earlier, the tested value was reduced by 3 percentage points to account for the inherent variability in the test method. Thus, the proposed minimum biobased content for this product category is 47 percent.

Information supplied by this manufacturer indicates that this product is being used commercially. However, this manufacturer and supplier did not identify any applicable performance

standards, test methods, or other industry measures of performance against which this product has been tested. USDA points out that the lack of identified performance standards is not relevant to the designation of a product category for Federal preferred procurement because it is not one of the criteria section 9002 requires USDA to consider in order to designate a product category for Federal preferred procurement. If and when performance standards, test methods, and other relevant measures of performance are identified for this product category, USDA will provide such information on the BioPreferred Program's Web site.

USDA has been unable to obtain data on the amount of Intermediates—Binders purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on this one Intermediates—Binders product and may be found on the BioPreferred Program's Web site.

9. Intermediates—Cleaner Components (Minimum Biobased Content 55 Percent)

Intermediates—Cleaner Components are intermediate ingredients used specifically for formulating finished cleaning products. Examples of Intermediates—Cleaner Components include chelating agents, surfactants, hydrotropes, fatty acids, or solvents.

USDA identified eight manufacturers and suppliers of 19 different biobased Intermediates—Cleaner Components. These eight manufacturers and suppliers do not necessarily include all manufacturers and suppliers of biobased Intermediates—Cleaner Components, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 19 biobased Intermediates—Cleaner Components range in biobased content from 58 percent to 99 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Cleaner Components. Thus, the proposed minimum biobased content for this product category is 55 percent, based on the products with a tested biobased content of 58 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, one of the manufacturers and suppliers identified five test methods (as shown below) used in evaluating its product within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test methods identified by the manufacturer and supplier include:

- ASTM D93; Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester,
- ASTM D1133; Standard Test Method for Kauri-Butanol Value of Hydrocarbon Solvents,
- ASTM D2887; Standard Test Method for Boiling Range Distribution of Petroleum Fractions by Gas Chromatography, and
- EPA Method 24; Determination of Volatile Matter Content, Water Content, Density, Volume Solids, and Weight Solids of Surface Coatings.

USDA has been unable to obtain data on the amount of Intermediates—Cleaner Components purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these 19 Intermediates—Cleaner Components and may be found on the BioPreferred Program's Web site.

10. Intermediates—Personal Care Product Components (Minimum Biobased Content 62 Percent)

Intermediates—Personal Care Product Components are ingredients used to formulate finished personal care products. Examples of Intermediates—Personal Care Product Components include surfactants, oils, humectants, emollients, or emulsifiers.

USDA identified nine manufacturers and suppliers of 37 biobased Intermediates—Personal Care Product Components. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Personal Care Product Components, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 37 biobased Intermediates—Personal Care Product Components range in biobased content from 65 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Personal Care Product Components. Thus, the proposed minimum biobased content for this product category is 62 percent, based on the products with a tested biobased content of 65 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, some these manufacturers and suppliers identified 3 test methods (as shown below) used in evaluating products within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test methods identified by the manufacturers and suppliers include:

- ASTM D6868; Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities, and
- EPA Method 24; Determination of Volatile Matter Content, Water Content, Density, Volume Solids, and Weight Solids of Surface Coatings.

USDA has been unable to obtain data on the amount of Intermediates—Personal Care Product Components purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on 37 Intermediates—Personal Care Product Components and may be found on the BioPreferred Program's Web site.

11. Intermediates—Oils, Fats, and Waxes (Minimum Biobased Content 65 Percent)

Intermediates—Oils, Fats, and Waxes include raw or modified fats and oils derived from plants or animals.

USDA identified five manufacturers and suppliers of 24 biobased Intermediates—Oils, Fats, and Waxes. These manufacturers and suppliers do not include all manufacturers and suppliers of biobased Intermediates—Oils, Fats, and Waxes, merely those identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These 24 biobased Intermediates—Oils, Fats, and Waxes range in biobased content from 68 percent to 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Oils, Fats, and Waxes. Thus, the proposed minimum biobased content for this product category is 65 percent, based on the products with a tested biobased content of 68 percent.

Information supplied by these manufacturers and suppliers indicates that these products are being used commercially. In addition, one of these manufacturers and suppliers identified one test method used in evaluating a product within the product category. While there may be additional test methods, as well as performance standards, product certifications, and other measures of performance, applicable to products within this product category, the test method identified by the manufacturer and supplier is California Technical Bulletin 117.

USDA has been unable to obtain data on the amount of Intermediates—Oils, Fats, and Waxes purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these 24 Intermediates—Oils, Fats, and Waxes and may be found on the BioPreferred Program's Web site.

12. Intermediates—Rubber Materials (Minimum Biobased Content 96 Percent)

Intermediates—Rubber Materials are used in finished products such as rubber gloves, vehicle tires, footwear, sports apparel and equipment, bedding and pillow foams, tubing, catheters, gasketing, or cosmetic adhesives and bases.

USDA identified one manufacturer and supplier of two biobased Intermediates—Rubber Materials. This manufacturer and supplier is not expected to be the only manufacturer and supplier of biobased Intermediates—Rubber Materials, merely the only one identified through the USDA Certified Biobased Products in the BioPreferred Program's database. These two biobased Intermediates—Rubber Materials have biobased contents of 99 percent and 100 percent, as measured by ASTM D6866. In establishing the minimum biobased content requirement for this product category, USDA did not find a reason to exclude any of the products categorized as Intermediates—Rubber Materials. Thus, the proposed minimum biobased content for this product category is 96 percent, based on the products with a tested biobased content of 99 percent.

The Information supplied by this manufacturer and supplier indicates that these products are being used commercially. However, this manufacturer and supplier did not identify any applicable performance standards, test methods, or other industry measures of performance against which these products have been tested. USDA points out that the lack of identified performance standards is not relevant to the designation of a product category for Federal preferred procurement because it is not one of the criteria section 9002 requires USDA to consider in order to designate a product category for Federal preferred procurement. If and when performance standards, test methods, and other relevant measures of performance are identified for this product category, USDA will provide such information on the BioPreferred Program's Web site.

USDA has been unable to obtain data on the amount of Intermediates—Rubber Materials purchased by Federal procuring agencies. As discussed earlier, the primary benefit of designating intermediate ingredient product categories is not to promote their direct purchase by Federal agencies but, rather, to establish the framework for designation of the extensive number of finished products that are made from these intermediate ingredients.

Specific product information, including company contact, intended use, biobased content, and performance characteristics, has been collected on these two Intermediates—Rubber Materials and may be found on the BioPreferred Program's Web site.

C. Compliance Date for Procurement Preference and Incorporation Into Specifications

USDA intends for the final rule to take effect thirty (30) days after publication of the final rule. USDA proposes that starting from the date of publication of the final rule, procuring agencies have a one-year transition period before the procurement preference for biobased products within a designated product category takes effect. This proposed timeframe is based on section 9002(a)(3)(B)(viii) of the 2014 Farm Bill, which clearly provides a compliance date for amendments to the Guidelines of up to one year after publication of a final rule.

Therefore, USDA is proposing a one-year period before the procurement preferences would take effect because, as indicated in 7 CFR 3201.4(c), it recognizes that Federal agencies will need sufficient time to incorporate the preferences into procurement documents and to revise existing standardized specifications. Additionally, procuring agencies will need time to evaluate the economic and technological feasibility of the available biobased products for their agency-specific uses and for compliance with agency-specific requirements.

By the time these product categories are promulgated for designation, Federal agencies will have had a minimum of 18 months (from the date of this **Federal Register** notice), and much longer considering when the Guidelines were first proposed and these requirements were first laid out, to implement these requirements.

Therefore, USDA proposes that the mandatory preference for biobased products under the designated product categories take effect one year after promulgation of the final rule, which will provide these agencies with ample time to evaluate the economic and technological feasibility of biobased products for a specific use and to revise the specifications accordingly. Some agencies may be able to complete these processes more expeditiously and not all uses will require extensive analysis or revision of existing specifications. Although it is allowing up to one year, USDA encourages procuring agencies to implement the procurement preferences

as early as practicable for procurement actions involving any of the designated product categories.

V. Where can agencies get more information on these USDA-designated product categories?

The information used to develop this proposed rule was voluntarily submitted by the manufacturers of products that are categorized within the product categories being proposed. These manufacturers sought to participate in the BioPreferred Program's USDA Certified Biobased Product labeling initiative and submitted product information necessary for certification. Information on each of these products can be found on the BioPreferred Program's Web site (*http://www.biopreferred.gov*).

Further, once the product category designations in today's proposal become final, manufacturers and vendors voluntarily may make available additional information on specific products for posting by the Agency on the BioPreferred Program's Web site. USDA has begun performing periodic audits of the information displayed on the BioPreferred Program's Web site and, where questions arise, is contacting the manufacturer or vendor to verify, correct, or remove incorrect or out-of-date information. Procuring agencies should contact the manufacturers and vendors directly to discuss specific needs and to obtain detailed information on the availability and prices of biobased products meeting those needs.

By accessing the BioPreferred Program's Web site, agencies may also be able to obtain any voluntarily-posted information on each product concerning: Relative price; life-cycle costs; hot links directly to a manufacturer's or vendor's Web site (if available); performance standards (industry, government, military, ASTM/ISO) that the product has been tested against; and environmental and public health information.

VI. Regulatory Information

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Executive Order 12866, as supplemented by Executive Order 13563, requires agencies to determine whether a regulatory action is ''significant.'' The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may: ''(1) Have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

Today's proposed rule has been determined by the Office of Management and Budget to be not significant for purposes of Executive Order 12866. We are not able to quantify the annual economic effect associated with today's proposed rule. USDA attempted to obtain information on the Federal agencies' usage within the 12 designated product categories. These efforts were largely unsuccessful. Therefore, attempts to determine the economic impacts of today's proposed rule would require estimation of the anticipated market penetration of biobased products based upon many assumptions. In addition, because agencies have the option of not purchasing products within designated product categories if price is ''unreasonable,'' the product is not readily available, or the product does not demonstrate necessary performance characteristics, certain assumptions may not be valid. While facing these quantitative challenges, USDA relied upon a qualitative assessment to determine the impacts of today's proposed rule. Consideration was also given to the fact that agencies may choose not to procure products within designated product categories due to unreasonable price.

1. Summary of Impacts

Today's proposed rule is expected to have both positive and negative impacts to individual businesses, including small businesses. These positive and negative impacts are expected to be minimized because Federal agencies do not typically purchase significant quantities of the types of intermediate ingredient products that are the subject of today's proposed rule. However, USDA anticipates that the Federal preferred procurement program will ultimately provide additional opportunities for businesses and manufacturers to begin supplying products under the proposed designated biobased product categories to Federal agencies and their contractors. However, other businesses and manufacturers that supply only non-qualifying products and do not offer biobased alternatives may experience a decrease in demand from Federal agencies and their contractors. USDA is unable to determine the number of businesses, including small businesses, which may be adversely affected by today's proposed rule. The proposed rule, however, will not affect existing purchase orders, nor will it preclude businesses from modifying their product lines to meet new requirements for designated biobased products. Because the extent to which procuring agencies will find the performance, availability and/or price of biobased products acceptable is unknown, it is impossible to quantify the actual economic effect of the rule.

2. Benefits of the Proposed Rule

The designation of these product categories provides the benefits outlined in the objectives of section 9002; to increase domestic demand for many agricultural commodities that can serve as feedstocks for production of biobased products, and to spur development of the industrial base through value-added agricultural processing and manufacturing in rural communities. On a national and regional level, today's proposed rule can result in expanding and strengthening markets for biobased materials used in these product categories.

3. Costs of the Proposed Rule

Like the benefits, the costs of today's proposed rule have not been quantified. Two types of costs are involved: Costs to producers of products that will compete with the preferred products and costs to Federal agencies to provide procurement preference for the preferred products. Producers of competing products may face a decrease in demand for their products to the extent Federal agencies refrain from purchasing their products. However, it is not known to what extent this may occur. Pre-award procurement costs for Federal agencies may rise minimally as the contracting officials conduct market research to evaluate the performance, availability, and price reasonableness of preferred products before making a purchase.

B. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601–602, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies

that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

USDA evaluated the potential impacts of its proposed designation of these product categories to determine whether its actions would have a significant impact on a substantial number of small entities. Because the Federal preferred procurement program established under section 9002 applies only to Federal agencies and their contractors, small governmental (city, county, etc.) agencies are not affected. Thus, the proposal, if promulgated, will not have a significant economic impact on small governmental jurisdictions.

USDA anticipates that this program will affect entities, both large and small, that manufacture or sell biobased products. For example, the designation of product categories for Federal preferred procurement will provide additional opportunities for businesses to manufacture and sell biobased products to Federal agencies and their contractors. Similar opportunities will be provided for entities that supply biobased materials to manufacturers.

The intent of section 9002 is largely to stimulate the production of new biobased products and to energize emerging markets for those products. Because the biobased product industry as a whole is still a developing market, it is unknown how many businesses will ultimately be affected by today's proposed rule. While USDA has no data on the number of small businesses that may choose to develop and market biobased products within the product categories designated by this rulemaking, the number is expected to be small because this industry is still materializing. As such, USDA anticipates that only a small percentage of all manufacturers, large or small, are expected to develop and market biobased products. Thus, the number of small businesses manufacturing biobased products affected by this rulemaking is not expected to be substantial.

The Federal preferred procurement program may decrease opportunities for businesses that manufacture or sell non-biobased products or provide components for the manufacturing of such products. Most manufacturers of non-biobased products within the product categories being proposed for designation for Federal preferred procurement in this rule are expected to be included under the following NAICS codes: 324191 (petroleum lubricating oil and grease manufacturing), 325320 (pesticide and other agricultural chemicals manufacturing), 325411 (medicinal and botanical manufacturing), 325412 (pharmaceutical preparation manufacturing), 325510 (paint and coating manufacturing), 325612 (polish and other sanitation goods manufacturing), and 325620 (toilet preparation manufacturing). USDA obtained information on these seven NAICS categories from the U.S. Census Bureau's Economic Census database. USDA found that the Economic Census reports about 4,756 companies within these 7 NAICS categories and that these companies own a total of about 5,374 establishments. Thus, the average number of establishments per company is about 1.13. The Census data also reported that of the 5,374 individual establishments, about 5,228 (97.3 percent) have fewer than 500 employees. USDA also found that the overall average number of employees per company among these industries is about 92 and that the pharmaceutical preparation manufacturing segment (with an average of about 250) is the only segment reporting an average of more than 100 employees per company. Thus, nearly all of the businesses meet the Small Business Administration's definition of a small business (less than 500 employees, in most NAICS categories).

USDA does not have data on the potential adverse impacts on manufacturers of non-biobased products within the product categories being designated, but believes that the impact will not be significant. Most of the product categories being proposed for designation in this rulemaking are used to produce typical consumer products widely used by the general public and by industrial/commercial establishments that are not subject to this rulemaking. Thus, USDA believes that the number of small businesses manufacturing non-biobased products within the product categories being designated and selling significant quantities of those products to government agencies affected by this rulemaking to be relatively low. Also, this proposed rule will not affect existing purchase orders and it will not preclude procuring agencies from continuing to purchase non-biobased products when biobased products do not meet the availability, performance, or reasonable price criteria. This proposed rule will also not preclude businesses from modifying their product lines to meet new specifications or solicitation requirements for these products containing biobased materials.

After considering the economic impacts of this proposed rule on small entities, USDA certifies that this action will not have a significant economic impact on a substantial number of small entities.

While not a factor relevant to determining whether the proposed rule will have a significant impact for RFA purposes, USDA has concluded that the effect of the rule will be to provide positive opportunities to businesses engaged in the manufacture of these biobased products. Purchase and use of these biobased products by procuring agencies increase demand for these products and result in private sector development of new technologies, creating business and employment opportunities that enhance local, regional, and national economies.

C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

This proposed rule has been reviewed in accordance with Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and does not contain policies that would have implications for these rights.

D. Executive Order 12988: Civil Justice Reform

This proposed rule has been reviewed in accordance with Executive Order 12988, Civil Justice Reform. This proposed rule does not preempt State or local laws, is not intended to have retroactive effect, and does not involve administrative appeals.

E. Executive Order 13132: Federalism

This proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Provisions of this proposed rule will not have a substantial direct effect on States or their political subdivisions or on the distribution of power and responsibilities among the various government levels.

F. Unfunded Mandates Reform Act of 1995

This proposed rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, for State, local, and tribal governments, or the private sector. Therefore, a statement under section 202 of UMRA is not required.

G. Executive Order 12372: Intergovernmental Review of Federal Programs

For the reasons set forth in the Final Rule Related Notice for 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), this program is excluded from the scope of the Executive Order 12372, which requires intergovernmental consultation with State and local officials. This program does not directly affect State and local governments.

H. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule does not significantly or uniquely affect ''one or more Indian tribes . . . the relationship between the Federal Government and Indian tribes, or . . . the distribution of power and responsibilities between the Federal Government and Indian tribes.'' Thus, no further action is required under Executive Order 13175.

I. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3520), the information collection under this proposed rule is currently approved under OMB control number 0503–0011.

J. E-Government Act Compliance

USDA is committed to compliance with the E-Government Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. USDA is implementing an electronic information system for posting information voluntarily submitted by manufacturers or vendors on the products they intend to offer for Federal preferred procurement under each designated product category. For information pertinent to E-Government Act compliance related to this rule, please contact Marie Wheat at (202) 239–4502.

List of Subjects in 7 CFR Part 3201

Biobased products, Procurement.

For the reasons stated in the preamble, the Department of Agriculture proposes to amend 7 CFR chapter XXXII as follows:

CHAPTER XXXII—OFFICE OF PROCUREMENT AND PROPERTY MANAGEMENT

PART 3201—GUIDELINES FOR DESIGNATING BIOBASED PRODUCTS FOR FEDERAL PROCUREMENT

■ 1. The authority citation for part 3201 continues to read as follows:

Authority: 7 U.S.C. 8102.

■ 2. Add §§ 3201.108 through 3201.119 to subpart B to read as follows:

Sec.
3201.108 Intermediates—Plastic Resins.
3201.109 Intermediates—Chemicals.
3201.110 Intermediates—Paint and Coating Components.
3201.111 Intermediates—Textile Processing Materials.
3201.112 Intermediates—Foams.
3201.113 Intermediates—Fibers and Fabrics.
3201.114 Intermediates—Lubricant Components.
3201.115 Intermediates—Binders.
3201.116 Intermediates—Cleaner Components.
3201.117 Intermediates—Personal Care Product Components.
3201.118 Intermediates—Oils, Fats, and Waxes.
3201.119 Intermediates—Rubber Materials.

§ 3201.108 Intermediates—Plastic Resins.

(a) *Definition.* Intermediates—Plastic Resins are materials that are typically viscous liquids with the ability to harden permanently and may exist in liquid or solid (powder or pellets) states. Intermediates—Plastic Resins may be used in a variety of finished products neat, consisting of a single resin, or a homogeneous blend of two or more neat resins, or composite, containing two or more distinct materials such as fiber-reinforced resins.

Additionally, Intermediates—Plastic Resins may be used in finished products as additives such as plasticizers, pigments, thermal stability agents, or impact modifiers.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 22 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Plastic Resins. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Plastic Resins.

§ 3201.109 Intermediates—Chemicals.

(a) *Definition.* Intermediates—Chemicals are those used as reactants for organic synthesis reactions rather than for their functional properties in a chemical mixture; those used as building block chemicals and secondary chemicals such as glycerol, succinic acid, propanediol, and monomers such as lactic acid and propylene; those used for specific functional properties during manufacturing of other products such as pH regulators, flocculants, precipitants, neutralizing agents, emulsifiers, detergents, wetting agents, foaming agents, or dispersants; those that are added to end-use products for their specific functional properties including solvents for thinning and drying applications but excluding solvents used for cleaning; and those used for dyes, pigments, and scents including flavorings for non-food products such as lip balm.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 22 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Chemicals. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Chemicals.

§ 3201.110 Intermediates—Paint and Coating Components.

(a) *Definition.* Intermediates—Paint and Coating Components are ingredients used to formulate finished waterborne or solvent borne paint and coating products. Examples of Intermediates—Paint and Coating Components include binders, pigments thickeners, curing agents, modifiers, alkyd latex resins, polyols, reactive oligomers, or reactive diluents.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 22 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Paint and Coating Components. By that date, Federal agencies responsible for drafting or reviewing specifications for products to

be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Paint and Coating Components.

§ 3201.111 Intermediates—Textile Processing Materials.

(a) *Definition.* Intermediates—Textile Processing Materials are used to treat or finish textiles for the purposes of altering textile characteristics such as color, fading, wrinkle resistance, texture, or moisture management.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 22 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Textile Processing Materials. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Textile Processing Materials.

§ 3201.112 Intermediates—Foams.

(a) *Definition.* Intermediates—Foams are dry polymer foams used for non-construction purposes, such as cushions for furniture.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 22 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Foams. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Foams.

§ 3201.113 Intermediates—Fibers and Fabrics.

(a) *Definition.* Intermediates—Fibers and Fabrics encompasses plant and animal fibers, fibers made from plant-derived polymers that are not yet formed into more complex products such as carpet or fabrics, fabrics made from natural fibers, fabrics made from synthetic fibers, or fabrics made from a blend of the two. These materials are used to manufacture finished products such as clothing, upholstery, or drapes.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 25 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Fibers and Fabrics. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Fibers and Fabrics.

§ 3201.114 Intermediates—Lubricant Components.

(a) *Definition.* Intermediates—Lubricant Components are ingredients that used specifically to formulate finished lubricant products. Examples of Intermediates—Lubricant Components include base oils, base fluids, additives, or friction modifiers.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 44 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Lubricant Components. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Lubricant Components.

§ 3201.115 Intermediates—Binders.

(a) *Definition.* Intermediates—Binders are materials used to provide cohesiveness throughout an entire finished product. The product category does not include adhesives and glues that are finished products used to attach the surfaces of two or more distinct and separate components to one another.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 47 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Binders. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Binders.

§ 3201.116 Intermediates—Cleaner Components.

(a) *Definition.* Intermediates—Cleaner Components are intermediate ingredients used specifically for formulating finished cleaning products. Examples of Intermediates—Cleaner Components include chelating agents, surfactants, hydrotropes, fatty acids, or solvents.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 55 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Cleaner Components. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Cleaner Components.

§ 3201.117 Intermediates—Personal Care Product Components.

(a) *Definition.* Intermediates—Personal Care Product Components are ingredients used to formulate finished personal care products. Examples of Intermediates—Personal Care Product Components include surfactants, oils, humectants, emollients, or emulsifiers.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 62 percent, which shall be based on the amount of qualifying biobased carbon in the product as a

percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Personal Care Product Components. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Personal Care Product Components.

§ 3201.118 Intermediates—Oils, Fats, and Waxes.

(a) *Definition.* Intermediates—Oils, Fats, and Waxes include raw or modified fats and oils derived from plants or animals.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 65 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Oils, Fats, and Waxes. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Oils, Fats, and Waxes.

§ 3201.119 Intermediates—Rubber Materials.

(a) *Definition.* Intermediates—Rubber Materials are used in finished products such as rubber gloves, vehicle tires, footwear, sports apparel and equipment, bedding and pillow foams, tubing, catheters, gasketing, or cosmetic adhesives and bases.

(b) *Minimum biobased content.* The Federal preferred procurement product must have a minimum biobased content of at least 96 percent, which shall be based on the amount of qualifying biobased carbon in the product as a percent of the weight (mass) of the total organic carbon in the finished product.

(c) *Preference compliance date.* No later than [date one year after the date of publication of the final rule], procuring agencies, in accordance with this part, will give a procurement preference for qualifying biobased Intermediates—Rubber Materials. By that date, Federal agencies responsible for drafting or reviewing specifications for products to be procured shall ensure that the relevant specifications require the use of biobased Intermediates—Rubber Materials.

Dated: December 16, 2016.

Gregory L. Parham,

Assistant Secretary for Administration, U.S. Department of Agriculture.

[FR Doc. 2016–31128 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–93–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9443; Airspace Docket No. 16–ASO–17]

Proposed Amendment of Class E Airspace; Kyle-Oakley Field Airport, Murray, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace at Murray, KY, as the Calloway Non-Directional Beacon (NDB) has been decommissioned, requiring airspace reconfiguration at Kyle-Oakley Field Airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport. This action also would update the geographic coordinates of the airport, and update the designation header.

DATES: Comments must be received on or before February 27, 2017.

ADDRESSES: Send comments on this proposal to: U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Bldg. Ground Floor Rm. W12–140, Washington, DC 20590; Telephone: 1–800–647–5527, or 202–366–9826. You must identify the Docket No. FAA–2016–9443; Airspace Docket No. 16–ASO–17, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Kyle-Oakley Field Airport, Murray, KY.

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. You may also submit comments through the Internet at *http://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2016–9443; Airspace Docket No. 16–ASO–17.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.regulations.gov.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, Georgia 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface at Kyle-Oakley Field Airport, Murray, KY. Airspace reconfiguration to within a 7 mile radius of the airport is necessary due to the decommissioning of the Calloway NDB and cancellation of the NDB approach, and for continued safety and management of IFR operations at the airport. The geographic coordinates of the airport would be adjusted to coincide with the FAAs aeronautical database, and the airport designation header would be updated to include the airport name.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal would be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, effective September 15, 2016, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO KY E5 Kyle-Oakley Field, Murray, KY [Amended]

Kyle-Oakley Field Airport, KY
(Lat. 36°39′52″ N., long. 88°22′22″ W.)

That airspace extending upward from 700 feet above the surface within a 7 mile radius of Kyle-Oakley Field Airport.

Issued in College Park, Georgia, on December 29, 2016.

Debra L. Hogan,

Acting Manager, Operations Support Group Eastern Service Center, Air Traffic Organization.

[FR Doc. 2017–00284 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–9118; Airspace Docket No. 16–AGL–3]

Proposed Amendment of Class D and E Airspace for the Following North Dakota Towns; Wahpeton, ND; Hettinger, ND; Fargo, ND; Grand Fork, ND; Carrington, ND; Cooperstown, ND; Pembina, ND; Rugby, ND; Devils Lake, ND; Bottineau, ND; Valley City, ND and Gwinner, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace extending upward from 700 feet above the surface at Wahpeton/Harry Stern Airport, Wahpeton, ND; Hettinger Municipal Airport, Hettinger, ND; Gwinner-Roger Melroe Field, Gwinner, ND; and Rugby Municipal Airport, Rugby, ND. Decommissioning of non-directional radio beacons (NDBs), cancellation of NDB approaches, and implementation of area navigation (RNAV) procedures have made this action necessary for the safety and management of Instrument

Flight Rules (IFR) operations at these airports. This action would also update the geographic coordinates and airport names for certain airports listed also under these airports in the Class D and E airspace areas.

DATES: Comments must be received on or before February 27, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366–9826, or 1–800–647–5527. You must identify FAA Docket No. FAA–2016–9118; Airspace Docket No. 16–AGL–3 at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FAA Order 7400.11, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Ron Laster, Contract Support, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5879.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend controlled airspace in the respective Class D and E airspace areas at Wahpeton/Harry Stern Airport, Wahpeton, ND; Hettinger Municipal Airport, Hettinger, ND; Gwinner-Roger Melroe Field, Gwinner, ND; Rugby Municipal Airport, Rugby, ND; Hector International Airport, Fargo, ND; Grand Forks Air Force Base, Grand Forks, ND; Carrington Municipal Airport, Carrington, ND; Pembina Municipal Airport, Pembina, ND; Bottineau Municipal Airport, Bottineau, ND; Cooperstown Municipal Airport, ND; Devils Lake Regional Airport, Devils Lake, ND, and Barnes County Municipal Airport, Valley City, ND.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2016–9118/Airspace Docket No. 16–AGL–3.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying:

Geographic coordinates in Class D airspace for Hector International Airport, Fargo, ND; Class E airspace extending upward from 700 feet above the surface:

Within a 6.4-mile radius (previously a 7-mile radius) of Harry Stern Airport, Wahpeton, ND, and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 6.4-mile radius (previously a 7-mile radius) of Hettinger Municipal Airport, Hettinger, ND, and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 6.5-mile radius (previously a 7-mile radius) of Gwinner-Roger Melroe Field, Gwinner, ND; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database;

Within a 6.3-mile radius (previously a 7-mile radius) of Rugby Municipal Airport, Rugby, ND; and updating the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

Airspace reconfiguration is necessary due to the decommissioning of NDBs, cancellation of NDB approaches, and

implementation of RNAV procedures that would enhance the safety and management of standard instrument approach procedures for IFR operations at these airports. The geographic coordinates would be adjusted for Hector International Airport, Fargo, ND; Grand Forks Air Force Base, Grand Forks, ND; Barnes County Municipal Airport, Valley City, ND; Pembina Municipal Airport, Pembina, ND; Devils Lake VOR/DME; Devils Lake Regional Airport, Devils Lake, ND; Carrington Municipal Airport, Carrington, ND; Bottineau Municipal Airport, Bottineau, ND; Cooperstown Municipal Airport, ND, as well as the airport names for Barnes County Municipal Airport (formerly Valley City/Barnes County Municipal), Valley City, ND, and Devils Lake Regional Airport (formerly Devils Lake Municipal Airport), Devils Lake, ND, to coincide with the FAA's aeronautical database.

Class D and E airspace designations are published in paragraph 5000, 6002, 6004 and 6005, respectively, of FAA Order 7400.11A, dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL ND D Fargo, ND [Amended]

Hector International Airport, ND
(Lat. 46°55′14″ N., long. 96°48′57″ W.)

That airspace extending upward from the surface to and including 3,400 feet MSL within a 4.5-mile radius of Hector International Airport.

* * * * *

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AGL ND E2 Devils Lake, ND [Amended]

Devils Lake Regional Airport, ND
(Lat. 48°06′53″ N., long. 98°54′30″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 98°54′45″ W.)

Within a 4-mile radius of Devils Lake Regional Airport, and within 3 miles each side of the Devils Lake VOR/DME 134° radial extending from the 4-mile radius to 8.7 miles southeast of the VOR/DME and within 2.3 miles each side of the Devils Lake VOR/DME 324° radial extending from the 4-mile radius to 8.7 miles northwest of the VOR/DME. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AGL ND E4 Fargo, ND [Amended]

Fargo, Hector International Airport, ND
(Lat. 46°55′14″ N., long. 96°48′57″ W.)
Fargo VORTAC
(Lat. 46°45′12″ N., long. 96°51′05″ W.)

That airspace extending upward from the surface within 1.7 miles each side of the Fargo VORTAC 009° radial, extending from the 4.5-mile radius of Hector International Airport to 7.8 miles south of the airport.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL ND E5 Bottineau, ND [Amended]

Bottineau Municipal Airport, ND
(Lat. 48°49′50″ N., long. 100°25′02″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Bottineau Municipal Airport, and that airspace extending upward from 1,200 feet above the surface within an area bounded on the north by lat. 49°00′00″ N., on the east by long. 99°49′00″ W., on the south by the 10.5-mile radius of Rugby, ND, Class E airspace area, and on the west by the 47-mile radius of the Minot, ND, Class E airspace area.

AGL ND E5 Carrington, ND [Amended]

Carrington Municipal Airport, ND
(Lat. 47°27′04″ N., long. 99°09′05″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 98°54′45″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Carrington Municipal Airport; and that airspace extending upward from 1,200 feet above the surface bounded on the north by the 22-mile arc south of Devils Lake VOR/DME, on the east by V–170, on the south by V–55, on the west by long. 99°30′00″ W., and on the northwest by V–169.

* * * * *

AGL ND E5 Cooperstown, ND [Amended]

Cooperstown Municipal Airport, ND
(Lat. 47°25′22″ N., long. 98°06′21″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 98°54′45″ W.)
Fargo, Hector International Airport, ND
(Lat. 46°55′14″ N., long. 96°48′57″ W.)
Grand Forks AFB, ND
(Lat. 47°57′41″ N., long. 97°24′04″ W.)
Jamestown VOR/DME
(Lat. 46°55′58″ N., long. 98°40′44″ W.)
Valley City, Barnes County Municipal Airport, ND
(Lat. 46°56′28″ N., long. 98°01′05″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Cooperstown Municipal Airport and that airspace extending upward from 1,200 feet above the surface within an area bounded on the north by V–430; on the northeast by the 34-mile radius of Grand Forks AFB; on the southeast by the 40-mile radius of Fargo, Hector International Airport; on the south by V–2/V–510 east of Valley City, ND, the 7.9-mile radius of Barnes County Municipal Airport, and V–2/V–510 west of Valley City, ND; on the southwest by the 16.5-mile radius of Jamestown VOR/DME; on the west by V–170; and on the

northwest by the 22-mile radius of Devils Lake VOR/DME.

* * * * *

AGL ND E5 Devils Lake, ND [Amended]

Devils Lake Regional Airport, ND
(Lat. 48°06′53″ N., long. 98°54′30″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 98°54′45″ W.)

That airspace extending upward from 700 feet above the surface within an 8.7-mile radius of Devils Lake Regional Airport and that airspace extending upward from 1,200 feet above the surface within a 22-mile radius of Devils Lake VOR/DME.

* * * * *

AGL ND E5 Gwinner, ND [Amended]

Gwinner-Roger Melroe Field, ND
(Lat. 46°13′06″ N., long. 97°38′36″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Gwinner-Roger Melroe Field Airport.

* * * * *

AGL ND E5 Hettinger, ND [Amended]

Hettinger Municipal Airport, ND
(Lat. 46°00′54″ N., long. 102°39′22″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Hettinger Municipal Airport; and that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 46°20′00″ N., long. 102°58′00″ W., to lat. 46°20′00″ N., long. 102°44′00″ W., to lat. 45°45′00″ N., long. 102°09′00″ W., to lat. 45°45′00″ N., long. 102°58′00″ W., to the point of beginning, excluding that airspace within V–491.

* * * * *

AGL ND E5 Pembina, ND [Amended]

Pembina Municipal Airport, ND
(Lat. 48°56′33″ N., long. 97°14′27″ W.)
Humboldt VORTAC
(Lat. 48°52′09″ N., long. 97°07′02″ W.)
Grand Forks AFB, ND
(Lat. 47°57′41″ N., long. 97°24′03″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 98°54′45″ W.)

That airspace extending upward from 700 feet above the surface within a 6.2-mile radius of Pembina Municipal Airport, and within 1.8 miles each side of Humboldt VORTAC 132/312° radials extending from the 6.2-mile radius to 7 miles southeast of the airport; and that airspace extending upward from 1,200 feet above the surface beginning at lat. 49°00′00″ N., long. 97°30′01″ W.; to lat. 48°48′00″ N., long. 97°30′01″ W.; to lat. 48°18′34″ N., long. 98°39′53″ W.; thence clockwise around a 15.3-mile radius of Devils Lake VOR/DME to V–430; thence east along V–430 to the intersection of a 34-mile radius of Grand Forks AFB; thence clockwise along the 34-mile radius of Grand Forks AFB to the North Dakota/Minnesota state boundary; thence north along the state boundary to the United States/Canada border; thence west along the United States/Canada border to the point of beginning, excluding that airspace within all Federal airways.

* * * * *

AGL ND E5 Rugby, ND [Amended]

Rugby Municipal Airport, ND
(Lat. 48°23′25″ N., long. 100°01′27″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Rugby Municipal Airport; and that airspace extending upward from 1,200 feet above the surface within a 13-mile radius of Rugby Municipal Airport, and within 8.1 miles north and 4.2 miles south of the 115° bearing from the airport extending from the 13-mile radius to 16.1 miles east of the airport, and within 8.5 miles south and 3.8 miles north of the 314° bearing from the airport extending from the 13-mile radius to 16.1 miles northwest of the airport, excluding that airspace within Minot, ND, and Rolla, ND, Class E airspace areas, and excluding all Federal airways.

* * * * *

AGL ND E5 Valley City, ND [Amended]

Barnes County Municipal Airport, ND
(Lat. 46°56′28″ N., long. 98°01′05″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4 mile radius of Barnes County Municipal Airport; and that airspace extending upward from 1,200 feet above the surface within a 7.9-mile radius of the airport, and within 4 miles southwest and 8.3 miles northeast of the 133° bearing from the airport extending from the 7.9-mile radius to 21.8 miles southeast of the airport.

* * * * *

AGL ND E5 Wahpeton, ND [Amended]

Harry Stern Airport, ND
(Lat. 46°14′40″ N., long. 96°36′26″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Harry Stern Airport and that airspace extending upward from 1,200 feet above the surface within a 25-mile radius of Harry Stern Airport bounded on the east by the Minnesota border and on the west by V–181.

Issued in Fort Worth, Texas, on December 15, 2016.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2017–00286 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2016–D–3401]

Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of availability of a draft guidance entitled ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition'' that appeared in the **Federal Register** of November 23, 2016. The draft guidance, when finalized, will describe our views on the scientific evidence needed and the approach to evaluating the scientific evidence on the physiological effects of isolated or synthetic non-digestible carbohydrates that are added to foods that are beneficial to human health. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: We are extending the comment period on the notice that published in the **Federal Register** of November 23, 2016 (81 FR 84516). Submit either electronic or written comments by February 13, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–3401 for ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2579.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 2016 (81 FR 84516), we published a notice announcing the availability of a draft guidance entitled ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition.'' The draft guidance explains the scientific review approach we plan to use for evaluating scientific evidence submitted to us in citizen petitions to determine whether a particular isolated or synthetic non-digestible carbohydrate that is added to food should be added to our definition of ''dietary fiber'' that is found in the Nutrition and Supplement Facts label final rule, which appeared in the **Federal Register** of May 27, 2016 (81 FR 33742). Only those isolated or synthetic non-digestible carbohydrates that meet the definition can be declared as a dietary fiber on a Nutrition and Supplement Facts label. We provided a 60-day comment period that was scheduled to close on January 23, 2017.

Elsewhere in this issue of the **Federal Register**, we have published a notice to reopen the comment period for a related notice that appeared in the **Federal Register** of November 23, 2016 (81 FR 84595). We requested scientific data, information and comments in the related November 23, 2016, notice to help us evaluate the potential beneficial physiological effects on human health of 26 specific isolated or synthetic non-digestible carbohydrates that are added to food so that we may determine whether any of them should be added to our definition of dietary fiber in our Nutrition Facts and Supplement Facts label final rule. The November 23, 2016, notice also announced the availability of a document entitled ''Science Review of Isolated and Synthetic Non-Digestible Carbohydrates,'' which summarizes a scientific literature review that we conducted of clinical studies associated with the 26 specific isolated or synthetic non-digestible carbohydrates. The original comment period for this notice closed on January 9, 2017.

We have received requests to extend the comment period for the isolated or synthetic non-digestible carbohydrates draft guidance. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the draft guidance.

We have considered the requests and are extending the comment period for the draft guidance until February 13, 2017. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance. The extended comment period deadline February 13, 2017, for the draft guidance also coincides with the reopened comment period for our related request for scientific data, information, and comments for the November 23, 2016, notice.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00724 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice: 9852]

Notice of Inquiry; Request for Comments Regarding United States Munitions List Category XII

AGENCY: Department of State.

ACTION: Notice of Inquiry, request for comments.

SUMMARY: The Department of State requests comments from the public regarding recent revisions to Category XII of the United States Munitions List (USML). In light of the ongoing transition of the USML to a more ''positive list'' pursuant to the President's Export Control Reform (ECR)

initiative, the Department requests that the public comment on (1) alternatives to controls on certain items when ''specially designed for a military end user,'' (2) the scope of the control in paragraph (b)(1), and (3) certain technical parameters that the Department is evaluating to replace ''specially designed'' controls.

DATES: The Department of State will accept comments on this Notice of Inquiry until March 14, 2017.

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

- *Email: DDTCPublicComments@state.gov* with the subject line, ''Request for Comments Regarding USML Category XII.''
- *Internet:* At *www.regulations.gov,* search for this notice using its docket number, DOS–2017–0002.

Comments submitted through *www.regulations.gov* will be visible to other members of the public; the Department will publish all comments on the Directorate of Defense Trade Controls Web site (*www.pmddtc.state.gov*). Therefore, commenters are cautioned not to include proprietary or other sensitive information in their comments.

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: Request for Comments Regarding USML Category XII.

SUPPLEMENTARY INFORMATION: On December 10, 2010, the Department provided notice to the public of its intent, pursuant to the ECR initiative, to revise the USML to create a ''positive list'' that describes controlled items using, to the extent possible, objective criteria rather than broad, open-ended, subjective, or design intent-based criteria (see 75 FR 76935). As a practical matter, this meant revising USML categories so that, with some exceptions, the descriptions of defense articles that continued to warrant control under the USML did not use catch-all phrases to control unspecified items. As a general matter, the defense articles that warranted control under the USML were those that provided the United States with a critical military or intelligence advantage. All other items were to become subject to the Export Administration Regulations. Since that time, the Department has published final rules setting forth revisions for eighteen USML categories, each of which has been reorganized into a uniform and more positive list structure.

The advantage of revising the USML into a more positive list is that its controls can be tailored to satisfy the national security and foreign policy objectives of the U.S. government by maintaining control over those defense articles that provide a critical military or intelligence advantage, or otherwise warrant control under the International Traffic in Arms Regulations (ITAR), without inadvertently controlling items in normal commercial use. This approach, however, requires that the lists be regularly revised and updated to account for technological developments, practical application issues identified by exporters and reexporters, and changes in the military and commercial applications of items affected by the list. In addition, the USML and the Commerce Control List require regular revision in order to ensure that they satisfy the national security and foreign policy objectives of the reform effort, which are to (i) improve interoperability of U.S. military forces with allied countries, (ii) strengthen the U.S. industrial base by, among other things, reducing incentives for foreign manufacturers to design out and avoid U.S.-origin content and services, which ensures continued U.S. visibility and control, and (iii) allow export control officials to focus government resources on transactions that pose greater concern.

Comments on Specially Designed for a Military End User Parameters: On October 12, 2016, the Department published a final rule amending USML Category XII, effective December 31, 2016 (81 FR 70340). In the final rule, the Department adopted control text in seven subparagraphs that controls specific items when they are specially designed for a military end user. The term military end user is defined in the new Note to Category XII, as the national armed services (army, navy, marine, air force, or coast guard), national guard, national police, government intelligence or reconnaissance organizations, or any person or entity whose actions or functions are intended to support military end uses. As the Note further states, an item is not specially designed for a military end user if it was developed for both military and non-military end users, or if the item was created for no specific end user. The Note also provides that contemporaneous documents are required to support the design intent; otherwise, use by a military end user establishes that the item is specially designed for a military end user.

As stated in the final rule, the Department adopted this control based on original design intent because the Department and its interagency partners cannot yet articulate objective technical criteria that would establish a bright line between military and commercial and civil systems. The Department is soliciting additional public input, asking for suggested control parameters for these seven entries in the final rule:

1. (b)(6) Light detection and ranging (LIDAR), laser detection and ranging (LADAR), or range-gated systems, specially designed for a military end user.
2. (c)(1) Binoculars, bioculars, monoculars, goggles, or head or helmet-mounted imaging systems (including video-based articles having a separate near-to-eye display), as follows:

(iii) Having an infrared focal plane array or infrared imaging camera, and specially designed for a military end user.

3. (c)(3) Electro-optical reconnaissance, surveillance, target detection, or target acquisition systems, specially designed for articles in this subchapter or specially designed for a military end user.
4. (c)(4) Infrared search and track (IRST) systems having one of the following: (ii) Specially designed for a military end user.
5. (c)(5) Distributed aperture systems having a peak response wavelength exceeding 710 nm specially designed for articles in this subchapter or specially designed for a military end user.
6. (c)(6) Infrared imaging systems, as follows:

(viii) Gimbaled infrared systems, as follows:

(B) Specially designed for articles in this subchapter or specially designed for a military end user.

and

7. (c)(7) Terahertz imaging systems as follows: (ii) Specially designed for a military end user.

Comments on Scope of Paragraph (b)(1): Paragraph (b)(1) includes all laser target designators and coded target markers that can mediate the delivery of ordnance to a target. This includes a laser target designator or coded target marker that may also be used for other purposes, including battlefield target handoff or communication of battlefield intelligence information. The Department requests that the public comment on this provision.

Comments to Assist with the Evaluation of Potential Control Parameters: The Department is also evaluating several potential parameters. The Department is requesting that the public comment on these parameters to aid in its evaluation. Specifically, the Department requests comment on

whether any civil or commercial items are described by the following parameters, including items for which civil or commercial use is anticipated in the next five years:

A. Free-space laser communication systems specially designed for articles in this subchapter.

B. Binoculars, bioculars, monoculars, goggles, or head or helmet-mounted imaging systems (including video-based articles having a separate near-to-eye display), having any of the following:

(i) A dynamically gain modulated image intensifier tube incorporating a GaAs, GaInAs, or other III–V semiconductor photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm;

(ii) An image intensifier tube incorporating a photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and incorporating a focal plane array in the tube vacuum space;

(iii) Fusing outputs of multiple infrared focal plane arrays each having a peak response at a wavelength greater than 1,000 nm;

(iv) An infrared focal plane array with a peak response in the wavelength range exceeding 1,000 nm but not exceeding 2,500 nm with a total noise floor less than 75 electrons at an operating temperature of 300 K; or

(v) An infrared focal plane array with a peak response in the wavelength range exceeding 7,500 nm, and a laser illuminator or pointer.

C. Weapon sights (*i.e.,* with a reticle), aiming or imaging systems (*e.g.,* clip-on), specially designed to mount to a weapon or to withstand weapon shock or recoil, with or without an integrated viewer or display, and also incorporating or specially designed to incorporate any of the following:

(i) An image intensifier tube having a multi-alkali photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and a luminous sensitivity exceeding 350 microamps per lumen;

(ii) An image intensifier tube having a GaAs, GaInAs, or other III–V semiconductor photocathode, with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm; or

(iii) An image intensifier tube having a photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and a focal plane array in the tube vacuum space.

D. Infrared imaging systems, as follows: Mobile reconnaissance, mobile scout, or mobile surveillance systems, that provide real-time target geolocation at ranges greater than 3 km (*e.g.,* LRAS3, CIV, HTI, SeeSpot, MMS).

E. Infrared imaging systems, as follows: Gimbaled infrared systems (*e.g.,* T-bar, yoke, ball turrets, or pods), as follows and specially designed parts and components therefor:

(i) Having a root mean square (RMS) stabilization better (less) than 25 microradians and incorporating an infrared camera having a peak response at a wavelength exceeding 1,000 nm with an optical angular resolution (*i.e.,* detector instantaneous field-of-view) of 25 microradians or less;

(ii) Having an RMS stabilization better (less) than 25 microradians for any payload having any dimension of 15 inches or greater; or

(iii) Specially designed for articles in this subchapter or specially designed for a military end user.

F. Image intensifier tubes having all the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 400 nm but not exceeding 1,050 nm;

(ii) A multi-alkali photocathode with a luminous sensitivity of 1,300 microamps per lumen or greater; and

(iii) A limiting resolution of 64 line pairs per millimeter or greater.

G. Image intensifier tubes having all of the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 400 nm but not exceeding 1,050 nm;

(ii) A GaAs, GaInAs, or other III–V compound semiconductor photocathode having a luminous sensitivity of 1,800 microamps per lumen or greater; and

(iii) A limiting resolution of 57 line pairs per millimeter or greater.

H. Image intensifier tubes having all of the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 1,050 nm but not exceeding 2,000 nm; and

(ii) A GaAs, GaInAs, or other III–V compound semiconductor photocathode having a radiant sensitivity of 10 milliamps per watt or greater.

I. Infrared focal plane arrays or dewars specially designed for optical augmentation reduction.

J. Infrared focal plane array dewar assemblies with peak response in the wavelength range greater than 3,000 nm but not exceeding 14,000 nm, and having a variable aperture mechanism.

K. Infrared focal plane arrays having all of the following:

(i) A peak response in the wavelength range exceeding 710 nm but not exceeding 1,100 nm;

(ii) A non-binned pixel pitch of 10 microns or greater;

(iii) More than 1,024 detector elements in any direction; and

(iv) Total noise of 3 electrons or less at an input light level of 1 millilux, in a binned or non-binned operating mode, and measured at an ambient operating temperature of 300 K.

L. Infrared focal plane arrays having greater than 81,920 but not exceeding 327,680 detector elements, a peak response in the wavelength range 1,100 nm but not exceeding 1,700 nm, and any of the following:

(i) Noise equivalent irradiance less than 829 million photons per centimeter squared per second;

(ii) Readout integrated circuits capable of pulse interval modulation decoding or pulse repetition frequency decoding (*e.g.,* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz); or

(iii) Temperature dependent non-uniformity correction (*e.g.,* without the use of a temperature stabilization)

Note: Noise equivalent irradiance is defined as a ratio with the numerator comprised of the focal plane noise floor in units of electrons at a focal plane array temperature of 300 K and the denominator as the multiplied value of detector area in square centimeters, spectral quantum efficiency at 1,550 nm, and an integration time of 0.032 seconds.

M. Infrared focal plane arrays having greater than 327,680 detector elements, a peak response in the wavelength range exceeding 1,100 nm but not exceeding 1,700 nm, and any of the following:

(i) Noise equivalent irradiance less than 1.54 billion photons per centimeter squared per second;

(ii) A readout integrated circuits capable of pulse interval modulation decoding or pulse repetition frequency decoding (*e.g.,* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz); or

(iii) Temperature dependent non-uniformity correction (*e.g.,* without the use of temperature stabilization)

Note: Noise equivalent irradiance is defined as a ratio with the numerator comprised of the focal plane noise floor in units of electrons at a focal plane array temperature of 300 K and the denominator as the numerator to the multiplied value of detector area in square centimeters, spectral quantum efficiency at 1,550 nm, and an integration time of 0.032 seconds.

N. Infrared focal plane arrays having greater than 327,680 detector elements, a peak response in the wavelength range exceeding 1,700 nm but not exceeding 3,000 nm, and any of the following:

(i) Readout integrated circuits capable of pulse interval modulation decoding

or pulse repetition frequency decoding (*e.g.* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz);

(ii) A total noise floor less than 75 electrons at an operating temperature of 300 K; or

(iii) A detector pitch less than or equal to 20 microns.

O. Infrared focal plane arrays having an internal quantum efficiency exceeding 10 percent anywhere in the wavelength range exceeding 3,000 nm but not exceeding 7,500 nm and any of the following:

(i) A detector pitch less than 12.5 microns; or

(ii) More than 1,331,200 detector elements.

P. Infrared focal plane arrays having a peak response in the wavelength range exceeding 7,500 nm but not exceeding 30,000 nm, and all of the following:

(i) A detector element of the photon, not thermal, type;

(ii) A detector pitch less than or equal to 30 microns; and

(iii) Greater than or equal to 262,144 detector elements.

Q. Infrared focal plane arrays having a peak response in the wavelength range exceeding 7,500 nm but not exceeding 14,000 nm and all of the following:

(i) A detector element of the photon, not thermal, type;

(ii) Greater than 300 detector elements; and

(iii) Time delay integration of detector elements.

R. Microbolometer focal plane arrays having an unfiltered response in the wavelength range exceeding 7,500 nm but not exceeding 14,000 nm and any of the following:

(i) Vacuum packaged and specially designed to withstand weapon shock; or

(ii) Greater than 328,000 detector elements with a detector pitch less than or equal to 14 microns.

S. Infrared focal plane arrays specially designed to provide distinct outputs corresponding to more than one spectral band, and having all the following:

(i) Multiple spectral bands with a photo-response in the wavelength range exceeding 1,100 nm but not exceeding 14,000 nm; and

(ii) A detector element pitch less than 50 microns.

T. Digital low-light-level sensors incorporating a photocathode and a focal plane array within the vacuum space, with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm, and having any of the following:

(i) A photocathode with a luminous sensitivity greater than 1,800 microamps per lumen; or

(ii) Greater than 2,040,000 focal plane array detector elements.

U. Analog readout integrated circuits specially designed for articles in this subchapter.

and

V. Digital readout integrated circuits specially designed for focal plane arrays having a peak spectral response in the wavelength band exceeding 1,100 nm but not exceeding 30,000 nm, a digital signal output, and any of the following:

(i) Dynamic range greater than 54 dB; or

(ii) Pixel read-out rate greater than 540 million bits per second.

The Department will review all comments from the public. If a rulemaking is warranted based on the comments received, the Department will respond to comments received in a proposed rulemaking in the **Federal Register**.

C. Edward Peartree,

Office Director, Defense Trade Controls Policy, Bureau of Political-Military Affairs, Department of State.

[FR Doc. 2017–00651 Filed 1–12–17; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–1113]

RIN 1625–AA00

Safety zone; Tennessee River, Mile 446.0 to 454.5

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone for all waters of the Tennessee River, beginning at mile marker 446.0 and ending at mile marker 454.5 during periods of high water flow. High water flow is determined by flow rates that have reached or exceeded 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0. This proposed safety zone is necessary to provide safety for mariners transiting on the Tennessee River during periods of high water flow. Entry into this area will be prohibited unless specifically authorized by the Captain of the Port Ohio Valley or designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before January 30, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2015–1113 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Ashley Schad, MSD Nashville, Nashville, TN, at 615–736–5421 or at *Ashley.M.Schad@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Captain of the Port Ohio Valley is proposing to establish a safety zone for all waters of the Tennessee River, from mile 446.0 to 454.5 during periods of high water flow. This proposed safety zone is necessary to provide safety for mariners transiting on the Tennessee River during periods of high water flow. There have been temporary final rules issued in the past establishing a safety zone on the Tennessee River beginning at mile marker 446.0 and ending at mile marker 454.5 when flow rates reached or exceeded 100,000 cubic feet per second at Chickamauga lock and dam. Examples of these previous temporary final rules were published under docket numbers USCG–2013–0025 and USCG–2011–1148. This proposed rulemaking is also necessary to more efficiently effect necessary safety measures during emergent high water events in the future by reducing administrative burden and the amount of paperwork required for multiple individual rulemakings. The Tennessee River beginning at mile marker 446.0 and ending at 454.5 poses a navigational hazard during periods of high water flow. A high water flow determination for this area is established when flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0. The Captain of the Port Ohio Valley has determined that additional safety measures are necessary to protect all mariners during periods of high water flow. Therefore, the Coast Guard

proposes to establish a permanent safety zone on specified waters of the Tennessee River triggered by high water flow. This proposed regulation would be in effect whenever flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0.

The Coast Guard proposes this rulemaking under the authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The Captain of the Port Ohio Valley is proposing to establish a safety zone for all waters of the Tennessee River beginning at mile marker 446.0 and ending at mile marker 454.5. Vessels or persons would not be able to enter into, depart from, or move within this area without permission from the Captain of the Port Ohio Valley or designated representative. Persons or vessels requiring entry into or passage through the proposed safety zone will be required to request permission from the Captain of the Port Ohio Valley, or designated representative. They can be contacted on VHF–FM Channel 13, 16, or through Coast Guard Sector Ohio Valley at 1–800–253–7465. This proposed rule would be effective during periods of high water flow when flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam. The Captain of the Port Ohio Valley would inform the public through broadcast notices to mariners during periods of high water flow when the safety zone is established as well as when flow rates fall below 100,000 cubic feet per second and the safety zone is no longer in effect.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders (E.O.s) related to rulemaking. Below we summarize our analyses based on a number of these statutes and E.O.s, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a ''significant regulatory action,'' under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic would only be impacted during times of high water which pose dangerous navigational hazards when flow rates exceed 100,000 cubic feet per second at Chickamauga lock and dam. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

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.

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. 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** section. 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.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

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 proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. 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 an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. 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 (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. This proposed rule involves a safety zone lasting only during periods of high water flow measured by Chickamauga lock and dam. Normally such actions are categorically excluded from further review under paragraph 34(g) of Figure

2–1 of Commandant Instruction M16475.lD. A preliminary environmental analysis checklist and Categorical Exclusion Determination 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.

G. 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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. Add § 165.844 to read as follows:

§ 165.844 Safety Zone; Tennessee River, Mile 446.0 to 454.5; Chattanooga, TN

(a) *Location.* All waters of the Tennessee River beginning at mile marker 446.0 and ending at mile marker 454.5 at Chattanooga, TN.

(b) *Effective date.* This rule is effective during periods of high water flow when flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0.

(c) *Periods of Enforcement.* This rule will be enforced whenever flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0. The Captain of the Port Ohio Valley or a designated representative will inform the public through broadcast notice to mariners of the enforcement period for the safety zone.

(d) *Regulations.*

(1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port Ohio Valley or a designated representative.

(2) Persons or vessels desiring entry into or passage through the zone must request permission from the Captain of the Port Ohio Valley or a designated representative. U. S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

(3) All persons and vessels shall comply with the instructions of the Captain of the Port Ohio Valley and designated U.S. Coast Guard patrol personnel. On-scene U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard.

Dated: January 10, 2017.

M.B. Zamperini,

Captain, U.S. Coast Guard, Captain of the Port Ohio Valley.

[FR Doc. 2017–00696 Filed 1–12–17; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Seamless Acceptance Program

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes to revise *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to add the mail preparation requirements governing participation in the Seamless Acceptance Program.

DATES: Submit comments on or before February 13, 2017.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *ProductClassification@usps.gov,* with a subject line of ''Seamless Acceptance Program.'' Faxed comments are not accepted.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor North, Washington, DC 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Direct questions or comments to Heather Dyer by email at *heather.l.dyer@usps.gov* or phone (207) 482–7217, or Jacqueline Erwin by email at *jacqueline.r.erwin@usps.gov* or phone (202) 268–2158.

SUPPLEMENTARY INFORMATION: Seamless Acceptance is an option for entering commercial mailings. It leverages full-service mailing technology by using scans from USPS® mail processing equipment and hand held devices to automate verification and payment for commercial First-Class Mail cards, letters, and flats, Periodicals, Standard Mail letters and flats, and Bound Printed Matter Flats. Mailers may participate in the Seamless Acceptance Program by contacting the *PostalOne!* Helpdesk at 1–800–522–9085. To participate in the Seamless Acceptance Program, mailers must meet the

standards in DMM 705.22.0. Additional information, including information regarding verification and associated assessments under the Seamless Acceptance Program, is provided in Publication 6850, *Publication for Streamlined Mail Acceptance for Letters and Flats,* at *https://postalpro.usps.com/node/581.*

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comments on the following proposed revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. *See* 39 CFR 111.1.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the following sections of *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

700 Special Standards

* * * * *

705 Advanced Preparation and Special Postage Payment Systems

* * * * *

[Add new section 22.0, to read as follows:]

22.0 Seamless Acceptance Program

22.1 Description

Seamless Acceptance uses Intelligent Mail barcodes, electronic documentation (eDoc), and scans from USPS mail processing equipment and hand held devices, to automate verification of and payment for First-Class Mail cards, letters, and flats, Periodicals, Standard Mail letters and flats, and Bound Printed Matter flats. Additional information, including information regarding verification and associated assessments on the Seamless Acceptance Program, is provided in Publication 6850, *Publication for Streamlined Mail Acceptance for Letters and Flats,* available at *https://postalpro.usps.com/node/581.*

22.2 Approval

Mailers may seek authorization to participate in the Seamless Acceptance Program by contacting the *PostalOne!* Helpdesk at 1–800–522–9085.

22.3 Basic Standards

First-Class Mail, Periodicals, and Standard Mail letters and flats and BPM barcoded flats, are potentially eligible for Seamless Acceptance. All mailpieces, including basic and nonautomation must be prepared as outlined in 23.0; mailers must meet the following standards:

a. Meet all the content and price eligibility standards for the price claimed.

b. Prepare 90% Full-Service eligible volume

c. Participate in the Seamless Parallel Program

d. Participate in eInduction under 20.0 for DMU-verified origin entry or destination entry-drop shipments.

22.3.1 Intelligent Mail Barcode Exception

Under special circumstances where mailers are unable to use an Intelligent Mail Barcode on every piece an exception may be granted by Business Mailer Support (BMS); see 608.8 for contact information.

* * * * *

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes, if our proposal is adopted.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–32057 Filed 1–12–17; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2015–0730; FRL–9958–24–OAR]

RIN 2060–AS93

National Emission Standards for Hazardous Air Pollutants: Nutritional Yeast Manufacturing Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; Notice of public hearing and extension of comment period.

SUMMARY: On December 28, 2016, the Environmental Protection Agency (EPA) published a notice to announce its proposed amendments to the National Emission Standards for Hazardous Air Pollutants for the Manufacturing of Nutritional Yeast source category. The notice also requested public comment on the proposed amendments. The EPA is announcing that a public hearing will be held. In addition, the EPA is extending the public comment period.

DATES: The public hearing will be held on January 25, 2017. Written comments must be received on or before February 24, 2017.

ADDRESSES: The public hearing will be held on January 25, 2017, at the EPA's North Carolina campus located at 109 T.W. Alexander Drive, Research Triangle Park, NC 27711. The hearing will convene at 10:00 a.m. (Eastern Time) and will conclude no later than 4:00 p.m. (Eastern Time). If there are no additional registered speakers, the EPA will end the hearing 2 hours after the last registered speaker has concluded their comments. The EPA will make every effort to accommodate all speakers. The EPA's Web site for the rulemaking, which includes the proposal and information about the hearing, can be found at: *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.*

For information on submitting your written comments, refer to the proposed reconsideration notice published at 81 FR 95810 in the **Federal Register** on December 28, 2016.

FOR FURTHER INFORMATION CONTACT: If you would like to present oral testimony at the public hearing, registration will begin on January 13, 2017. To register to speak at a hearing, please contact Aimee St. Clair at (919) 541–1063 or at *stclair.aimee@epa.gov.* The last day to pre-register to present oral testimony in advance will be January 23, 2017. If using email, please provide the following information: The time you wish to speak, name, affiliation, address, email address, and telephone number. Time slot preferences will be given in the order requests are received. Additionally, requests to speak will be taken the day of the hearing at the hearing registration desk, although preferences on speaking times may not be able to be fulfilled. Please note that registration requests received before each hearing will be confirmed by the EPA via email. We cannot guarantee

that we can accommodate all timing requests and will provide requestors with the next available speaking time, in the event that their requested time is taken. Please note that the time outlined in the confirmation email received will be the scheduled speaking time. Again, depending on the flow of the day, times may fluctuate. Please note that any updates made to any aspect of the hearing will be posted online at: *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.* While the EPA expects the hearing to go forward as set forth above, we ask that you monitor our Web site or contact Aimee St. Clair at (919) 541–1063 or at *stclair.aimee@epa.gov* to determine if there are any updates to the information on the hearing. The EPA does not intend to publish a notice in the **Federal Register** announcing any such updates.

Questions concerning the rule that was published in the **Federal Register** on December 28, 2016, should be addressed to Allison Costa, Office of Air Quality Planning and Standards, Sector Policies and Programs Division (E140), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number:(919) 541–1322; facsimile number: (919) 541–3470; email address: *costa.allison@epa.gov.*

Public hearing: The proposal for which the EPA is holding the public hearing was published in the **Federal Register** on December 28, 2016, and is available at: *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards,* and also in Docket ID No. EPA–HQ–OAR–2015–0730. The public hearing will provide interested parties the opportunity to present oral comments regarding the EPA's proposed standards, including data, views, or arguments concerning the proposal. The EPA may ask clarifying questions during the oral presentations, but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearing. The period for providing written comments to the EPA will remain open until February 24, 2017.

Commenters should notify Aimee St. Clair if they will need specific equipment or if there are other special needs related to providing comments at the public hearing. The EPA will provide equipment for commenters to make computerized slide presentations if we receive special requests in advance. Oral testimony will be limited to 5 minutes for each commenter. The EPA encourages commenters to submit to the docket a copy of their oral testimony electronically (via email or CD) or in hard copy form.

Because the hearing will be held at a U.S. government facility, individuals planning to attend the hearing should be prepared to show valid picture identification to the security staff in order to gain access to the meeting room. Please note that the REAL ID Act, passed by Congress in 2005, established new requirements for entering federal facilities. If your driver's license is issued by Minnesota, Missouri or the State of Washington, you must present an additional form of identification to enter the federal building. Acceptable alternative forms of identification include: Federal employee badges, passports, enhanced driver's licenses, and military identification cards. In addition, you will need to obtain a property pass for any personal belongings you bring with you. Upon leaving the building, you will be required to return this property pass to the security desk. No large signs will be allowed in the building, cameras may only be used outside of the building, and demonstrations will not be allowed on federal property for security reasons.

The public hearing schedule, including lists of speakers, will be posted on the EPA's Web site at: *https://www.epa.gov/stationary-sources-air-pollution/manufacturing-nutritional-yeast-national-emission-standards.* Verbatim transcripts of the hearing and written statements will be included in the docket for the rulemaking. The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule.

How can I get copies of this document and other related information?

The EPA has established a docket for the proposed rule, ''National Emission Standards for Hazardous Air Pollutants: Nutritional Yeast Manufacturing Risk and Technology Review,'' under Docket ID No. EPA–HQ–OAR–2015–0730, available at *http://www.regulations.gov.*

Dated: January 9, 2017.

Mary Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2017–00762 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 123

[EPA–HQ–OW–2016–0376; FRL–9957–40–OW]

RIN 2040–AF67

Public Notification Requirements for Combined Sewer Overflows to the Great Lakes Basin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing a rule to implement section 425 of the Consolidated Appropriations Act of 2016, which requires EPA to work with the Great Lakes states to establish public notification requirements for combined sewer overflow (CSO) discharges to the Great Lakes. The proposed requirements address signage, notification of local public health departments and other potentially affected public entities, notification to the public, and annual notice provisions.

The proposed rules, when finalized, will protect public health by ensuring timely notification to the public and to public health departments, public drinking water facilities and other potentially affected public entities, including Indian tribes. Timely notice may allow the public to take steps to reduce their potential exposure to pathogens associated with human sewage, which can cause a wide variety of health effects, including gastrointestinal, skin, ear, respiratory, eye, neurologic, and wound infections.

DATES: Comments must be received on or before March 14, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2016–0376 to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*e.g.,*

on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-s*.

FOR FURTHER INFORMATION CONTACT: Kevin Weiss, Office of Wastewater Management, Water Permits Division (MC4203), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–0742; email address: *weiss.kevin@epa.gov*.

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I. General Information

A. Does this action apply to me?

Entities within the Great Lakes Basin potentially regulated by this proposed action include:

Category	Examples of regulated entities	North American industry classification system (NAICS) code
Federal and state government	EPA or state NPDES permit authorities	924110
Local governments	NPDES permittees with a CSO discharge to the Great Lakes Basin.	221320

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated or otherwise affected by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in § 122.32 title 40 of the Code of Federal Regulations, and the discussion in the preamble. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency proposing?

EPA is proposing a rule to establish public notification requirements for CSOs to the Great Lakes Basin. The proposed rule would implement Section 425 of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113) (hereafter referred to as ''Section 425''), which requires EPA to work with the Great Lake states to establish public notice requirements for CSO discharges to the Great Lakes and prescribes minimum requirements for such notice. EPA sought and considered public input during the development of the proposed rule.

This proposal includes required methods for CSO permittees in the Great Lakes Basin to provide public notification of CSO discharges and for the minimum content of such notification. The proposed requirements for methods of providing public notice of CSO discharges include signage, initial and supplemental notice to potentially affected public entities and to the public, and an annual notice that allows for analysis of trends in combined sewer system performance and the operator's plans for CSO controls. In addition, EPA proposes requirements for Great Lakes Basin CSO permittees to develop a public notification plan that reflects community-specific details (*e.g.,* proposed monitoring locations, means for disseminating information to the public) as to how the permittee would implement the proposed public notification requirements. EPA proposes that Great Lakes Basin CSO permittees would submit the public notification plan to the NPDES permitting authority (''Director'') within six months after publication of a final regulation. The public notification plan would provide a means of public engagement on the details of implementation of the notification requirements.

Under the proposal, the public notification provisions, including the requirement to develop a public notification plan, would be implemented through two regulatory mechanisms. First, EPA proposes to add

a new section to the NPDES permit regulations, to be codified at 40 CFR 122.38, establishing the public notification requirements for Great Lakes CSO permittees. The proposed requirements in § 122.38 would apply directly to Great Lakes CSO permittees until their NPDES permits are next reissued after publication of a final regulation.

EPA proposes that the requirements for developing the public notification plan and the methods of notification other than the annual notice would directly apply to CSO permittees that discharge to the Great Lakes Basin six months after publication of a final regulation. EPA proposes that the annual notice requirements would directly apply one year after publication of a final regulation to allow permittees time to collect data for a full year. Under this proposal, the Director could extend the compliance dates for notification and/or submittal of the public notification plan for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship.

Second, under this proposal, the public notification requirements for CSO discharges to the Great Lakes Basin would be implemented as a condition in NPDES permits when they are next reissued after publication of a finale regulation. EPA proposes that when the permittee's CSO NPDES permit is reissued, the permit would be required to include a permit condition addressing public notification of CSO discharges to the Great Lakes Basin. The proposed permit condition would incorporate the proposed requirements in § 122.38 for signage, methods of notification and annual notice, as well as requirements to provide specific information relevant to the permittee's implementation of the notification requirements. This two-stage implementation approach would ensure that the requirements of Section 425 will be implemented during the interim period before the permit condition is incorporated into the relevant NPDES permits, consistent with Section 425, which requires implementation by December 18, 2017.

The objectives of these proposed requirements are to:

- Ensure *timely notice to the public* of CSO discharges. This notice is intended to alert members of the public to CSO discharges which may allow them to take steps to reduce their potential exposure to pathogens associated with the discharges.
- Ensure *timely notice to local public health departments, public drinking water facilities and other potentially affected public entities, including Indian tribes,* of CSO discharges. This notice is intended to alert these entities to specific CSO discharges and support the development of appropriate responses to the discharges, such as ensuring that beach closures and advisories reflect the most accurate and up-to-date information or adjusting the intake or treatment regime of drinking water treatment facilities that have intakes from surface waters affected by CSO discharges.
- Provide the community and interested stakeholders with *effective and meaningful follow-up notification* that allows for analysis of trends in combined sewer system (CSS) performance and provides stakeholders with information on the CSS operator's plans to control CSO discharges. This information is intended to help the community understand the current performance of their collection system and how the community's ongoing investment to reduce overflows would address the impacts of CSOs.

C. What is the Agency's authority for taking this action?

The authority for this rule is Section 425 of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113) and the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.,* including sections 1314(i), 1318, 1342 and 1361(a).

II. Background

A. Combined Sewer Overflows From Municipal Wastewater Collection Systems

Municipal wastewater collection systems collect domestic sewage and other wastewater from homes and other buildings and convey it to wastewater treatment plants for treatment and disposal. The collection and treatment of municipal sewage and wastewater is vital to the public health in our cities and towns. In the United States, municipalities historically have used two major types of sewer systems—separate sanitary sewer systems and CSSs.

Municipalities with separate sanitary sewer systems use that system solely to collect domestic sewage and convey it to a publicly owned treatment works (POTW) treatment plant for treatment. These municipalities also have separate sewer systems to collect surface drainage and stormwater, known as ''municipal separate storm sewer systems'' (MS4s). Separate sanitary sewer systems are not designed to collect large amounts of runoff from rain or snowmelt or provide widespread surface drainage, although they typically are built with some allowance for some amount of stormwater or groundwater that enters the system as a result of storm events.

The other type of sewer system, CSSs, is designed to collect both sanitary sewage and stormwater runoff in a single-pipe system. This type of sewer system provides the primary means of surface drainage by carrying rain and snowmelt away from streets, roofs, and other impervious surfaces. CSSs were among the earliest sewer systems constructed in the United States and were built until the first part of the 20th century.

Under normal, dry weather conditions, combined sewers transport all of the combined wastewater (sewage and stormwater runoff) collected to a sewage treatment plant for treatment. However, under wet weather conditions when the volume of wastewater and stormwater exceeds the capacity of the CSS or treatment plant, these systems are designed to divert some of the combined flow prior to reaching the POTW treatment plant and to discharge combined stormwater and sewage directly to nearby streams, rivers and other water bodies. These discharges of sewage from a CSS that occur prior to the POTW treatment plant are referred to as combined sewer overflows or CSOs. Depending on the CSS infrastructure design, CSO discharges may be untreated or may receive some level of treatment, such as solids settling in a retention basin and disinfection, prior to discharge.

CSO discharges contain human and industrial waste, toxic materials, and debris as well as stormwater. CSO discharges can be harmful to human health and the environment because they introduce pathogens (*e.g.,* bacteria, viruses, protozoa) and other pollutants to receiving waters, causing beach closures, water quality impairment, and contaminate drinking water supplies and shellfish beds. CSOs can also cause depleted oxygen levels which can impact fish and other aquatic populations.

CSSs serve a total population of about 40 million people nationwide. Most communities with CSSs are located in the Northeast and Great Lakes regions, particularly in Illinois, Indiana, Maine, Michigan, New York, Ohio, Pennsylvania, and West Virginia. Although large cities like Chicago, Cleveland, and Detroit have CSSs, most communities with CSSs have fewer than 10,000 people. Most CSSs have multiple CSO discharge locations or outfalls, with some larger communities with

combined sewer systems having hundreds of CSO outfalls.

B. Combined Sewer Overflows to the Great Lakes Basin

As of September 2015, 859 active NPDES permits for CSO discharges had been issued in 30 states plus the District of Columbia and Puerto Rico. Of these 859 permits, 190 permits [1] are for CSO discharges to waters located in the watershed for the Great Lakes and the Great Lakes System (''Great Lakes Basin'').[2] The 190 permits for CSO discharges to the Great Lakes Basin have been issued to 182 communities [3] or permittees. These permittees are located in the states of New York, Pennsylvania, Ohio, Michigan, Illinois, Indiana, and Wisconsin. CSO communities are scattered across the Great Lakes Basin, with the greatest concentration in Ohio, southeastern Michigan and northeastern Indiana discharging to Lake Erie, and in northern Indiana and southwestern Michigan discharging to Lake Michigan (see Figure 1). Hereafter, the owner or operator of a CSS is referred to as a ''CSO permittee.''

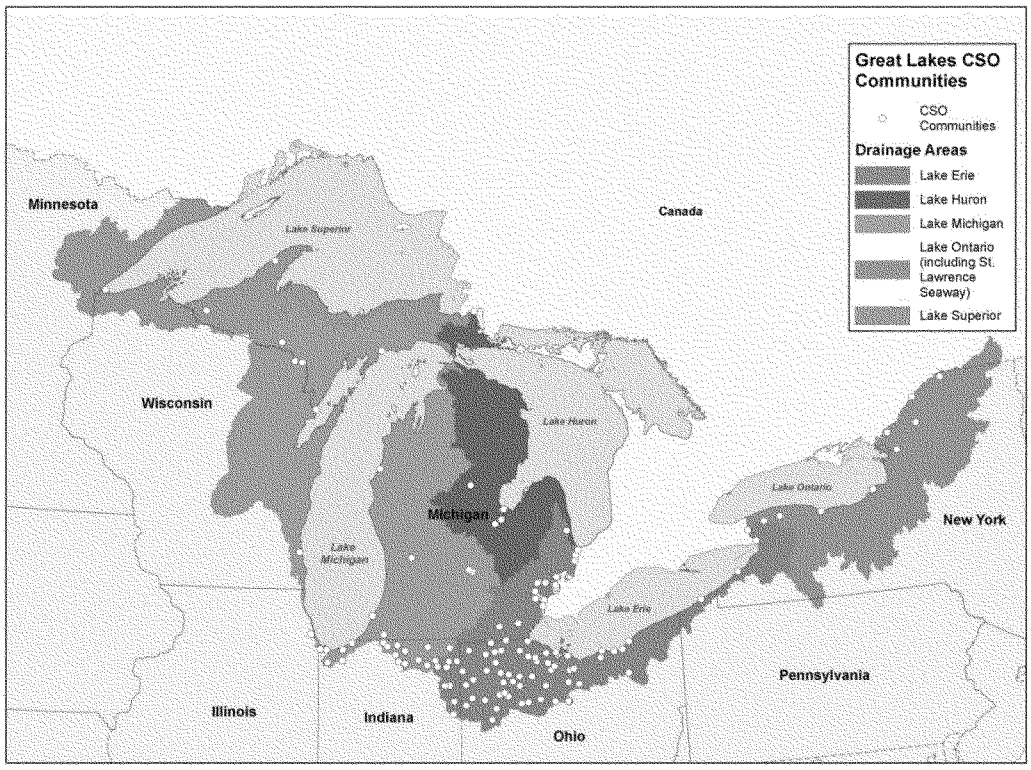

Figure 1. CSO Permittees in the Great Lakes Basin

EPA recently summarized available information on the occurrence and volume of discharges from CSOs to the Great Lakes Basin during 2014 (see Report to Congress: Combined Sewer Overflows into the Great Lakes Basin (EPA 833–R–16–006)), contained in the public docket for this rulemaking. As summarized in this report, seven states reported 1,482 events where untreated sewage was discharged from CSOs to the Great Lakes Basin in 2014 and an additional 187 CSO events where treated sewage was discharged. For the purposes of the Report, treated discharges referred to CSO discharges that received a minimum of:

- Primary clarification (removal of floatables and settleable solids may be achieved by any combination of treatment technologies or methods that are shown to be equivalent to primary clarification);
- Solids and floatable disposal; and
- Disinfection of effluent, if necessary to meet water quality standards and protect human health, including removal of harmful disinfection chemical residuals, where necessary.

[1] EPA identified 184 CSO permits in the Great Lakes Basin in the 2016 Report to Congress: Combined Sewer Overflows into the Great Lakes Basin (EPA 833–R–16–006). EPA has adjusted that estimate to reflect additional information. First, six CSO permittees identified in the Report to Congress were subtracted because their permit coverage had been terminated due to sewer separation or other reasons. Second, EPA conducted a GIS analysis and verified with States that 12 permits for CSO discharges to the Great Lakes Basin were not identified in the 2016 Great Lakes CSO Report to Congress. A list of these 18 permits is available in the docket for this rulemaking.

[2] Section 425 specifies in Section 425(a)(4) that the term ''Great Lakes'' means ''any of the waters as defined in the Section 118(a)(3) of the Federal Water Pollution Control Act (33 U.S.C. 1292).'' This, therefore, includes Section 118(a)(3)(B), which defines ''Great Lakes'' as ''Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior, and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border);'' and Section 118(a)(3)(C), which defines ''Great Lakes System'' as ''all the streams, rivers, lakes, and other bodies of water within the drainage basin of the Great Lakes.'' Collectively, EPA is referring to the Great Lakes and the Great Lakes System as the ''Great Lakes Basin.''

[3] The number of CSO communities in the Great Lakes Basin is different than the number of CSO permits. Four CSO communities have more than one CSO NPDES permit. These include Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) (4 permits); Wayne County, MI (4 permits); Oakland County, MI (2 permits); and the City of Oswego, NY (2 permits). For the purposes of counting communities, communities with multiple CSO permits are counted as one CSO community.

Additional information regarding CSO discharges to the Great Lakes Basin, including the Report to Congress, is available at *https://www.epa.gov/npdes/combined-sewer-overflows-great-lakes-basin.* Table 1 provides the size distribution of the 182 CSO communities in the Great Lakes Basin.

TABLE 1—GREAT LAKES BASIN CSO COMMUNITIES BY COMMUNITY POPULATION

Community Population	Over 50,000	10,000–49,999	Under 10,000	Total
Number of CSO Communities	32	70	80	182

Permits issued to Metropolitan Water Reclamation District of Greater Chicago and Wayne County used the population for Chicago and Wayne County, respectively.

As stated above, CSOs can cause human health and environmental impacts.[4] CSOs often discharge simultaneously with other wet weather sources of water pollution, including stormwater discharges from various sources including municipal separate storm sewers, wet weather sanitary sewer overflows (SSOs) from separate sanitary sewer systems, and nonpoint sources of pollution. The cumulative effects of wet weather pollution can make it difficult to identify and assign specific cause-and-effect relationships between CSOs and observed water quality problems. The environmental impacts of CSOs are most apparent at the local level.[5]

C. The CSO Control Policy and Clean Water Act Framework for Reducing and Controlling Combined Sewer Overflows

The Clean Water Act (CWA) establishes national goals and requirements for maintaining and restoring the nation's waters. CSO discharges are point sources subject to the technology-based and water quality-based requirements of the CWA under NPDES permits. Technology-based effluent limitations for CSO discharges are based on the application of best available technology economically achievable (BAT) for toxic and nonconventional pollutants and best conventional pollutant control technology (BCT) for conventional pollutants. BAT and BCT effluent limitations for CSO discharges are determined based on ''best professional judgment.'' CSO discharges are not subject to permit limits based on secondary treatment requirements that are applicable to discharges from POTWs.[6] Permits authorizing discharges from CSO outfalls must include more stringent water quality-based requirements, when necessary, to meet water quality standards (WQS).

EPA issued the CSO Control Policy on April 19, 1994 (59 FR 18688). The CSO Control Policy ''represents a comprehensive national strategy to ensure that municipalities, permitting authorities, water quality standards authorities, and the public engage in a comprehensive and coordinated effort to achieve cost-effective CSO controls that ultimately meet appropriate health and environmental objectives.'' (59 FR 18688). The policy assigns primary responsibility for implementation and enforcement to NPDES permitting authorities (generally referred to as the ''Director'' in the NPDES regulations) and water quality standards authorities.

The policy also established objectives for CSO permittees to: (1) Implement ''nine minimum controls'' and submit documentation on their implementation; and (2) develop and implement a long-term CSO control plan (LTCP) to ultimately result in compliance with the CWA, including water quality-based requirements. In describing NPDES permit requirements for CSO discharges, the CSO Control Policy states that the BAT/BCT technology-based effluent limitations ''at a minimum include[s] the nine minimum controls.'' (59 FR 18696) One of the nine minimum controls is ''Public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts.''

In December 2000, as part of the Consolidated Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554), Congress amended the CWA by adding Section 402(q). This amendment is commonly referred to as the ''Wet Weather Water Quality Act of 2000.'' It requires that each permit, order, or decree issued pursuant to the CWA after the date of enactment for a discharge from a municipal combined sewer system shall conform to the CSO Control Policy.

D. NPDES Regulations Addressing CSO Reporting

The NPDES regulations require NPDES permits to include requirements for monitoring discharges, including CSO discharges, and reporting the results, on a case-by-case basis with a frequency dependent on the nature and effect of the discharge, but in no case less than once a year (see 40 CFR 122.44(i)(2)). In addition, permits must require that permittees orally report to the NPDES permitting authority any noncompliance with NPDES permits related to CSO discharges that may endanger human health or the environment within 24 hours from the time the permittee becomes aware of the circumstances, and in writing within 5 days (see § 122.41(l)(6)). Permits must also require reporting of other noncompliance related to CSOs when their discharge monitoring reports are submitted (see § 122.41(l)(7)).

On October 22, 2015, EPA published a final rule to modernize CWA reporting for municipalities, industries, and other facilities by converting to an electronic data reporting system. Known as the NPDES Electronic Reporting Rule, or E-Reporting Rule, this final rule requires regulated entities and state and federal regulators to report electronically data required by the NPDES permit program instead of filing written paper reports. EPA is phasing in the requirements of the E-Reporting Rule over a five-year period. Starting on December 21, 2016, permittees will begin submitting their Discharge Monitoring Reports (DMRs) electronically. Starting on December 21, 2020, permittees will begin submitting electronically certain other NPDES reports, including ''Sewer Overflow/Bypass Event Reports,'' which may include information on some CSO discharges. Under the rule, Table 2 of Appendix A of Part 127 identifies data elements that are required to be reported in a DMR for CSO discharges (pursuant to § 122.41(4)(i)) after December 21, 2016, and in ''Sewage Overflow/Bypass Event Reports'' (pursuant to

[4] Report to Congress—Implementation and Enforcement of the Combined Sewer Overflow Control Policy. EPA 833–R–01–003, 2002; Report to Congress—Impacts and Control of CSOs and SSOs. EPA 833–R–04–001, 2004; Report to Congress: Combined Sewer Overflows to the Lake Michigan Basin. EPA 833–R–07–007, 2007. See *https://www.epa.gov/npdes/combined-sewer-overflows-policy-reports-and-training.*

[5] Report to Congress—Impacts and Control of CSOs and SSOs. EPA 833–R–04–001, 2004. See *https://www.epa.gov/npdes/combined-sewer-overflows-policy-reports-and-training.*

[6] *Montgomery Environmental Coalition et al.* v. *Costle,* 646 F.2d 568, 592 (D.C. Cir. 1980).

§§ 122.41(l)(6) or (7) and 122.41(m)(3)) submitted after December 21, 2020. A subset of the data elements that are required to be reported that are relevant to public notification of a CSO discharge include the following data elements:

- Sewer Overflow Cause;
- Duration of Sewer Overflow (hours);
- Sewer Overflow Discharge Volume (gallons);
- Corrective Actions Taken or Planned for Sewer Overflow; and
- Type of Potential Impact of Sewer Overflow.

In addition, starting on December 21, 2020, NPDES authorities are required to provide, and update as appropriate, information regarding the following data elements for each CSO permittee:

- Long-Term CSO Control Plan (LTCP) Permit Requirements and Compliance;
- Nine Minimum CSO Controls Developed;
- Nine Minimum CSO Controls Implemented;
- LTCP Submission and Approval Type;
- LTCP Approval Date;
- Enforceable Mechanism and Schedule to Complete LTCP and CSO Controls;
- Actual Date Completed LTCP and CSO Controls;
- Approved Post-Construction Compliance Monitoring Program; and
- Other CSO Control Measures with Compliance Schedule.

EPA is working with states to define data standards for the sewer overflow data elements in 40 CFR 127, Appendix A, and how this data can be best presented on EPA's Enforcement and Compliance History Online (ECHO) Web site.[7]

E. Section 425 of the Consolidated Appropriations Act of 2016—Requirements for Public Notification of CSO Discharges to the Great Lakes Basin

Section 425 was enacted as part of the 2016 Consolidated Appropriations Act and did not amend the CWA. Section 425(b)(1) requires EPA to work with the Great Lakes states to establish public notice requirements for CSO discharges to the Great Lakes Basin. Section 425(b)(2) provides that the notice requirements are to address the method of the notice, the contents of the notice, and requirements for public availability of the notice. Section 425(b)(3)(A) provides that at a minimum, the contents of the notice are to include the dates and times of the applicable discharge; the volume of the discharge; and a description of any public access areas impacted by the discharge. Section 425(b)(3)(B) provides that the minimum content requirements are to be consistent for all affected states.

Section 425(b)(4)(A) calls for follow-up notice requirements that provide a description of each applicable discharge; the cause of the discharge; and plans to prevent a reoccurrence of a CSO discharge to the Great Lakes Basin consistent with section 402 of the Federal Water Pollution Control Act (33 U.S.C. 1342) or an administrative order or consent decree under such Act. Section 425(b)(4)(B) provides for annual publication requirements that list each treatment works from which the Administrator or the affected state receive a follow-up notice.

Section 425(b)(5) requires that the notice and publication requirements described in Section 425 shall be implemented by not later than December 18, 2017. However, the Administrator of the EPA may extend the implementation deadline for individual communities if the Administrator determines the community needs additional time to comply in order to avoid undue economic hardship. Finally, Section 425(b)(6) clarifies that ''[n]othing in this subsection prohibits an affected State from establishing a State notice requirement in the event of a discharge that is more stringent than the requirements described in this subsection.''

F. Examples of Existing Local Public Notification Practices in CSO Communities

In 1995, EPA published a guidance entitled ''Combined Sewer Overflows—Guidance for Nine Minimum Controls'' [8] to assist with the implementation of the 1994 CSO Policy. As mentioned above, one of the nine minimum controls called for in that policy is ''public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts.'' The 1995 guidance recognizes that the most appropriate mechanism for public notification will probably vary with local circumstances, such as the character and size of the use area and means of public access to waters affected by CSOs. The guidance also provides examples of potential measures for notifying the public about CSO events that were available at the time, including:

- Posting at affected use areas;
- Posting at selected public places;
- Posting at CSO outfalls;
- Notices in newspapers or on radio and TV news programs;
- Letter notification to affected residents that reflect long-term restrictions; and
- Telephone hot lines.

While the general themes identified in the 1995 guidance are still useful and appropriate, the significant technology changes that have occurred since then allow for a much wider set of tools to be used in public notification. EPA's 2016 document ''National Pollutant Discharge Elimination System Compendium of Next Generation Compliance Examples [9] '' provides examples of CSO notification using current technology. This compendium describes examples of CSO public notice efforts in New York and Ohio and provides examples of CSO public notification outside the Great Lakes Basin.

In addition to those examples outlined in the Next Generation Compliance Compendium, EPA has summarized other existing public notification practices for CSO discharges both to the Great Lakes Basin and to other waters.[10]

Existing public notice practices summarized in these two resources include, but are not limited to:

- The NPDES permit for CSO discharges from the City of Seattle, Washington requires the city to implement a web-based public notification system to inform the citizens of when and where CSOs occur. Seattle and King County maintain a real-time public notification Web site that has CSO overflow information updated with available data every 10 minutes for King County sites, and every 60 minutes for Seattle sites.
- The City of Cambridge, Massachusetts and the City of Chelsea, Massachusetts post signs at all CSO structures and at public access locations and other sites identified by the Massachusetts Department of Environmental Protection. Cities notify local health agents and local watershed advocacy groups by email and issue an annual press release discussing past CSOs. Cambridge also provides the following information on its Web site:
  - General information regarding CSOs, including their potential health impacts;

[7] *https://echo.epa.gov.*

[8] *https://www.epa.gov/sites/production/files/2015-10/documents/owm0030_2.pdf.*

[9] *https://www.epa.gov/compliance/compendia-next-generation-compliance-examples-water-air-waste-and-cleanup-programs.*

[10] see ''Summary of CSO Public Notification provisions,'' Docket ID No. EPA–HQ–OW–2016–0376 at *http://www.regulations.gov.*

○ Locations of CSO discharges in the Charles River and Alewife Brook watersheds;

○ The overall status of all CSO abatement programs;

○ Web links to CSO communities and watershed advocacy groups; and

○ The most recent information on all CSO activations and volumes in both watersheds.

• The District of Columbia Water and Sewer Authority (DC Water) operates CSO Event Indicator Lights to notify river users of CSO discharges. A red light must be illuminated during a CSO occurrence and a yellow light must be illuminated for 24 hours after a CSO has stopped.

• Connecticut's two-part Public Act: ''An Act Concerning The Public's Right to Know of a Sewage Spill'' requires the Connecticut Department of Energy and Environmental Protection (DEEP) to provide a map indicating the CSOs anticipated to occur during certain storm events.

• The Vermont Department of Environmental Conservation (DEC) posts on its Web site a report of any sewage release that reaches waters of the State.

• The Allegheny County Sanitary Authority (ALCOSAN) raises orange flags signifying CSOs have occurred at eight locations along the Allegheny, Monongahela and Ohio rivers during and after CSO discharge events. ALCOSAN also provides notifications of sewer overflows via text message and/or email.

• Sanitation District No. 1 (SD1) of Northern Kentucky issues an email advisory when a rainfall of 0.25 inches or more is predicted or recorded. They also issue an advisory when the Ohio River level exceeds 38 feet. Advisories will remain in effect for 72 hours after rainfall and 72 hours after river levels have fallen below 38 feet.

• Onondaga County, New York maintains a ''Save the Rain'' Web site which serves as a notification system to alert the public of the occurrence of CSO events and as a prediction of elevated bacteria levels in Onondaga Lake and its tributaries. The discharge status of CSO outfalls are mapped on this Web page. The information on the map is updated using a model to anticipate the quantity of rainfall that will trigger each CSO.

• The Metropolitan Sewer District (MSD) of Greater Cincinnati issues a CSO advisory via a CSO hotline or email alert when a rainfall of 0.25 inches or more is predicted or recorded or when water levels in area rivers and streams are elevated and could cause a CSO to occur. Advisories will remain in place for 72 hours after a rainfall event and 72 hours after water levels in area waterways have returned to normal. Actual occurrences of CSO discharges are reported and summarized in reports that are posted on MSD's Web site.

G. Existing State-Level Public Notification Requirements for CSOs in the Great Lakes Basin

EPA worked with the Great Lake states to identify existing state-level notification requirements for CSO discharges to the Great Lakes Basin, which are summarized in the proposed rule docket, see ''Summary of State CSO Public Notification Requirements in the Great Lakes Basin'' See Docket ID No. EPA–HQ–OW–2016–0376 at *http://www.regulations.gov.* Almost all of the NPDES permits for CSO discharges to the Great Lakes Basin currently require some level of public notification to ensure citizens receive adequate information regarding CSO occurrences and CSO impacts. Permit requirements which add specificity to this requirement and additional state public notification requirements are discussed below. Table 2 summarizes some of the main components of existing Great Lakes state programs that relate to public notification of CSO discharges.

TABLE 2—SUMMARY OF STATE PROGRAM REQUIREMENTS FOR PUBLIC NOTICE REQUIREMENTS FOR CSO DISCHARGES TO THE GREAT LAKES BASIN

	NY	PA	OH	MI	IN	IL	WI
State CSO public notification regulation	X			X	X		
Requires Public Notification Plan	X		/		X	X	X
Requires CSO Outfall Signs	X	X	X	X	X	X	
Alert system (text/email)	X				/	X	X
Immediate notification of local public health department and drinking water supply	X		X	X	X		
Annual reporting on CSO discharges	X	X	/	X			

'X' indicates all CSO discharges to the Great Lakes Basin are subject to requirement.
'/' indicates that some CSO discharges to the Great Lakes Basin are subject to requirement.

Illinois

All forty Illinois CSO communities in the Great Lakes Basin are in the Metropolitan Water Reclamation District of Greater Chicago (MWRD) service area. The NPDES permits for these CSO communities provide that public notification programs may be developed in conjunction with MWRD. MWRD's NPDES permits for each of its four treatment plants require MWRD to develop a public notification plan. MWRD is implementing its plan by:

• Providing the public with the opportunity to sign up for emails and/or text messages when a confirmed CSO discharge or diversion to Lake Michigan occurs.

• Posting a map of the city's waterways showing the status of discharges at CSO outfalls.

Indiana

Indiana requires NPDES CSO permittees to:

• Post signs within the permittee's jurisdiction at access points to an affected water or to make attempts to do so when access is not on community property.

• Provide notification to the affected public, local health departments and drinking water suppliers having surface water intakes located within ten miles downstream of a discharging CSO outfall whenever information indicates that a CSO discharge is occurring or is imminent based on predicted or actual precipitation or a related event.

• Incorporate CSO notification procedures into the permittee's CSO operational plan which must be approved by the Indiana Department of Environmental Management. A member of the public may request that the department reevaluate the CSO notification procedures.

Michigan

Michigan state regulations and permits require CSO permittees to:

• Notify the Michigan Department of Environmental Quality (DEQ); local health departments; a daily newspaper

of general circulation in the county or counties in which the municipality is located; and a daily newspaper of general circulation in the county in which CSO discharges occurred immediately, but not more than 24 hours after the discharge begins.

○ Initial notification that the discharge is occurring is to be by telephone or other manner required by DEQ.

○ At the conclusion of the discharge, in writing or in another manner required by DEQ, additional notice provides more detailed information including the volume and quality of the discharge as measured pursuant to procedures and analytical methods approved by the department, reason for discharge, receiving water or land affected, date and time discharge began and ended, and compliance status.

• Contact each municipality annually whose jurisdiction contains waters that may be affected by the discharge and provide immediate notification of CSO discharges to these municipalities if requested.

• Test the affected waters for *E. coli* to assess the risk to the public health as a result of the discharge and provide the test results to the affected local county health departments and to DEQ. The testing is to be done at locations specified by each affected local county health department. This testing requirement may be waived by the affected local county health department if it is determined that such testing is not needed to assess the public health risks.

Michigan state regulations require Michigan DEQ to:

• Promptly post the notification on its Web site upon being notified of a discharge.

• Maintain and publish a list of occurrences of discharges of untreated or partially treated sewage that have been reported. The list is to be posted on the department's Web site and published annually and made available to the general public.

New York

New York state statutes, regulations, and permits require CSO permittees to:

• Install and maintain signs at all CSO outfalls owned and operated by the permittee.

• Implement a public notification program to inform citizens of the location and occurrence of CSO events.

• Notify the local public health department of CSO discharges immediately, but in no case later than two hours after discovery.

• Notify any adjoining municipality that may be affected as soon as possible, but no later than four hours from discovery of the CSO discharge.

CSO communities can report CSO discharges to a state operated electronic notification system, NY-Alert. The NY-Alert system provides public health departments, adjoining municipalities and subscribing citizens with notice of CSO discharges.

CSO permittees are required to submit an annual report to the state that describes implementation of 14 CSO best management practices. The state uses this and other information to prepare an annual report on sewer system discharges. The New York Department of Environmental Conservation's Web site includes a map of CSO outfalls in New York that provides information about CSO discharges.

Ohio

Ohio state regulations and permits require CSO permittees to:

• Install and maintain signs at all regulated outfalls, including CSOs; and

• Notify public water supply operators as soon as practicable if a spill, overflow, bypass, or upset reaches a water of the state within a set distance of a public water supply intake.

Public notification plans and annual reporting of CSO discharges are required on a case-by-case basis.

Pennsylvania

The NPDES permit for Erie, Pennsylvania (the only city with a CSS in Pennsylvania that discharges to the Great Lakes Basin) requires Erie to submit an annual CSO status report to the state, which is available to the public upon request.

Wisconsin

Of Wisconsin's two CSO permittees, one permit does not specify any public notification requirements. The other requires the permittee to have a public notification process in place and to make personal contact with affected members of the public in the event of an overflow.

H. Working With the Great Lake States and Requesting Public Input

EPA has worked with the Great Lakes states on creating proposed requirements to implement Section 425 of the 2016 Consolidated Appropriations Act. NPDES program officials in each state with CSO discharges to the Great Lakes Basin have described existing state notification requirements, shared insights on implementation issues and provided individual perspectives on what should be included in the proposed rule.

On August 1, 2016, EPA published a document in the **Federal Register** requesting stakeholder input regarding potential approaches for developing public notice requirements for CSO discharges to the Great Lakes Basin under Section 425. As part of this effort, EPA held a public ''listening session'' on September 14, 2016, which provided stakeholders and other members of the public an opportunity to share their views regarding potential new public notification requirements for CSO discharges to the Great Lakes Basin. A summary of the oral comments made at the public listening session is included in the docket for this rulemaking.[11] In addition, the Agency requested written comments. EPA received 40 unique written comments and a total of 787 written comments, all of which were submitted to the docket (see EPA–HQ–OW–2016–0376–2 through EPA–HQ–OW–2016–0376–41). These comments have informed the development of the proposed rule and are discussed throughout the preamble below.

III. Proposed Requirements

A. Overview of Proposal

The proposed requirements to implement Section 425 are based on an evaluation of current notification requirements and practices in the Great Lakes Basin and elsewhere, and input from officials in the Great Lakes states and the public, including input received in response to EPA's August 1, 2016 request. The proposal clarifies EPA's expectations for CSO permittees discharging to the Great Lakes Basin to provide public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts. The proposed requirements would conform to the CSO Control Policy by specifying requirements for implementation of one of the nine minimum controls for the CSO discharges addressed by Section 425.

EPA proposes requirements for public notification of CSO discharges to the Great Lakes Basin to be codified at 40 CFR 122.38. This section would apply directly to Great Lakes Basin CSO permittees six months after publication of a final rule, except for annual notice requirements which would apply one year after publication. EPA proposes to implement section 425(b)(5)(B) of the Consolidated Appropriations Act of 2016 by providing that the NPDES permitting authority (referred to in the NPDES regulations as the Director)

[11] See Docket ID No. EPA–HQ–OW–2016–0376 at *http://www.regulations.gov.*

could extend the compliance dates for notification and/or submittal of the public notification plan for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship.

The proposed requirements address signage, initial and supplemental notification of local public health departments and other potentially affected public entities (which may include neighboring municipalities, public drinking water utilities, state and county parks and recreation departments and Indian tribes) whose waters may be potentially impacted, initial and supplemental notification of the public and annual notice to the public and the Director.

EPA further proposes to require NPDES permittees authorized to discharge CSOs to the Great Lakes Basin to develop a public notification plan that would provide community-specific details (*e.g.,* proposed flow monitoring locations, means for disseminating information to the public) as to how they would implement the notification requirements. Under the proposed rule, CSO permittees in the Great Lakes Basin would be required to seek and consider input from local public health departments, any potentially affected public entities and Indian tribes whose waters may be impacted by the permittee's CSO discharges in developing the public notification plan that would be submitted to the Director. The proposal would require the plan to be made available to the public and to be submitted to the Director within six months of the date the final rule is published.

Ultimately, public notice requirements for CSO discharges in the Great Lakes Basin would be incorporated as requirements in NPDES permits when such permits are next reissued at least six months after the date the final regulation is published. (This process will follow normal permit reissuance timelines). Under both proposed §§ 122.21(j)(8)(iii) and 122.38(d), the public notification plan would be submitted to the Director as part the Great Lakes Basin CSO permittee's application for a renewed permit. The plan would provide information to the Director to inform the development of a NPDES permit condition implementing the public notification requirements. EPA proposes minimum requirements at § 122.42(f) for a permit condition for all permits issued for CSO discharges within the Great Lakes Basin. See Preamble section III.D.2. for a discussion of the proposed permit condition.

B. Types of Notification

EPA proposes to require several types of public notification, as follows:

- Signage;
- Initial and supplemental notice to local public health department and other potentially affected public entities, such as drinking water utilities, public beach and recreation agencies;
- Initial and supplemental notice to the public; and
- Annual CSO notice to the Director and the public.

The types of notification are discussed below.

1. Signage

Signage at CSO outfalls and public access areas potentially impacted by CSO discharges can raise public awareness of the potential for CSO discharges and impacts. EPA's 1995 guidance, ''Combined Sewer Overflows—Guidance for Nine Minimum Controls'' [12] provides examples of signage that can be used to notify the public of CSO discharges, such as posting at affected use areas (*e.g.,* along a beach front), selected public places (*e.g.,* public information center at a public park or beach) and posting at CSO outfalls where outfalls are visible and the affected shoreline area is accessible to the public.[13]

EPA proposes that the Great Lakes Basin CSO permittee provide adequate signage where signage is feasible at CSO outfalls and potentially impacted public access areas. The Agency proposes that signage contain at a minimum the following information:

- The name of the combined sewer system operator;
- A description of the discharge (*e.g.,* untreated human sewage, treated wastewater);
- Notice that sewage may be present in the water; and
- The permittee's contact information, including a telephone number, NPDES permit number and outfall number as identified in the NPDES permit.

EPA also proposes that the Great Lakes Basin CSO permittee conduct periodic maintenance of the sign to ensure that it is legible, visible and factually correct.

The proposal would require the permittee to provide signage at potentially affected public areas. The permittee's identification of potentially affected public areas where signage is required is to be based on a review and consideration of local conditions and circumstances of a particular community. This determination may be informed by the identification of sensitive areas in the community's long term CSO control plan (LTCP). Under today's proposal, when a Great Lakes Basin CSO permit is reissued, the NPDES authority will determine specific locations where signs are required and will identify in the permit the location of any outfall where a sign is not required because it is not feasible.

EPA requests comment on providing more specific regulatory language that would require signage at locations other than the CSO outfalls, such as potentially impacted public access areas and selected public places that CSO discharges may impact.

One commenter on the August 1, 2016 notice suggested that signs at public access areas include quick response codes that could provide a link to either a public health department's Web site or the permittees Web site. EPA requests comment on requiring quick response codes on signs. EPA also requests comment on the proposed signage requirements and on whether the proposal includes the appropriate minimum information to be included on signs.

EPA notes that several of the Great Lakes states do not require signage at every CSO outfall for various reasons, such as limited or no public access to the area or the infeasibility for the permittee to physically access the outfall point for inspections and maintenance of signs. For example, Ohio does not require signs at outfalls that are not accessible to the public by land or by recreational use of the water body.[14] Indiana allows for alternatives to signs for outfalls located on private property or that are outside the jurisdiction of the CSO discharger.[15] New York allows permittees to apply for a waiver from the requirement to install a sign under limited circumstances which are listed in the state's regulations.[16]

The Agency requests comment on specific situations where it may not be feasible to provide signage at a CSO outfall. In addition, the Agency requests comment on alternative or additional regulatory criteria to clarify or describe

[12] See ''Combined Sewer Overflow Guidance for Nine Minimum Controls'' EPA 832–B–95–003, (1995). *https://www.epa.gov/sites/production/files/2015-10/documents/owm0030_2.pdf.*

[13] The 2016 ''National Pollutant Discharge Elimination System Compendium of Next Generation Compliance Examples'' and the 2016 ''Summary of CSO Public Notification provisions'' EPA–HQ–OW–2016–0376, identify additional examples of signage used by CSO communities.

[14] Ohio Admin. Code 3745–33–08 (2011), available at *http://codes.ohio.gov/oac/3745-33-08.*

[15] See 327 IAC 5–2.1–6 (2003), available at *http://www.in.gov/legislative/iac/iac_title?iact=327.*

[16] See 6 NYCRR 750–1.12 (2003), available at *http://www.dec.ny.gov/regs/2485.html.*

where signs are not possible. The Agency also requests comment on whether it is appropriate to remove the proposed qualification that signage be feasible and instead require signage at all CSO outfalls.

EPA recognizes that the Great Lake NPDES authorities require permittees to install signs at many CSO outfalls and potentially impacted public access areas. EPA proposes that where a permittee has installed a sign at a CSO outfall or potentially impacted public access area before the effective date of this rule, the sign does not have to meet the minimum requirements specified in the proposed rule until the sign is replaced or reset. EPA requests comment on this approach. The Agency requests comment on any specific language with regard to the proposed signage requirements that may be inconsistent with existing signs, and whether the proposed language should be adjusted to provide more flexibility.

EPA does not propose to prescribe the specific circumstances under which other methods of notice such as indicator lights (as used by the District of Columbia Water and Sewer Authority) or alert flags (as used by the Allegheny County Sanitary Authority) must be used. These types of notification may not be appropriate for every CSO community in the Great Lakes Basin. Rather, such requirements may be established on a permit-by-permit basis where appropriate. Nothing in the proposed rule or Section 425 would, however, preclude any Great Lakes state from establishing such requirements.

2. Initial and Supplemental Notice to Local Public Health Officials and Other Potentially Affected Public Entities

Local public health officials play a vital role in responding to environmental risks. Local public health organizations typically have a role in water quality monitoring of waterways and public beaches and in providing swimming and beach advisories and beach closures. Timely notice of CSO discharges to local public health departments can provide information needed to determine appropriate actions such as issuing swimming or beach advisories or beach closures.

When CSOs discharge into sources of drinking water, operators of drinking water facilities that have intakes in waters impacted by the discharge can make adjustments to their intake and treatment procedures after receiving notice of the CSO discharge.

EPA proposes that the operator of a CSO outfall in the Great Lakes Basin provide initial notice of the CSO discharge as soon as possible to the local public health department (or if there is no local health department, to the state health department), any potentially affected public entity (such as the superintendent of a public drinking water supply with potentially affected intakes), and Indian tribes whose waters may be affected, but no later than four hours after becoming aware as determined by monitoring, modeling or other means of a CSO discharge. The initial notice would be required to include, at a minimum, the following information:

- The location of the discharge(s) and the water body that received the discharge(s);
- The location and a description of any public access areas that may be potentially impacted by the discharge;
- The date(s) and time(s) that the discharge commenced or the time the permittee became aware of the discharge;
- Whether, at the time of the notification, the discharge has ended or is continuing and, if the discharge(s) has ended, the approximate time that the discharge ended; and
- A point of contact for the CSO permittee.

EPA proposes that the CSO permittee describe the location of the discharge. Typically, this would be the location of the CSO outfall that is discharging. However, for larger combined sewer systems with multiple outfalls, where CSO discharges occur at multiple locations at the same time, the CSO permittee may provide a description of the area in the waterbody where discharges are occurring and does not have to identify the specific location of each discharge. This approach may be more protective in that it may provide for a better description of potentially impacted areas, and could avoid delays associated with identifying when individual discharges commenced.

EPA also proposes that Great Lakes Basin CSO permittees be required to seek and consider input from local public health departments and other potentially affected entities to develop protocols for providing notification. Under the proposal, the CSO permittee is to seek and consider input from local health departments and other potentially affected entities prior to submitting its public notification plan initially and resubmitting as part of the process for reapplying for their permit.

The Agency anticipates that the Great Lakes Basin CSO permittee will establish protocols that will address the timing of notification. This could include predictive notifications that are based on weather forecasts. Under the proposed rule, the public notification plan would help inform the development of NPDES permit requirements that would specify the timing of this notification. EPA anticipates that this approach would allow for the consideration of community-specific factors, development of programs and changes in technology.

Timely notice of CSO discharges to public health departments, drinking water facilities and other affected municipal entities and Indian tribes is critical to the effectiveness and timeliness of their response. EPA does not propose to prescribe the specific means (*e.g.,* email, phone call) for this notice. Rather, the proposed rule would allow the CSO discharger to seek and consider input from local public health departments and other potentially affected public entities to determine the most appropriate way to provide this notice.

EPA proposes that the timeframe for initial notice to local public health departments and other potentially affected public entities be as soon as possible, but no later than four hours after the Great Lakes Basin CSO permittee becomes aware of the CSO discharge as determined by monitoring, modeling or other means. EPA expects, however, that as technologies change and communities and states improve their notice protocols, communities may be able to notify public health departments and the public in less than four hours. In addition, nothing in the proposed rule would preclude the permitting authority from establishing a maximum timeframe for notification that is more stringent (shorter) than four hours. EPA anticipates that NPDES permit authorities would consider more stringent notification timeframes based on a variety of factors, including the nature of the receiving waters, technology advances and the experience and progress of the permittee. EPA notes that New York and Connecticut require CSO permittees to notify public health departments within two hours. Both states have state-run Web sites that facilitate notification. The Agency also notes that most Great Lake states currently have not established a state Web site to facilitate public notification. EPA specifically requests comment on the appropriate maximum timeframe for providing initial notification to the local public health department and other potentially affected entities. The Agency also requests comment on the minimum contents of the initial and supplemental notification to the local public health department and other potentially affected entities.

Section 425(b)(3)(A)(ii) provides that public notice requirements also must include the volume of the discharge. EPA recognizes that for a number of reasons, determining the volume of a CSO discharge within the short timeframe provided for the initial notice may not be practical. EPA therefore proposes that notification of the volume of the discharge may occur in a supplemental notice that would be required within 24 hours of the end of the CSO discharge. EPA proposes this approach because the initial notification that a CSO discharge may occur or is occurring should not be delayed by waiting until the discharge stops or volume estimates are developed. EPA is concerned that requiring the Great Lakes Basin CSO permittee to include the volume of the CSO discharge as part of the initial notification would mean that the initial notification would need to be delayed, which would in turn cause delays in responding to the overflow. In addition, requiring an estimate or calculation of the discharge volume as part of the initial notification may discourage predictive notifications. It is critical that the local public health department and other affected municipalities or tribes be notified of the occurrence of the event as soon as possible without delays associated with waiting for the discharge to end or determining the CSO volume. Accordingly, EPA proposes that the CSO permittee may either provide notification of the time the discharge ended and the volume of the CSO discharge as part of the initial notification when CSO discharges are of a short enough duration to allow for this information to be known, or as a separate supplemental notification within 24 hours of the end of the CSO discharge.

EPA requests comment on whether 24 hours from the time the permittee becomes aware that the discharge ended is the appropriate time period for completing notification. EPA also requests comment on whether the proposed minimum requirements for the 24-hour supplemental notice are sufficient and appropriate.

The proposed requirement to provide a volume estimate would not mandate monitoring or direct measurement of CSO discharges. As discussed below, EPA proposes that the operator of a CSS with CSO discharges to the Great Lakes Basin develop a public notification plan that, among other things, describes for each outfall how the volume and duration of CSO discharges would be measured or estimated. In addition, as discussed below, EPA proposes that NPDES permits for CSO discharges to the Great Lakes Basin specify the location of CSO discharges that must be monitored for volume and discharge duration and the location of CSO discharges where CSO volume and duration may be estimated rather than monitored.

In addition to seeking comment generally on the proposed requirements for notifying local health departments and other potentially affected public entities, EPA requests comment specifically on whether the initial notice to public health departments and other potentially affected entities should also be provided to the Director and/or the state public health agency.

3. Initial and Supplemental Notice to the Public

Initial notice of CSO discharges to the public via text alerts, social media, posting on a Web site, or other appropriate means can be an effective, efficient means of alerting the public to CSO discharges in a timely manner. This initial notice may allow the public to make informed decisions regarding areas where they would visit and recreate. EPA proposes requirements for the Great Lakes Basin CSO permittee to provide initial notification to the public within four hours of becoming aware as determined by monitoring, modeling or other means of the CSO discharge. Under the proposal, the Great Lakes Basin CSO permittee would be required to use electronic media, such as text, email, and social media alerts to subscribers, or posting a notice on its public access Web site, to provide members of the public with notice of CSO discharges. Other electronic media that could be used include broadcast media (radio and/or television) and newspaper Web sites. However, EPA is not proposing a specific type of electronic media to be used by all CSO communities as electronic media technologies and usage continue to change and the availability and appropriateness of different media options will vary from community to community. EPA seeks comment on whether public notice by broadcast media and/or local newspapers should be required for all CSO permittees in the Great Lakes Basin, or whether this specificity is better addressed in permits.

EPA proposes the same minimum information content requirements that it proposes for the initial notice to the local public health department, with the exception that a point of contact for the discharger is not included in the notice to the general public. EPA does not propose to require that a point of contact be provided in the notice for the public because this could generate a large number of calls or emails to the CSO permittee that could hinder the permittee's ability to respond to the CSO discharge and to communicate with public health officials and other affected municipal entities.

EPA also proposes that the Great Lakes Basin CSO permittee provide a supplemental notice specifying the time the discharge ended and the volume of the CSO discharge unless this information has already been provided in the initial notice. EPA proposes that the supplemental public notice would be required within 24 hours of the end of the CSO discharge.

As mentioned above, EPA received a number of comment in response to the August 1, 2016 **Federal Register** document, in writing and at the public listening session on September 14, 2016, regarding notification methods and timeframes for notification to the public. One commenter recommended that information on how to receive email or text alerts should be provided to the public on the permittee's Web site and in wastewater bill mailings. EPA requests comment on whether the proposed regulation should include specific requirements for the permittee to make information on how to receive alerts available to the public.

One commenter indicated that it would not be possible to estimate system-wide CSO volumes within 24 hours, given the size of their system, size of the storm, number of outfalls, number of receiving waters, and other complex factors that are considered to determine overflow locations, timing, and volumes. Another commenter recommended that the supplemental notice be required within 24 to 48 hours. Another commenter recommended that the Great Lakes Basin CSO permittee be given five days before discharge volume estimates must be provided. Other commenters advocated for real-time or faster alerts such as requiring public notification within 15 minutes, if possible. Another commenter suggested that if real time monitoring is not feasible, all discharges should be required to notify the public within two hours of the start of the CSO discharge.

Other commenters expressed concerns about the time it would take to provide detailed notification. For example, one comment said reporting in-depth on volume, length of discharge and preventative measures for each CSO event would take resources away from more critical water quality initiatives. EPA requests comment on whether the 24-hour time period is appropriate and whether the minimum information

requirements for the 24-hour notice are appropriate.

EPA requests comment on providing a longer timeframe than four hours for small communities to make the initial notification, such as eight or twelve hours as well as appropriate population thresholds (*e.g.,* under 2,000 or 1,000) for such a requirement. Some of the representatives of the Great Lakes states expressed concerns that introducing an alternative timeframe for initial reporting for small communities could create confusion in the regulated community. EPA requests comment on the appropriateness of the proposed four-hour time period and on whether all communities should be subject to the same four-hour maximum timeframe for providing initial notification.

Some commenters responding to the August 1, 2016 **Federal Register** document raised concerns that overuse of text alerts of CSO discharges to the public could be counter-productive because the public could be over saturated by the alerts and the alerts overly simplify a complex message about health risks. Another commenter raised concerns that supplemental notifications indicating that CSO discharges have ceased may send an incorrect message that the waters are safe. EPA requests comment on allowing permittees flexibility to use different mechanisms for providing initial and supplemental notice (*e.g.* text/email alerts and Web site notice for initial notification and limiting supplemental notice to posting information on the permittees Web site).

4. Annual CSO Notice

EPA proposes that all permittees authorized to discharge a CSO to the Great Lakes Basin are required to make an annual notice available to the public by the first of May each year. In addition, EPA proposes that the permittee notify the Director of the availability of the annual notice. The information in the annual notice would provide the public with a comprehensive understanding of how the permittee's CSS is performing and of the permittee's CSO control program. The Agency proposes that the annual notice would include a summary of both the prior year's discharges and upcoming implementation of CSO controls. EPA proposes that the annual notice include at a minimum:

- A description of the availability of the permittee's public notification plan and a summary of significant modifications to the plan that were made in the past year;
- A description of the location, treatment provided, and receiving water of each CSO outfall;
- The date, location, duration, and volume of each wet weather CSO discharge that occurred during the past calendar year;
- The date, location, duration, and volume of each dry weather CSO discharge that occurred during the past calendar year;
- A summary of available monitoring data from the past calendar year;
- A description of any public access areas impacted by the discharge;
- Representative rain gauge data in total inches to the nearest 0.1 inch that resulted in each CSO discharge;
- A point of contact; and
- A concise summary of implementation of the nine minimum controls and the status of implementation of the long-term CSO control plan (or other plans to reduce or prevent CSO discharges), including:
  - A description of key milestones remaining to complete implementation of the plan; and
  - A description of the average annual number of CSO discharges anticipated after implementation of the long-term control plan (or other plan relevant to reduction of CSO overflows) is completed.

The proposed elements of the annual notice summarize the information provided in the initial and supplemental notifications to the public and provide additional follow-up information required in Section 425(b)(4)(A). Section 425(b)(4)(A) requires inclusion of follow-up notice requirements that provide a description of ''(i) each applicable discharge; (ii) the cause of the discharge; and (iii) plans to prevent a reoccurrence of a combined sewer overflow discharge to the Great Lakes Basin consistent with section 402 of the Federal Water Pollution Control Act (33 U.S.C. 1342) or an administrative order or consent decree under such Act.''

EPA proposes an annual notice requirement that would address the information required by Section 425(b)(4)(A)(ii) and (iii) by requiring a summary of how the CSO permittee is implementing the nine minimum controls and their LTCP. The summary would include a description of key milestones remaining to complete implementation of the LTCP and a description of the anticipated average annual number of CSO discharges after the LTCP is completed.

As described in section II.C of this preamble, Section 402(q) of the CWA (33 U.S.C. 1342(q)), provides that NPDES permits and enforcement orders for discharges from combined sewer systems ''shall conform'' to the 1994 CSO Control Policy. By requiring the annual report to summarize how the permittee is implementing the nine minimum controls and LTCP, the proposed rule would result in a description of the permittee's plans under their permit, administrative order or consent decree, ''consistent with section 402 of the Federal Water Pollution Control Act (33 U.S.C. 1342) or an administrative order or consent decree under such Act'' as required by Section 425(b)(4)(A)(iii). This information is intended to provide the public with a description of the current performance of their system as well as progress on CSO reduction. This notice can serve to increase public awareness, and enable the public to better understand the community's current and future investments into collection system infrastructure. This can promote stronger public support for actions necessary to reduce CSOs. EPA requests comment on the proposed elements of the annual notice.

EPA anticipates that any community that already generates an annual CSO report would ensure that the required elements of the proposed rule are addressed in that report and then use that annual CSO report to comply with the annual notice requirements proposed today, rather than generating a separate report solely to meet these new requirements. Communities choosing this approach under the proposed rule would need to ensure that the annual report is published to their Web site by the date specified in the proposed rule (May 1 of each calendar year).

EPA requests comment on requiring permittees to supplement the annual notice by providing quarterly notice of a description of each CSO discharge, the cause of the discharge, and plans to prevent a reoccurrence of the CSO discharge. This approach may assist interested members of the public in following the status of CSO remediation efforts in their communities in a more up-to-date timeframe. EPA requests comment on this approach or other means of updating the public more frequently than annually.

C. Public Notification Plans

EPA proposes requirements for public notification plans at § 122.38(d). The Agency proposes that Great Lakes Basin CSO permittees be required to develop and submit to the Director a public notification plan within six months after publication of a final rule and then as part of the permittee's application for permit renewal. In addition, EPA proposes at § 122.38(e) that, prior to

submitting the proposed public notification plan, CSO permittees must seek and consider input from the local public health department (or if there is no local health department, the state health department) and potentially affected public entities and Indian tribes whose waters may be affected by CSO discharges.

The public notification plans are intended to provide system-specific detail (*e.g.,* proposed monitoring locations, means for disseminating information to the public) describing the discharger's public notification efforts. The plan will enhance communication with public health departments and other potentially affected public entities and Indian tribes whose waters may be affected by the CSO discharge. The plan would also assist NPDES permit writers in establishing public notification permit conditions. In addition, the plan would provide the public with a better understanding of the permittee's public notification efforts.

Under the proposal, the plan would describe:

- The permittee's signage program;
- The identification of municipal entities that may be affected by the permittee's CSO discharges;
- Input from the health department and other potentially affected entities;
- Protocols for the initial and supplemental notice of the public, public health departments and other public entities;
- How the volume and duration of CSO discharges would be determined; and
- Protocols for making the annual notice available to the public.

Regarding signage, the plan would describe what information is in the message on the signs and identify any CSO outfall where a sign under § 122.38(a)(1) is not and will not be provided, explain why a sign at that location is not feasible. The plan would also describe the maintenance protocols for signage, such as inspection intervals and replacement schedule.

Section 425(b)(3)(A)(iii) of the 2016 Consolidated Appropriations Act provides that public notice for CSO discharges is to include a description of any public access areas impacted by the discharge. EPA proposes to lay the groundwork for this provision by requiring that public notification plans identify which municipalities and other public entities may be affected by the permittee's CSO discharges. Potentially affected public entities whose waters may be affected by the CSO discharge could include adjoining municipalities, public drinking water utilities, state and county parks and recreation departments. Such areas may have already been identified in the CSO permittee's LTCP, which should identify CSO discharges to sensitive areas.[17] In deciding which public entities and Indian tribes are ''potentially impacted'' and should be contacted for their input, the Great Lakes Basin CSO permittee should evaluate:

- The location of the CSO discharge point and what users of that waterbody may exist in the surrounding region;
- The direction of flow in the receiving water and uses of that waterbody, or connected waterbodies, downstream of the CSO discharge point;
- The presence of public access areas near, or downstream of, the discharge point;
- The presence of drinking water supply systems near, or downstream of, the discharge point; and
- The presence of municipal entities, Indian tribes, and/or parks and recreation department lands near, or downstream of, the discharge point.

EPA proposes that the plan would identify any municipality and Indian tribe that was contacted for input on public notification protocols. In addition, the plan would provide a summary of the comments and any recommendations from these entities, as well as a summary of the significant comments and recommendations provided by the local public health department(s).

Local public health departments, public entities, and Indian tribes whose waters may be affected by a CSO discharge are in a unique position to recommend the timing, means and content of the public notification requirements addressed in this proposal. Seeking input from these entities would allow the permittee to reflect in the public notification plan the needs and preferences of these entities with regard to notice of CSO discharges. Also, these groups can help inform decisions regarding what is the most appropriate means of communicating information to the public, taking into consideration specific populations in the community and their access to various electronic communication methods and social media. For example, if there is a segment of the population without access to cell phones or computers, or who would incur costs by receiving text notifications, the consulted entities may suggest other communications means that would be more appropriate to reach these groups (*e.g.,* radio broadcast, postings in public places, announcements through community flyers).

The plan would also be required to describe how the volume and duration of CSO discharges would be either measured or estimated. If the Great Lakes Basin CSO permittee intends to use a model to estimate discharge volumes and durations, the plan would be required to summarize the model and describe how the model was or would be calibrated. CSO permittees that are a municipality or sewer district with a population of 75,000 or more must calibrate their model at least once every 5 years.

EPA requests comment on the minimum elements of a plan listed in § 122.38(c) and whether additional minimum requirements may be appropriate. Other such elements could include: A description of outreach that would be conducted to alert the public of the notification system and how to subscribe or otherwise gain access to the information, and information on how the public notification plan would be made available to the public. In addition, EPA seeks comment on requiring Great Lakes Basin CSO permittees to seek and consider input from public health departments and other potentially affected entities in developing their public notification plans. EPA also requests comment on whether the final rule should specifically require that the permittee provide an opportunity for members of the public to review and comment on the public notification plan, as was suggested by one commenter responding to the August 1, 2016 **Federal Register** document.

EPA proposes that the Great Lakes Basin CSO permittee make its public notification plan available to the public on the permittee's Web site (if it has a Web site) and periodically provide information in bill mailings and by other appropriate means on how to view the notification plan. The EPA seeks comment on whether there should be specific requirements for requiring notice of the plan and if so, how the plan should be made available. In addition, EPA seeks comment on whether there should be specific requirements for requiring notice of when significant modifications are made to the plan.

[17] The CSO Policy clarifies EPA's expectation that a permittee's LTCP give the highest priority to controlling overflows to sensitive areas. The Policy provides that sensitive areas, as determined by the NPDES authority in coordination with State and Federal agencies, as appropriate, include designated Outstanding National Resource Waters, National Marine Sanctuaries, waters with threatened or endangered species and their habitat, waters with primary contact recreation, public drinking water intakes or their designated protection areas, and shellfish beds. (59 FR 18692).

D. Implementation

EPA proposes to implement the public notification provisions as a stand-alone regulatory requirement until the proposed required condition is incorporated into the NPDES permit of the Great Lakes Basin CSO permittee. Section 425(b)(5) of the 2016 Consolidated Appropriations Act provides that the notice and publication requirements described in the Act are to be implemented by ''not later than'' December 18, 2017. The Act also provides that the Administrator of the EPA may extend the implementation deadline for individual communities if the Administrator determines the community needs additional time to comply in order to avoid undue economic hardship. The Agency recognizes that if NPDES permits were the only means of implementing these requirements, permits would have to be reissued with these requirements before they would take effect. Given the current status of CSO permits in the Great Lakes Basin, it would take over five years for the proposed public notification requirements to be incorporated into all permits. Implementing the public notification requirements by regulation would result in all Great Lakes Basin CSO permittees establishing their public notification system within the same timeframe, and is more consistent with the implementation deadline in Section 425(b)(5)(A).

In addition to Section 425 of the Consolidated Appropriations Act of 2016, EPA's authority for these public notification requirements includes Sections 304(i) and 308 of the CWA, which provide broad authority to issue procedural requirements for reporting (including procedures to make information available to the public) and to require point source owners and operators to establish and maintain records, make reports, monitor, and provide other ''reasonably required'' information.

The requirements of § 122.38(a) (signage and notification requirements), § 122.38(b) (annual notice), § 122.38(c) (reporting) would be enforceable under the CWA prior to incorporation into a permit as requirements of CWA section 308. With respect to the public notification plan, the requirement to develop a public notification plan consistent with § 122.38(d) and (e) would also be enforceable under the CWA as a requirement of CWA section 308. Once public notification requirements are incorporated into an NPDES permit, they would enforceable as a condition of permit issued under CWA section 402.

The details and content of the public notification plan, however, would not be enforceable under § 122.38(d) or as effluent limitations of the permit, unless the document or the specific details with the plan were specifically incorporated into the permit. Under the proposed approach, the contents of the public notification plan would instead provide a road map for how the permittee would comply with the requirements of the permit (or with the requirements of § 122.38(a)–(c) prior to inclusion in the permit as a permit condition). Once the public notification requirements are incorporated into the permit as a permit condition, the plan could be changed based on adaptions made during the course of the permit term, thereby allowing the permittee to react to new technologies, circumstance and experience gained and to make adjustments to its program to provide better public notification and better comply with the permit. This approach would allow the CSO permittee to modify and continually improve its approach during the course of the permit term without requiring the permitting authority to review each change as a permit modification.

1. Section 122.38 Requirements

As discussed in detail above, a new § 122.38 would set forth requirements that would apply to all permittees with CSO discharges to the Great Lakes Basin. Under the proposed rule, Great Lakes Basin CSO permittees would be required to develop a public notification plan, after seeking and considering input from public health departments and other potentially affect public entities. EPA proposes that the plan must be submitted to the Director and made available to the public within six months of publication of the final rule. Proposed § 122.38 would also require implementation of the signage and notice to affected public entities and the public within six months of publication of the final rule. Thus, a Great Lakes Basin CSO permittee would be required to develop its plan and implement it within six months of the final rule.

EPA has considered how much time it should take to implement public notification requirements. EPA also recognizes that every Great Lakes Basin CSO permittee already provides some public notification, in order to implement one of the nine minimum control measures in the 1994 CSO Control Policy. However, small communities in particular may not provide public notification to the extent that would be required under the proposed rule. Therefore, EPA seeks comment on whether six months is adequate for implementing the proposed public notification requirements, including development of a public notification plan. In particular, EPA seeks comment on whether some (*e.g.,* small) communities should have more time than others to implement public notification requirements and/or whether there should be additional time to implement the signage or notification requirements after the public notification plan is developed, submitted to the Director, and made available to the public, and if so, how much additional time should be allowed. For example, should municipal permittees with a population of less than 10,000, or in the case of sewerage districts, a service population of less than 10,000, be required to submit a public notification plan to the Director within nine or 12 months after the publication of the final rule, rather than six months?

2. Required Permit Condition

EPA's long-term objective is to use NPDES permits to implement public notice requirements for CSO discharges in the Great Lakes Basin. To that end, EPA proposes to revise both the permit application regulation requirements in § 122.21(j) and to add a required permit condition for NPDES permits issued for these discharges. EPA proposes to add § 122.21(j)(8)(iii) to require the CSO permittees in the Great Lakes Basin to submit a public notification plan to the Director with its permit application (and any updates to its plan that may have occurred since the last plan submission). EPA also proposes to add a new condition at § 122.42(f) that would apply to permits for CSO discharges to the Great Lakes Basin. The proposed provision would ensure that CSO public notice requirements are incorporated into the NPDES permit where they can be updated as appropriate with each permit cycle. Public notification plans, submitted with subsequent permit applications, would reflect changes in collection systems and technology, as well as public notice practices. By requiring the Great Lakes Basin CSO permittee to include its updated public notice plan with its permit application, the Director would have the information that would be needed for including requirements for public notification in the permit when it is reissued.

The proposed required permit condition would provide flexibility in a number of areas to allow NPDES permit writers to address in their plans the particular circumstances of each

community (*e.g.,* size of community, differences in public access areas potentially impacted by a CSO discharge). This provision would not preclude the Great Lake states from modifying the condition to establish more stringent public notification requirements (see Section 425(b)(6) of the 2016 Consolidated Appropriations Act).

As outlined in § 122.42(f) of the proposed rule, permits for CSO discharges within the Great Lakes Basin would, at a minimum:

- Require implementation of the public notification requirements in § 122.38(a);
- Specify the information that must be included on outfall signage;
- Specify outfalls and public access areas where signs are required;
- Specify the timing and minimum information for providing initial notification to local public health departments and other potentially affected entities and the public;
- Specify the location of CSO discharges that must be monitored for volume and discharge duration and the location of CSO discharges where CSO volume and duration may be estimated;
- Require submittal of an annual notice;
- Specify protocols for making the annual notice available to the public; and
- Require all CSO discharges be reported electronically either in a discharge monitoring report or as a non-compliance event.

Section 402(q) of the CWA requires NPDES permits for discharges from combined sewers to ''conform'' to the 1994 CSO Control Policy. One of the ''Nine Minimum Controls'' identified in the Policy is that NPDES permits for CSO discharges require public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts. The proposed required permit condition would conform to the 1994 CSO Control Policy's minimum control to provide the public with ''adequate notification'' and would further provide specificity to better implement the public notification provision identified in the Policy. Including this provision in permits would give the Great Lakes states an opportunity to update and fine-tune public notice requirements to reflect continued development of the permittee's public notice effort, ensure consistency with state legislative and regulatory requirements for public notification, reflect new technologies and be informed by public input. In addition, by including public notification requirements as a condition in permits, the public would have a formalized opportunity to comment on the proposed permit conditions.

E. Additional Considerations

1. Definitions

EPA proposes to add three definitions to the NPDES regulations, ''Combined Sewer System,'' ''Combined Sewer Overflows,'' and ''Great Lakes Basin.'' The proposed definition of *combined sewer system* is based on the description of combined sewer system found in the 1994 CSO Policy. The Policy provides that ''A combined sewer system (CSS) is a wastewater collection system owned by a state or municipality (as defined by § 502(4) of the CWA) which conveys sanitary wastewaters (domestic, commercial and industrial wastewaters) and storm water through a single-pipe system to a Publicly Owned Treatment Works (POTW) Treatment Plant (as defined in § 403.3(p)).'' The proposed definition of *combined sewer overflow* also conforms to the description of CSO in the CSO Policy which provides that a ''CSO is the discharge from a CSS at a point prior to the POTW Treatment Plant.''

The 2016 Consolidated Appropriations Act specifies in Section 425(a)(4) that the term ''Great Lakes'' means ''any of the waters as defined in the § 118(a)(3) of the Federal Water Pollution Control Act (33 U.S.C. 1292).'' This, therefore, includes § 118(a)(3)(B), which defines ''Great Lakes'' as ''Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior, and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border);'' and § 118(a)(3)(C), which defines ''Great Lakes System'' as ''all the streams, rivers, lakes, and other bodies of water within the drainage basin of the Great Lakes.'' Collectively, EPA is referring to the Great Lakes and the Great Lakes System as the ''Great Lakes Basin.''

2. List of Treatment Works

Section 425(b)(4)(B) provides that EPA shall work with the Great Lakes states to establish annual publication requirements that list each treatment works from which the Administrator or the affected state receive a follow-up notice. EPA has developed a Web page that identifies the communities in the Great Lakes Basin with CSO discharges.[18] In the future, EPA will update this Web page with information on how to access the annual notices of these communities.

3. Adjusting Deadlines To Avoid Economic Hardship

Section 425(b)(5)(A) of the 2016 Appropriations Act provides that the notice and publication requirements of the provision must be implemented by not later than December 17, 2017, unless the EPA Administrator determines the community needs additional time to comply in order to avoid undue economic hardship. All of the Great Lakes states are authorized to administer the NPDES program. Because EPA proposes to implement Section 425 as part of the NPDES permit program, under proposed § 122.38(f), this determination would be made by the Director. As the NPDES authority, the state is in a better position to evaluate the economic conditions and financial capability of the permittee as they have worked with individual communities to ensure implementation of their LTCPs.

EPA proposes that the Great Lakes Basin CSO permittee must submit a public notification plan to the Director of the NPDES program not later than six months after publication of a final rule. The Great Lakes Basin CSO permittee would be required to comply with the public notice requirements of § 122.38 by six months for initial and supplemental notifications and 12 months in the case of annual notification, after publication of a final rule, unless the Director specifies a later date to avoid economic hardship. Under the proposed rule at § 122.38(e), the Director may extend the compliance dates for public notification under § 122.38(a), annual notice under § 122.38(b), and/or public notification plan submittal under § 122.38(c) for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship. The proposed rule would require the Director to notify the Regional Administrator of the extension and the reason for the extension. In addition, the Director would be required to post on its Web site a notice that includes the name of the community and the new compliance date(s). EPA also proposes to amend 40 CFR 123.25, which sets forth the requirements of an approved state NPDES program, to include a requirement for Great Lakes States to have the authority to implement the public notification requirements in § 122.38. No revision to § 123.25 would be needed with respect to proposed revisions to § 122.21(j) and § 122.42, as both of those sections are already included in § 123.25. As noted above in

[18] *https://www.epa.gov/npdes/combined-sewer-overflows-great-lakes-basin.*

section II.G of today's preamble, all of the Great Lakes States already have some form of public notification requirements, therefore EPA does not anticipate that any Great Lakes state would need to revise its regulations or seek additional authority from the legislature to implement proposed § 122.38 or revised § 122.21(j) and § 122.42.

EPA requests comment on this proposed implementation of Section 425(b)(5)(B).

4. Notification of CSO volumes

Most NPDES permits for CSO discharges to the Great Lakes Basin require the permittee to report CSO volumes in DMRs. In addition, CSO discharge volume information is typically needed to implement the nine minimum controls and LTCPs under the CSO Policy. One of the nine minimum controls identified in the CSO Control Policy addresses monitoring to effectively characterize CSO impacts and the efficacy of CSO controls. Similarly, one of the minimum elements of a LTCP is characterization monitoring and modeling of the CSS. In addition, the post-construction compliance monitoring program in the CSO Policy calls for effluent and ambient monitoring. EPA has issued technical guidance on monitoring and modeling of CSO discharges.[19] EPA has also identified examples of where CSO monitoring technologies have also been used by regulators and communities to better identify significant pollution and noncompliance problems in the ''NPDES Compendium of Next Generation Compliance Examples.''[20]

Typically, CSO permittees use a combination of monitoring and modeling to estimate CSO volume. This approach is reflected in many CSO permits that require monitoring of CSO discharges from some outfalls, and for other outfalls allows for estimating CSO discharge volumes by modeling or some other means. For larger collection systems with multiple outfalls, the permit may require monitoring the volume discharged at the most active outfalls with the largest discharge volumes. CSO permits may provide that for less active CSO outfalls, the permittee report volume in the DMR based on estimates. In some cases, volume estimates for DMR reporting purposes are based on models which were developed to characterize flows in the collection system as part of developing and implementing a LTCP. These models can vary in complexity, and may be calibrated by periodic flow measurements or other data from various locations in the collection system.

The Agency recognizes that for many CSO permittees, CSO monitoring efforts have tended to become more robust as monitoring technology has evolved and continues to evolve. In general, EPA encourages CSO permittees to consider using monitoring to determine CSO discharge durations and volume. Traditionally, the cost of installing and maintaining monitoring sensors has been high when compared to modeling. However, the cost of monitoring technologies has decreased and is expected to continue to do so. In addition, new tools are being developed to communicate, analyze and display data collected by these monitoring technologies. One example of a CSO community with a more comprehensive monitoring program is the City of Seattle, WA. The NPDES permit for CSO discharges in Seattle (WA0031682) requires the permittee to use automatic flow monitoring equipment to monitor the discharge volume, discharge duration, storm duration and precipitation at all 86 CSO outfalls from the CSS. In another example, the Capital Region Water (CRW) in Harrisburg, PA is conducting a pilot study to evaluate the potential use of CSO activation monitoring equipment.[21] CRW will use the results of this pilot study to determine which technology to implement to send an alert each time a monitored CSO outfall begins discharging.

Some of the public comments received in response to EPA's August 1, 2016 **Federal Register** document discussed several challenges associated with volume measurement and reporting. Some commenters suggested that wastewater monitoring devices may be placed in a harsh environment and require active maintenance. One commenter suggested that the configuration of a CSO outfall may present unique and challenging circumstances which make monitoring difficult. For example, discharges from the outfall may include contributions from separate storm sewers or wastewater flows may be influenced by currents and tides in the receiving water.

Many commenters discussed the importance of flexibility for Great Lakes Basin CSO permittees to determine the data collection method that works best for their community. A commenter also recommended that CSO discharge volume be noticed in a simplified way that is easier to understand for the public, such as small, medium, or large discharges. Another commenter indicated that installing, operating, and maintaining meters at each of their 52 CSO locations would be cost prohibitive.

The proposed rule would require the Great Lakes Basin CSO permittee to provide an estimate of CSO discharges volumes as part of the supplemental notice to the initial notification to the local public health department and other potentially affected public entities and the supplemental notification to the public. The proposal would require this information within 24-hours of becoming aware that the CSO discharge has ended. In addition, the proposal would require the CSO discharger to provide the volume of each CSO discharge that occurred during the past calendar year in the annual notice. EPA anticipates that the information in the annual notice may reflect refinements in the volume and duration estimates provided at the time of the supplemental notification, and therefore these numbers may not be the same. EPA requests comment on the adequacy of a 24-hour reporting window for reporting CSO discharge volume and duration data. EPA also requests comment on whether these data should be required to be reported for each outfall, or whether it would be appropriate to allow for reporting aggregated data at the water body or stream or river segment level.

Under the proposed approach, where a CSO permittee has CSO discharges occurring at multiple locations at the same time, the CSO permittee would not have to estimate the volume discharged for each outfall, but would be allowed to make an estimate of the cumulative volume of CSOs discharged to a given waterbody. This approach would simplify the information provided to the public and focus on individual watersheds. This is consistent with the proposed notification requirements for outfalls, which would not require identification of individual outfalls in all cases. EPA requests comment on this approach.

Under the proposed approach, the Great Lake states would determine

[19] See ''Combined Sewer Overflows—Guidance for Monitoring and Modeling'' EPA–832–B–99–022, 1999 and ''CSO Post Construction Compliance Monitoring Guidance'', EPA–833–K–11–001, 2012). *https://www.epa.gov/npdes/combined-sewer-overflows-csos.*

[20] See *https://www.epa.gov/compliance/compendia-next-generation-compliance-examples-water-air-waste-and-cleanup-programs.*

[21] See the Consent Decree between Harrisburg, PA, Capital Region Water (CRW), the Pennsylvania Department of Environmental Protection and EPA (U.S. District Court for the Middle District of Pennsylvania, Civil Action No. 1:15–cv–00291–WWC). (*https://www.epa.gov/sites/production/files/2015-02/documents/cityofharrisburg-cd.pdf.*)

which outfalls must be monitored and where volume estimates are appropriate for the purpose of public notification when reissuing CSO permits. This approach would provide flexibility for adapting volume reporting requirements that would be consistent with and build on ongoing compliance and implementation monitoring and could respond to technology advancements that occur in the future. The flexibility would also allow states and permittees to focus on system specific priorities (*e.g.,* highest priority outfalls, predictive modeling).

5. Treated Discharges

Section 425(b)(1) of the 2016 Consolidated Appropriations Act requires EPA to work with the Great Lake states to establish public notice requirements for CSO discharges. The Agency recognizes that some CSO discharges receive treatment, including solids removal and disinfection, such that the end-of-pipe discharge may meet state water quality standards, including standards for bacteria indicators designed to protect recreational uses. Under the proposal and consistent with Section 425(b)(1), permittees would be required to provide public notice for all CSO discharges, regardless of the level or type of treatment a CSO received, if any, prior to discharge. However, nothing in the proposed rule would preclude permittees from also describing the level of treatment that various CSO discharges receive.

EPA received comments at the listening session on September 14, 2016 in response to EPA's August 1, 2016 **Federal Register** document that indicate that some municipalities with engineered treatment systems for CSO discharges do not believe primary treated and disinfected CSO discharges should be subject to the same public notification requirements as untreated discharges. In addition, some state workgroup members have also made this recommendation, including those from Michigan and Indiana.

The Agency requests comment on whether it would be appropriate to establish alternative public notice requirements for CSO discharges that are treated to a specified level (*e.g.,* primary treatment plus disinfection). EPA requests comment on whether the final regulations should provide additional flexibility for Great Lakes Basin CSO permittees to recommend in their public notification plan different public notification procedures for treated CSO discharges as compared to untreated CSO discharges. One approach would be to provide the NPDES authority with flexibility to not require initial notification requirements in the permit for treated CSO discharges. Another approach would be to only establish initial notification requirements in proposed § 122.38 for CSO discharges that are not in compliance with permit limits or that do not receive at least primary treatment and disinfection. EPA requests comment on this flexibility. The existing practices in the state of Indiana allow such flexibility.[22] Other states, such as New York, require public notification for all CSO discharges, including treated discharges.[23] Still another approach is to limit initial notification of treated CSO discharges to public health officials and other impacted communities. However, EPA notes that traditional bacteria indicators that are used in state water quality standards may not be the best indicators of viral and other pathogens associated with fecal contamination.[24] CSO discharges that only receive primary treatment prior to disinfection and that meet water quality standards based on indicator bacteria may have levels of viruses and other pathogens that are higher than discharges of wastewater that are treated by secondary treatment processes prior to disinfection. This is because bacteria respond to water treatment processes and environmental degradation processes differently than viruses. In addition, particles in wastewater may shield pathogens from disinfection.[25] CSO discharges that only receive primary treatment prior to disinfection may also have higher levels of trihalomethanes and other disinfection byproducts due to the higher concentration of chlorine needed to disinfect and potential interactions with particles in the wastewater.

Some of the entities from whom input is sought in the plan development may prefer to receive notice of all CSO discharges, regardless of treatment status, because of the potential risks posed by elevated pathogen levels (*e.g.,* drinking water facilities may want notification because of concerns about elevated levels of viruses or other pathogens in the source water).

6. More Stringent State Requirements

Consistent with Section 425(b)(6) of the 2016 Consolidated Appropriations Act, nothing in the proposal would prohibit a Great Lakes state from establishing notice requirements for Great Lakes Basin CSO permittees in that state that are more stringent than the requirements proposed today. The NPDES regulations specifically allow for state NPDES permit authorities to establish permit requirements that are more stringent than the permit conditions specified at § 122.42 (see § 123.25(a)).

7. Reporting

Most NPDES permits for CSO discharges to the Great Lakes Basin require all CSO discharges be reported in a DMR at a frequency specified in the permit or within 24 hours pursuant to § 122.41(l)(6). As discussed in section II.D of today's preamble, the NPDES electronic reporting rule requires that these reports be made electronically. EPA proposes that all NPDES permits for CSO discharges to the Great Lakes Basin require that all CSO discharges are reported electronically. In addition, the Agency proposes a provision in § 122.43(f) that would require Great Lakes Basin CSO permittees to electronically report any CSO discharge that occurred during the past calendar year that has not been previously reported pursuant to a permit requirement by May 1 of the following calendar year.

These proposed provisions are intended to ensure that the NPDES electronic database has complete information on CSO discharges to the Great Lakes Basin and to minimize any potential discrepancies between a permittee's annual notice and the NPDES electronic database.

8. Ambient Monitoring

One municipality has suggested that a targeted approach to public notification

[22] Indiana's interpretation is based on the stated purposes in 327 IAC 5–2.1–1, and the definitions of ''Affected Public'' and ''Affected Waters'' in 327 IAC 5–2.1–3(1) & (2). These provisions signify the intent of the notification rule is to properly warn citizens of possible health impacts from exposure to waterborne pathogens/E. coli related to CSO events. Notifications to health departments and drinking water suppliers are also related primarily to waterborne pathogen concerns. Any ''treated'' CSOs in Indiana must meet the minimum treatment requirements of the Federal CSO Policy (which includes disinfection). ''Treated'' CSO discharges are regulated in Indiana's NPDES permits with appropriate effluent sampling and numeric limitations for E. coli applied during the defined recreational season. As these ''treated'' CSO discharges must comply with E. coli limitations which are protective of full body contact recreational uses, such discharges are not considered to be imminent risks to human health (in regards to waterborne pathogens), any more than are discharges from wastewater treatment plant outfalls which disinfect and discharge continuously. Therefore, public notification for ''treated'' CSO discharges is not required in Indiana.

[23] New York Environmental Conservation Law § 17–0826–a requires public notification for all CSO discharges.

[24] ''Review of Coliphages as Possible Indicators of Fecal Contamination for Ambient Water Quality,'' EPA, 820–R–15–098, April 17, 2015.

[25] ''Impact of Wet-Weather Peak Flow Blending on Disinfection and Treatment: A Case Study at Three Wastewater Treatment Plants,'' Interstate Environmental Commission, March, 2008.

that prioritizes high-use recreational areas may reduce health risks more than an overly broad, general notification requirement. They suggested a targeted public notification approach could include monitoring the water quality of recreational areas for *E. coli* and cyanobacteria, public notification, posting water quality advisories, predictive modeling and source tracking. They suggested posting information from predictive models and the previous day *E. coli* sampling results on multiple Web sites and working with local television stations, newspapers, and radio stations to provide public notice.

The proposed rule would not mandate ambient monitoring for all CSO permittees as part of a public notification program. However, the proposal would provide flexibility for such approaches to be incorporated into an NPDES permit. EPA requests comment on when ambient monitoring and predictive monitoring of ambient water conditions should be incorporated as a requirement for the public notification program.

IV. Incremental Costs of Proposed Rule

The economic analysis estimates the incremental costs of requiring operators of a CSO discharge to the Great Lakes Basin to provide public notification of CSO discharges. Table 3 summarizes the estimated incremental costs for the proposed rule.

TABLE 3—ANNUAL INCREMENTAL COSTS BY RESPONDENT CATEGORY

[Average of first three years]

	Respondents	Labor costs	Capital/ start-up/ O&M costs	Total
CSO permittees with a population of less than 10,000	80	$102,114	$55,251	$157,365
CSO permittees with a population of between 10,000 and 50,000	70	118,894	1,296	120,190
CSO permittees with a population of more than 50,000	32	86,720	3,456	90,176
States	7	17,526	0	17,526
Totals		325,254	60,003	385,257

The average incremental cost per CSO permittee is about $2,000 per CSO permittee per year. These estimates are all below the threshold level established by statute and various executive orders for determining that a rule has a significant or substantial impact on affected entities. See further discussion in Section V of this document.

The Economic Analysis assumes that costs will be borne by Great Lakes Basin CSO permittees in the form of one-time implementation activities that would occur within one to two years, once per year activities including an annual notice, and ongoing activities that would occur during and after CSO discharges. The Economic Analysis also assumes costs for state agencies, mainly in the review of CSO permittee plans and reports.

V. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and therefore this proposal was not submitted to the Office of Management and Budget (OMB) for review. The final rule may be submitted to OMB for review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2562.01. The ICR is summarized here; a complete copy can be found in the docket.

As discussed in section II.C of today's notice, NPDES permits for CSO discharges to the Great Lakes Basin should require permittees to provide public notification to ensure that the public receives adequate notification of CSO occurrences and CSO impacts. The information burden associated with this provision is approved in ''Information Collection Request for NPDES Program (Renewal)'', OMB Control No. 2040–0004, EPA ICR No. 0229.21. EPA has developed an additional analysis to provide a better, updated estimate of the public notification requirements proposed today. The analysis used to develop these estimates is described in ''ICR Supporting Statement, Information Collection Request: Public Notification Requirements for CSOs in the Great Lakes Basin,'' EPA ICR number 2562.01. Key estimates and assumptions in the analysis include:

- 93% percent of existing outfalls for all CSO permittees have installed signs and that they are being maintained;
- Approximately half of the CSO permittees already have a system for developing estimates of the occurrence and volume of discharges from CSO outfalls;
- Each Great Lakes Basin CSO permittee already operates a Web site that can be modified to provide the public with notification of an CSO event;
- Larger CSO communities may have access to listserv technology;
- Electronic technology significantly reduces the burden of providing initial and supplemental notification to the public and to local public health departments and other affected public entities;
- Much of the effort in developing public notification plan are included in burden estimates for the individual public notification components in the proposal. The activities attributed to the burden for the public notification plan include preparation of the document describing the public notification activities.
- The burdens on NPDES authority are applied to one-fifth of all Great Lakes Basin CSO permits within each state beginning in year 2 of the ICR to account for the five year permit term.

The public notification requirements in this proposed rule are designed to alert the public and public health departments, and other potentially affected entities of CSO discharges in a more wide-spread and timely manner than is currently practiced. The notification requirements which involve distribution of CSO discharge related information (*e.g.,* CSO discharge location, receiving waterbody, time started, time ended, volume) to the

public and affected local governmental agencies would enable potentially affected parties to take action that may help prevent serious health effects that may otherwise occur if they were to remain unaware of the occurrence of CSO discharges.

Respondents/affected entities: The ICR covers information that must be provided by operators of combined sewer systems (Great Lakes Basin CSO permittees) that discharge within the watershed of the Great Lakes Basin. In addition, the ICR covers information burdens of the seven NPDES authorized States that are implementing the program.

Respondent's obligation to respond: Compliance with the notification requirements would be mandatory. Requirements for public notification of CSO discharge are part of the ''nine minimum controls'' established as part of EPA's CSO Control Policy. Section 425 of the consolidated Appropriations Act of 2016 (Pub. L. 114–113) requires EPA to work with the Great Lakes states to establish these public notice requirements.

Estimated number of respondents: EPA has identified 182 CSO communities that discharge to the Great Lakes Basin and seven state NPDES permitting authorities.

Frequency of response: Responses include one-time implementation activities, such as signage, activities that occur once per year, such as providing annual notice, and ongoing activities that would occur during and after CSO discharge events.

Total estimated burden: EPA estimates that the burden of implementing the rule would be 8,641 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimates that the rule would cost $385,257 per year during the three year ICR period. This is the total annual incremental cost for all 182 Great Lakes Basin CSO permittees. The average incremental cost per CSO permittee is about $2,000 per year and the average incremental cost per state NPDES authority is about $2,500.

EPA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA *submission@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 13, 2017. The EPA will respond to any ICR-related comment in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small governmental jurisdictions. The Agency has determined that 152 (83%) of the 182 communities discharging CSOs to the Great Lakes Basin are governmental jurisdictions with a population of less than 50,000 and thus can be classified as small entities and may experience an impact of between 0% and 0.75% of annual revenue. Details of this analysis are presented in the Economic Analysis for the proposed rule (see ''Economic Analysis for the Proposed Public Notification of CSOs to the Great Lakes Rule,'' EPA, 2016).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. EPA has conducted an economic analysis examining the potential burden to state, tribal and local governments. Details of this analysis are presented in the economic analysis for the proposed rule (see ''Economic Analysis for the Proposed Public Notification of CSOs in the Great Lakes Rule,'' EPA, 2016). EPA estimates that the costs of rule to states, tribes and local governments will be well below $100 million per year. In addition, EPA compared the estimated annualized cost of the rule and revenue estimates for small local governments using four estimates of revenue data. The annualized compliance cost as a percentage of annual government revenues were all well below 1% for all four revenue estimate methods. EPA concludes that the impact of the rule is very unlikely to reach or exceed 1% of small local government revenue.

EPA has provided small local governments an opportunity to share their views regarding potential new public notification requirements for CSO discharges in the Great Lakes Basin as part of the September 14, 2016 listening session and August 1, 2016 request for stakeholder input discussed in Section I.K of this notice. EPA is also encouraging the Great Lake states to notify small local governments affected by this rule about the opportunity to review and comment on this proposal.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

The rule proposes a requirement for CSO permittees to notify the public of CSO discharges. This requirement includes the development of a public notification plan and the release of an annual notice that includes monitoring data. The incremental impact to state permitting authorities is estimated to be $2,503.71 annually per state. The incremental impact to local permittees may range from a total of $1,000 to $3,000 annually per CSO permittee, depending on the number of CSO events and preparation time for the annual notice. Details of this analysis are presented in ''Economic Analysis for the Public Notification Requirements for Combined Sewer Overflow discharges within the Great Lakes Basin,'' which is available in the docket for the proposed rule (Docket ID No. EPA–HQ–OW–2016–0376 *http://www.regulations.gov*).

Keeping with the spirit of E.O. 13132 and consistent with EPA's policy to promote communications between EPA and state and local governments, EPA met with state and local officials throughout the process of developing the proposed rule and received feedback on how potential new regulatory requirements would affect them. EPA engaged in extensive outreach via conference calls to affected states to enable officials of affected state to have meaningful and timely input into the development of the proposed rule. EPA also held a public listening session and solicited written comments from the public and impacted stakeholder groups, including affected municipalities, to inform the development of the public notice proposed requirements. See Docket ID No. EPA–HQ–OW–2016–0376 to the *Federal eRulemaking Portal: http://www.regulations.gov.*

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 since it does not have a direct substantial impact on one or more federally recognized tribes. No tribal governments are authorized NPDES permitting authorities and none of the combined sewer systems subject to this rule are located on Indian nation lands.

The proposed rule would address the way in which municipalities share information with the public, public health departments, and potentially impacted communities (including Indian tribes) about CSOs in the Great Lakes Basin. EPA therefore evaluated the proximity of CSSs that would be subject to the proposed rule in relation to Indian lands. EPA identified six CSO permittees with the potential to affect waters near four Indian nations in New York State:

- *Seneca Nation of Indians (SNI):* The Dunkirk WWTP is located south of the Cattaraugus Reservation. The Buffalo Sewer Authority and Niagara Falls WWTP are located close to SNI lands within the city of Niagara Falls, NY and Buffalo, NY (where the Seneca casinos are located).
- *Tuscarora Nation (TN):* The Tuscarora Nation lands are located directly between the Niagara Falls WWTP and Lockport WWTP but not on the Niagara River or Eighteen Mile Creek.
- *Tonawanda Seneca Nation (TSN):* The Medina WWTP is located 10 miles north of the Tonawanda Seneca Nation lands.
- *St. Regis Mohawk Tribe (SRMT):* Any of the three WWTP plants along the St. Lawrence River would be of concern to the Mohawks at Akwesasne. SRMT is directly impacted by the Massena WWTP as the St. Lawrence River goes directly thru the heart of Akwesasne, the St. Regis Mohawk Tribe's reservation lands.

Consistent with the EPA Policy on *Consultation and Coordination with Indian Tribes,*[26] EPA conducted outreach to tribal officials during the development of this action. EPA contacted the above mentioned tribes through outreach conducted by EPA's Office of Environmental Justice to ensure they were aware of the public listening session held regarding this rulemaking, and the associated opportunity to provide written comments to the Agency. In addition, the proposed rule would require Great Lakes Basin CSO permittees to consult with potentially affected Indian Tribes whose waters may be affected by a CSO discharge prior to submitting the public notification plan. This requirement would ensure that needs of tribes using potentially affected waters are considered in terms of timing of notification, the type of information that is provided, and the means by which public notification is communicated.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The proposed rule would, in some cases, increase public awareness of CSO discharges to the Great Lakes Basin, including information about public use areas such as beaches that may be impacted by contaminated CSO discharges, and by doing so could decrease health risks for children, infants, and adults.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it does not significantly affect energy supply, distribution or use.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA determined that the human health or environmental risk addressed by this action would not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. This action affects the way in which Great Lakes Basin CSO permittees communicate information regarding CSO discharges to the public. It does not change any current human health or environmental risk standards.

However, because the proposed rule would address the way in which information about CSO discharges is communicated to the public, EPA did reach out to environmental justice organizations to specifically solicit input on what may be the best approaches to reaching environmental justice communities with this information. Prior to the public listening session on September 14, 2016, EPA contacted over 800 environmental justice stakeholders through the Office of Environmental Justice Listserv, to ensure they were aware of the listening session and the opportunity to provide written input to the Agency through the public docket.

In addition, the proposed rule would require the Great Lakes Basin CSO permittee to consult with local public health departments and potentially affected public entities when developing the public notification plan. These consultations may alert the Great Lakes Basin CSO permittee to specific environmental justice community considerations regarding the best ways to effectively communicate this information. EPA requests comment on this requirement and whether it is expected to sufficiently account for the needs of environmental justice communities that may utilize waters that could be affect by a CSO discharge to the Great Lakes Basin.

List of Subjects

40 CFR Part 122

Environmental protection, Administrative practice and procedure, Combined sewer overflow, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control, Water pollution, public notification, reporting.

40 CFR Part 123

Environmental protection, Administrative practice and procedure, Combined sewer overflow, Hazardous substances, Indians—lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water pollution, public notification, reporting.

Dated: December 16, 2016.

Gina McCarthy,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 122 as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

[26] *https://www.epa.gov/sites/production/files/2013-08/documents/cons-and-coord-with-indian-tribes-policy.pdf.*

■ 2. Amend § 122.2 by adding the definitions for ''Combined sewer overflow,'' ''Combined sewer system,'' and ''Great Lakes Basin'' in alphabetical order to read as follows:

§ 122.2 Definitions.

* * * * *

Combined sewer overflow (CSO) means a discharge from a combined sewer system (CSS) at a point prior to the Publicly Owned Treatment Works (POTW) Treatment Plant (defined at § 403.3(r) of this chapter).

Combined sewer system (CSS) means a wastewater collection system owned by a State or municipality (as defined by section 502(4) of the CWA) which conveys sanitary wastewaters (domestic, commercial and industrial wastewaters) and storm water through a single-pipe system to a Publicly Owned Treatment Works (POTW) Treatment Plant (as defined at § 403.3(r) of this chapter).

* * * * *

Great Lakes Basin means the waters defined as ''Great Lakes'' and ''Great Lakes System'' as those terms are defined in § section 132.2 of this chapter.

* * * * *

■ 3. Amend § 122.21 by adding paragraph (j)(8)(iii).

§ 122.21 Application for a permit (applicable to State programs, see § 123.25).

* * * * *

(j) * * *

(8) * * *

(iii) *Public Notification Plan for CSO discharges to the Great Lakes Basin.* Each applicant that discharges a combined sewer overflow to the Great Lakes Basin as defined in § 122.2 must submit a public notification plan developed in accordance with § 122.38 as part of its permit application. The public notification plan shall describe any significant updates to the plan that may have occurred since the last plan submission.

* * * * *

■ 4. Add § 122.38 to read as follows:

§ 122.38 Public Notification requirements for CSO discharges to the Great Lakes Basin.

(a) All permittees authorized to discharge a combined sewer overflow (CSO) to the Great Lakes Basin (''Great Lakes Basin CSO permittee'') must provide public notification of CSO discharges as described in this paragraph after [date 6 months after publication of final rule]. Public notification shall consist of:

(1) *Signage.* (i) The Great Lakes Basin CSO permittee shall ensure that there is adequate signage where signage is feasible at CSO outfalls and potentially impacted public access areas. At a minimum, signs shall include:

(A) The name of the Great Lakes Basin CSO permittee,

(B) A description of the discharge (*e.g.,* untreated human sewage, treated wastewater) and notice that sewage may be present in the water, and

(C) The Great Lakes Basin CSO permittee contact information, including a telephone number, NPDES permit number and outfall number as identified in the NPDES permit.

(ii) The Great Lakes Basin CSO permittee shall perform periodic maintenance of signs to ensure that they are legible, visible and factually correct.

(iii) Where a permittee has before [date 6 months after publication of final rule] installed a sign at a CSO outfall or potentially impacted public access area that is consistent with state requirements, the sign is not required to meet the minimum requirements specified in paragraph (a)(1)(i) of this section until the sign is replaced or reset.

(2) *Notification of Local Public Health Department and other potentially affected public entities.* (i) As soon as possible, but no later than four (4) hours after becoming aware by monitoring, modeling or other means that a CSO discharge has occurred, the Great Lakes Basin CSO permittee shall provide initial notice of the CSO discharge to the local public health department (or if there is no local health department, to the state health department), any potentially affected public entities (such as municipalities, public drinking water utilities, state and county parks and recreation departments), and Indian Tribes whose waters may be affected. Such initial notice shall, at a minimum, include the following information:

(A) The water body that received the discharge(s);

(B) The location of the discharge(s). Where CSO discharges from the same system occur at multiple locations at the same time, the Great Lakes Basin CSO permittee may provide a description of the area in the waterbody where discharges are occurring and identification of the public access areas potentially impacted by the discharge, and the permittee is not required to identify the specific location of each discharge;

(C) The date(s) and time(s) that the discharge(s) commenced or the time the permittee became aware of the discharge(s) or when discharges are expected to occur;

(D) Whether, at the time of the notification, the discharge(s) is continuing or has ended. If the discharge(s) has ended, the approximate time that the discharge ended; and

(E) A point of contact for the CSO permittee.

(ii) Within twenty-four (24) hours after becoming aware by monitoring, modeling or other means that the CSO discharge(s) has ended, the Great Lakes Basin CSO permittee shall provide the following supplemental information to the public health department and affected public entities and Indian Tribes receiving the initial notice under paragraph (a)(2)(i) of this section unless the information had been provided in an earlier notice:

(A) The measured or estimated volume of the discharge(s). Where CSO discharges from the same system occur at multiple locations at the same time, the Great Lakes Basin CSO permittee may provide an estimate of the cumulative volume discharged to a given waterbody; and

(B) The approximate time that the discharge(s) ended.

(3) *Notification of the Public.* (i) As soon as possible, but no later than four (4) hours after becoming aware by monitoring, modeling or other means that a CSO discharge has occurred, the Great Lakes Basin CSO permittee shall provide public notification of CSO discharges. The Great Lakes Basin CSO permittee shall provide public notification of CSO discharges electronically, such as by text, email, social media alerts to subscribers or by posting a notice on its public access Web site, and by other appropriate means (*e.g.* newspaper, radio, television).

(ii) At a minimum, the notice shall include:

(A) The water body that received the discharge(s);

(B) The location of the discharge(s). Where CSO discharges from the same system occur at multiple locations at the same time, the Great Lakes Basin CSO permittee may provide a description of the area in the waterbody where discharges are occurring and identification of the public access areas potentially impacted by the discharge, and the permittee is not required to identify the specific location of each discharge;

(C) The date(s) and time(s) that the discharge(s) commenced or the time the permittee became aware of the discharge(s); and

(D) Whether, at the time of the notification, the discharge(s) is continuing or has ended. If the discharge(s) has ended, the approximate time that the discharge(s) ended.

(iii) Within twenty-four (24) hours after becoming aware by monitoring,

modeling or other means that the CSO discharge(s) has ended, the Great Lakes Basin CSO permittee shall update the electronic notice with the following information unless the information had been provided in an earlier notice:

(A) The measured or estimated volume of the discharge(s). Where CSO discharges from the same system occur at multiple locations at the same time, the Great Lakes Basin CSO permittee may provide an estimate of the cumulative volume discharged to a given waterbody; and

(B) The approximate time that the discharge(s) ended, unless this information was provided in an earlier notice.

(b) *Annual Notice.* By May 1 of each calendar year (or an earlier date specified by the Director), all permittees authorized to discharge a CSO to the Great Lakes Basin shall make available to the public an annual notice describing the CSO discharges from its outfall(s) that occurred in the previous calendar year and shall provide the Director with notice of how the annual notice is available. Permittees that are owners or operators of a satellite collection system with one or more CSO outfalls shall provide the annual notice to the public and a copy of the annual notice to the operator of the POTW treatment plant providing treatment for its wastewater. At a minimum, the annual notice shall include:

(1) Information on the availability of the permittee's public notification plan and a summary of significant modifications to the plan that were made in the past year;

(2) A description of the location, treatment provided and receiving water for each CSO outfall;

(3) The date, location, duration, and volume of each wet weather CSO discharge that occurred during the past calendar year. Where CSO discharges from the same system occur at multiple locations at the same time, the Great Lakes Basin CSO permittee may provide an estimate of the cumulative volume discharged to a given waterbody;

(4) The date, location, duration, and volume of each dry weather CSO discharge that occurred during the past calendar year;

(5) A summary of available monitoring data for CSO discharges from the past calendar year;

(6) A description of any public access areas impacted by each CSO discharge;

(7) Representative rain gauge data in total inches to the nearest 0.1 inch that resulted in a CSO discharge;

(8) A point of contact; and

(9) A concise summary of implementation of the nine minimum controls and the status of implementation of the long-term CSO control plan (or other plans to reduce or prevent CSO discharges), including:

(i) A description of key milestones remaining to complete implementation of the plan; and

(ii) A description of the average annual number of CSO discharges anticipated after implementation of the long-term control plan (or other plan relevant to reduction of CSO overflows) is completed.

(c) *Reporting.* By May 1 of each calendar year (or an earlier date specified by the Director), all permittees authorized to discharge a CSO to the Great Lakes Basin shall electronically report any CSO discharge that occurred during the past calendar year that has not been previously reported pursuant to a permit requirement. to the initial recipient, as defined in 40 CFR 127.2(b), in compliance with 40 CFR 127 using the discharge monitoring report (NPDES Data Group 3, Appendix A to 40 CFR 127) or the Sewer Overflow Event Report (NPDES Data Group 9, Appendix A to 40 CFR 127).

(d) *Public Notification Plan.* The Great Lakes Basin CSO permittee shall develop a public notification plan that describes how the Great Lakes Basin CSO permittee will ensure that the public receives adequate notification of CSO occurrences and CSO impacts. The Great Lakes Basin CSO permittee must provide notice of the availability of the plan on the permittee's Web site (if it has a Web site), and periodically provide information in bill mailings and by other appropriate means on how to view the notification plan. The Great Lakes Basin CSO permittee must submit its public notification plan to the Director by [date 6 months after publication of a final rule] and as part of a permit application under § 122.21(j)(8)(iii). The plan must:

(1) Identify the location of signs required under paragraph (a)(1) of this section and the location of any CSO outfall where a sign is not feasible. Where a sign has not been provided at an outfall, the plan shall explain why a sign at that location is not feasible.

(2) Describe the message used on signs required under paragraph (a)(1) of this section;

(3) Describe protocols for maintaining signage (*e.g.,* inspections at set intervals);

(4) Identify (with points of contact) the municipalities, public drinking water supplies, public parks with water access, Indian Tribe(s), and describe other sensitive area(s) identified in the permittee's long-term CSO control plan, that may be affected by the permittee's CSO discharges;

(5) Summarize significant comments and recommendations raised by the local public health department under paragraph (e) of this section;

(6) Identify other affected public entities and Indian Tribes whose waters may be affected by a CSO discharge that were contacted under paragraph (e) of this section and provide a summary of their significant comments and recommendations;

(7) Describe protocols for the initial and supplemental notice to public health departments and other public entities;

(8) Describe protocols for the initial and supplemental notice to the public;

(9) Describe, for each outfall, how the volume and duration of CSO discharges shall be either measured or estimated for the purposes of complying with paragraphs (a)(2)(B)(i), (a)(3)(C)(i), (b)(2), and (b)(3) of this section. If the Great Lakes Basin CSO permittee intends to use a model to estimate discharge volumes and durations, the plan must summarize the model and describe how the model was or will be calibrated. CSO permittees that are a municipality or sewer district with a population of 75,000 or more must calibrate their model at least once every 5 years; and

(10) Describe protocols for making the annual notice described in paragraph (b) of this section available to the public and to the Director.

(e) Prior to submitting the public notification plan, or resubmitting under § 122.21(j)(8)(iii), the Great Lakes Basin CSO permittee must:

(1) Seek input from the local public health department (or if there is no local health department, the state health department), to:

(i) Develop recommended protocols for providing notification of CSO discharges to the public health department. The protocols will specify which CSO discharges are subject to notification, the means of notification, timing of notification and other relevant factors; and

(ii) Develop recommendations for providing notice to the general public of CSO discharges electronically and by other appropriate means.

(2) Seek input from other potentially affected public entities and Indian Tribes whose waters may be affected by a CSO discharge.

(3) Consider the recommendations of the public health department and other potentially affected entities in developing protocols in its public notification plan for providing notification of CSO discharges to the public health department and

potentially affected public entities and Indian Tribes.

(f) The Director may extend the compliance dates in paragraphs (a), (b), and (d) of this section for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship. Where the Director extends the compliance date of any of these requirements for a community, the Director shall notify the Regional Administrator of the extension and the reason for the extension. The Director shall post on its Web site a notice that includes the name of the community and the new compliance date(s). The notice shall remain on the Director's Web site until the new compliance date.

■ 5. Amend § 122.42 by adding paragraph (f) to read as follows:

§ 122.42 Additional conditions applicable to specified categories of NPDES permits (applicable to State NPDES programs, see § 123.25).

* * * * *

(f) *Public Notification requirements for CSO discharges to the Great Lakes Basin.* Any permit issued for combined sewer overflow (CSO) discharges to the Great Lakes Basin must:

(1) Require implementation of the public notification requirements in § 122.38(a);

(2) Specify the information that must be included on outfall signage, which, at a minimum, must include those elements in § 122.38(a)(1)(i);

(3) Specify outfalls and public access areas where signs are required pursuant to § 122.38(a)(1)(i);

(4) Specify the timing and minimum information required for providing initial and supplemental notification to:

(i) Local public health department and other potentially affected entities under § 122.38(a)(2); and

(ii) The public under § 122.38(a)(3).

(5) Specify the location of CSO discharges that must be monitored for volume and discharge duration and the location of CSO discharges where CSO volume and duration may be estimated;

(6) Require submittal of an annual notice in accordance with § 122.38(b);

(7) Specify protocols for making the annual notice under § 122.38(b) available to the public; and

(8) Require all CSO discharges be electronically reported in a discharge monitoring report or a sewer overflow event report pursuant to 40 CFR 122.41(l)(6) or (7).

* * * * *

PART 123—STATE PROGRAM REQUIREMENTS

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

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 7. Amend § 123.25 by revising paragraph (a)(46) and adding paragraph (a)(47) to read as follows:

§ 123.25 Requirements for permitting.

(a) * * *

(46) For states that wish to receive electronic documents, 40 CFR part 3—(Electronic Reporting); and

(47) For a Great Lakes State, § 122.38.

* * * * *

[FR Doc. 2016–31745 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2016–0426; FRL–9956–28]

RIN 2070–AK24

TSCA Inventory Notification (Active-Inactive) Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The recent amendments to the Toxic Substances Control Act (TSCA) require EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either ''active'' or ''inactive'' in U.S. commerce. To accomplish that, EPA is proposing to require a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for non-exempt commercial purposes during the ten-year time period ending on June 21, 2016. EPA would also accept such notices for chemical substances that were processed. EPA would use these notifications to distinguish active substances from inactive substances. EPA would include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. EPA is also proposing to establish procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for non-exempt commercial purposes is expected to resume. Upon receipt of a valid notice, EPA would change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. EPA is proposing the procedures regarding the manner in which such retrospective and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.

DATES: Comments must be received on or before March 14, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0426, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Myrta R. Christian, Chemistry, Economics, and Sustainable Strategies Division (Mailcode 7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–8498; email address: *christian.myrta@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you domestically manufactured, imported, or processed chemical substances listed on the TSCA Chemical Substance Inventory for nonexempt commercial purposes during the ten-year time period ending on June 21,

2016. You may also be affected by this action if you intend to domestically manufacture, import, or process chemical substances listed on the TSCA Chemical Substance Inventory in the future. The following list of North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturing or processing (NAICS code 325).
- Petroleum and Coal Products Manufacturing (NAICS code 324).

In addition, the discussion in Unit III.A. describes in more detail which chemical substances would and would not be subject to reporting under this proposed action. You may also consult 40 CFR 710.3 and 710.4, as well as the proposed regulatory text in this document, for further information on the applicability of exemptions to this proposed rule. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

EPA is proposing this rule under TSCA section 8(b), 15 U.S.C. 2607(b). As described in more detail in Unit II.A., TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114–182. The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

Note that TSCA's statutory definition of ''manufacture'' includes importing. Accordingly, the regulatory definition of ''manufacture'' for this rule includes importation. All references to manufacturing in this notice should be understood to also encompass importing. Where EPA's intent is to specifically refer to domestic manufacturing or importing (both activities constitute ''manufacture''), this notice will do so expressly.

C. What action is the Agency taking?

Pursuant to TSCA section 8(b)(4)(A), EPA is proposing procedural, retrospective notification requirements for persons who manufactured chemical substances on the TSCA Inventory as described in Unit III.A. Persons who manufactured these chemical substances for nonexempt commercial purposes during the ten-year time period ending on June 21, 2016, would be required to notify the Agency of certain information described in Unit III.C., including chemical identity and the date range when manufacture occurred in that ten-year time period. EPA would use the chemical identity information obtained from this retrospective reporting to designate as active those chemical substances on the TSCA Inventory for which notices were received. If no notice is received during this retrospective reporting for a chemical substance subject to designation on the TSCA Inventory, then that substance would be designated as inactive. EPA would require date range information in order to obtain confirmation that the chemical substance in question had indeed been manufactured or processed between June 21, 2006 and June 21, 2016.

Pursuant to TSCA section 8(b)(5)(B), EPA is also proposing procedural, forward-looking notification requirements for persons who intend to manufacture or process inactive chemical substances on the TSCA Inventory. After EPA's first publication of the TSCA Inventory that includes active and inactive designations determined by the retrospective reporting, persons who intend to manufacture or process for nonexempt commercial purposes those chemical substances designated as inactive on the TSCA Inventory would be required to notify the Agency of certain information described in Unit III.C. Such notification must occur before the actual date of manufacturing or processing. EPA is proposing that notification, which shall include chemical identity and the actual date of manufacturing or processing, occur no more than 30 days before the actual date of manufacturing or processing.

Included in this proposed rule are electronic reporting requirements described in Unit III.D. that are similar to those established in 2013 for reporting other kinds of information to EPA under TSCA sections 4, 5, 8(a), and 8(d). See 78 FR 72818, December 4, 2013 (FRL 9394–6). The Agency is proposing to require submitters to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, for reporting information under this proposed rule. The information would be submitted to the Agency under TSCA section 8(b), but the practical rationales for requiring submissions to proceed through CDX, cited in 2013, are also pertinent here by analogy.

Also included in this proposal are amendments to 40 CFR part 710, which conform the definitions applicable to these reporting requirements with those that apply to Chemical Data Reporting rule requirements (definitions found at 40 CFR 704.3 and 711.3) and the submission of Premanufacture Notifications (definitions found at 40 CFR 720.3). EPA believes that basing Section 8(b) reporting on definitions that are already familiar to the public from CDR and PMN reporting would reduce the potential for confusion and reduce the burden of rule familiarization. EPA is not proposing to modify the 40 CFR part 710 definitions in any manner that either is not conforming to Part 704, 710, or 720, or is a purely technical correction (*e.g.,* eliminating references to the Canal Zone from the definition of ''State''). Any other changes to the definitions in 40 CFR part 710 are beyond the scope of this proposal.

Included in this proposed rule are procedures for persons who co-manufacture or co-process a reportable chemical substance. These procedures would allow the submission of a single commercial activity notification in single instances of co-manufacturing or co-processing of a particular volume of a chemical substance. These proposed procedures are similar to Chemical Data Reporting rule requirements (40 CFR 711.22) when two or more persons are involved in a particular manufacture or import transaction. EPA believes that allowing a single notification for co-manufacturers and co-processors would serve to provide the Agency with the information necessary to designate a chemical substance as active on the TSCA Inventory while reducing duplicative reporting.

Also included in this proposed rule are requirements for filing a joint submission when specific chemical identity information is claimed confidential by a supplier. If an importer cannot provide the specific chemical identity of a reportable substance to EPA because the information is claimed confidential by a supplier, and therefore is unknown to the importer, the importer would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. If a domestic manufacturer or processor cannot provide the specific chemical identity of a reportable substance to EPA because the chemical identity of a reactant is claimed confidential by a supplier, and therefore is unknown to the domestic manufacturer or processor, the manufacturer or processor would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. EPA would only accept joint submissions that are submitted electronically using CDX.

This requirement is similar to Chemical Data Reporting rule requirements (40 CFR 711.15) and would allow EPA to obtain the information necessary to identify the specific chemical identity of a reportable substance and designate it as active on the TSCA Inventory.

D. Why is the Agency taking this action?

TSCA section 8(b)(4)(A) requires EPA to issue a final retrospective reporting rule by June 22, 2017. These proposed reporting requirements would enable EPA to fulfill a statutory obligation to designate chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. This proposed rule is not intended to indicate conclusions about the risks of chemical substances on the TSCA Inventory. Nonetheless, the designation of a chemical substance as active or inactive would be relevant to the Agency's prioritization of chemical substances in U.S. commerce under TSCA section 6(b).

Furthermore, TSCA section 8(b)(5) establishes a forward-looking notification requirement that goes into effect as soon as EPA designates inactive substances. EPA is proposing to establish the procedural framework whereby manufacturers and processors would discharge their notice obligations under this section of TSCA.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing the proposed reporting requirements for manufacturers and processors. This analysis, which is available in the docket, is discussed in Unit VI. and is briefly summarized here (Ref. 1).

During the retrospective (or ''start-up'') period, between approximately June 2017 and June 2018, typical costs per firm are estimated at $1,346 per submission (with an estimated seven chemicals per submission), with possible additional costs at $40.22 per CDX registration in the event that the submitter is not currently registered in CDX. Among manufacturers, an estimated 6,169 firms would undertake rule familiarization with 4,692 completing compliance determination, form completion, and recordkeeping. For manufacturers, the total burden during start-up is estimated at 86,783 hours with an associated total cost of $6.68 million. For processors, the estimate of the universe of potentially affected firms is 161,550 who might initiate rule familiarization. For processors initiating rule familiarization, the cost would be 4 hours per firm (about $300 per firm). EPA believes that it is unlikely that 100% of processors will initiate rule familiarization and that the percentage will be less. EPA estimates that only 100 processors will complete compliance determination, form completion, and recordkeeping. For the 100 processors who complete a submission with one chemical, the burden during start-up is estimated at 692 hours with an associated cost of $0.05 million. Lastly, for 469 new CDX registrations (for individuals lacking previous experience with electronic reporting to EPA), burden during start-up is estimated at 249 hours with an associated cost of $0.02 million.

The rule has minimal burden and cost implications related to ongoing reporting after the start-up year. The forward-looking (or ''Ongoing'') reporting after June 2018 involves compliance determination, form completion, and recordkeeping for twenty manufacturers and/or processors per year. Burden and cost are estimated to total 142 burden hours per year with an associated cost of $10,790 per year.

Agency activities due to the rule include CDX and Chemical Information Submission System (CISS) capacity expansions, time to manage commercial activity notices, and increased costs incurred when making revisions to the TSCA Inventory. Associated costs are estimated at $3.84 million during start-up, and $0.20 million annually thereafter.

Combining Industry and Agency cost estimates, and annualizing over a 10-year period, the total cost of the rule is estimated at $7.22 million per year using a 3% discount rate, and at $8.77 million per year using a 7% discount rate.

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a CD–ROM or other electronic media that you mail to EPA, mark the outside of the media as CBI and then identify electronically within the media the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked would not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

A. Overview of Applicable Authority

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current a list of chemical substances manufactured or processed in the United States. In 1977, EPA promulgated a rule under TSCA section 8(a), 15 U.S.C. 2607(a), to provide the information necessary for EPA to compile a list of chemical substances that had been in commerce since January of 1975 (Ref. 2). This list is known as the TSCA Chemical Substance Inventory (or simply the ''TSCA Inventory''). Since compiling the initial TSCA Inventory, EPA regularly adds new chemical substances that have completed new chemical review requirements pursuant to TSCA section 5(a), 15 U.S.C. 2604(a), and that have been manufactured or processed for nonexempt commercial purposes. EPA maintains the TSCA Inventory as the authoritative list of all the chemical substances reported to the Agency for inclusion on the TSCA Inventory.

1. Retrospective reporting under TSCA section 8(b)(4)(A). TSCA section 8(b)(4)(A) requires EPA to promulgate a rule that requires manufacturers to notify the Agency, by not later than 180 days after the date on which the final rule is published in the **Federal Register**, of each chemical substance on the TSCA Inventory that was manufactured for nonexempt commercial purpose during the 10-year period ending on June 21, 2016. If EPA receives a valid notice for a chemical substance on the TSCA Inventory, EPA must designate that chemical substance as an active substance. If EPA receives no valid notice for a chemical substance on the TSCA Inventory (and that is subject to designation), EPA must designate that chemical substance as an inactive substance.

2. Forward-looking reporting under TSCA section 8(b)(5)(B). TSCA section 8(b)(5)(B) requires persons who intend to manufacture or process chemical substances for nonexempt commercial purposes in the future that are designated on the TSCA Inventory as inactive to notify EPA prior to the date that these chemicals are to be manufactured or processed. Upon receiving a valid notice, EPA must change the designation of the chemical substance from inactive to active.

3. Processors. TSCA section 8(b)(4)(A) indicates that the Administrator may require processors to report similarly to

manufacturers under the rule. This proposed rule would not require processors to report during the retrospective reporting period. However, once EPA has designated a chemical substance as an inactive substance, the processing of that chemical substance for a non-exempt commercial purpose would be unlawful, unless the processor first submits a notice as required by TSCA section 8(b)(5)(B). Therefore, this proposed rule would allow processors to report during the retrospective reporting period, extended to not later than 360 days after the date on which the final rule is published in the **Federal Register** (which will be 180 days after EPA's publication of the first version of the TSCA Inventory with preliminary commercial activity designations). Processors could report any chemical substance that they had processed for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016. The extended submission period for processors would allow processors time to evaluate whether they wish to voluntarily report chemical substances that have not been reported by manufacturers or importers and that are preliminarily designated as inactive on EPA's publication of the first version of the revised TSCA Inventory. (These designations would be merely preliminary so there would not yet be an obligation to report under TSCA Section 8(b)(5)(B).) If EPA receives no notice on a chemical substance that is subject to designation, EPA then must designate that preliminarily inactive substance as actually inactive. Hence, persons who processed a chemical substance between June 2006 and June 2016 may wish to report under TSCA section 8(b)(4)(A) in order to avoid a subsequent obligation to curtail processing on the day that EPA designates the substance as inactive, under TSCA section 8(b)(5)(B). Processing could resume as soon as the notice under TSCA section 8(b)(5)(B) is submitted, but processors may nonetheless find it less disruptive to ensure that the chemical substance is earlier reported as active under TSCA section 8(b)(5)(A).

4. General provisions. General provisions for TSCA section 8(b) rules appear in 40 CFR part 710. These provisions include definitions that apply to reporting under this proposed rule and also describe the scope of the Inventory. For example, 40 CFR 710.1 describes requirements for EPA to compile and keep current the TSCA Inventory of chemical substances manufactured or processed for commercial purposes, including the periodic updates to the Inventory to include new chemical substances reported under TSCA section 5(a) and commercialized for nonexempt purposes. In addition, the definitions in TSCA section 3 apply to this rulemaking.

5. Electronic reporting under the Government Paperwork Elimination Act (GPEA). GPEA, 44 U.S.C. 3504, provides that, when practicable, Federal organizations should use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), provides that any requirement in title 40 of the CFR to submit a notice directly to the Agency can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form (Ref. 3). For more information about CROMERR, go to *http://www.epa.gov/cromerr*.

III. Summary of Proposed Rule

EPA is proposing reporting and procedural requirements for manufacturers and processors of chemical substances pursuant to TSCA section 8(b).

A. What chemical substances would be reportable under this rule?

1. Reportable chemical substances. As a general matter, the retrospective reporting requirement of this proposed rule would apply to chemical substances listed on the TSCA Inventory that were manufactured for a nonexempt commercial purposes during the 10-year period ending on June 21, 2016. This lookback period is set by statute. TSCA also establishes forward-looking reporting requirements, at section 8(b)(5)(B), with respect to chemical substances listed on the TSCA Inventory that EPA designates as inactive. The TSCA Inventory is available at *https://www.epa.gov/tsca-inventory*.

2. Exemptions from reporting. i. Statutory background. This proposed rule provides exemptions from reporting based on sections 8(b)(4) and (5) and the general objectives that EPA can infer from that text. Unlike the reporting that informed the initial compilation of the TSCA Inventory (which arose under TSCA section 8(a)), the reporting requirements described in this proposed rule arise directly under TSCA section 8(b). EPA must finalize the retrospective reporting requirements by June 22, 2017, and all mandatory reporting under TSCA section 8(b)(4) must be completed by not later than 180 days thereafter. TSCA section 8(b)(4) and 8(b)(5) reporting requirements apply to ''each chemical substance,'' found on the TSCA Inventory, subject to the provision that reporting obligations shall only be triggered by manufacturing or processing for a ''nonexempt commercial purpose.'' The retrospective reporting requirements under TSCA section 8(b)(4) are expressed as being ''subject to the limitations'' of TSCA section 8(a)(5)(A). TSCA section 8(a)(5)(A), in turn, specifies that ''to the extent feasible,'' EPA shall: (1) Avoid requiring reporting that is ''unnecessary or duplicative;'' (2) ''minimize the cost of compliance'' to small manufacturers and processors; and (3) apply reporting obligations to the persons likely to have information relevant for effective implementation.

Furthermore, as EPA interprets its statutory authority, the reporting is intended to support two key objectives. First, to enable EPA to determine which reportable chemical substances are active in U.S. commerce. EPA will accomplish this based on notices received. Reportable chemical substances for which no notices are received would be considered inactive in U.S. commerce. See TSCA section 8(b)(4)(A)(iii). Second, with respect to chemical substances identified as being active in commerce that are listed on the confidential portion of the TSCA Inventory, to require that persons manufacturing or processing such chemical substances request that existing claims for protection against disclosure of the specific chemical identity be maintained. See TSCA sections 8(b)(4)(B)(ii), 8(b)(4)(C), 8(b)(5).

ii. Excluded chemical substances. If a chemical substance is not listed on the TSCA Inventory, then by the terms of TSCA sections 8(b)(4) and (5), it is not subject to reporting under this proposed rule. For example, chemical substances that are manufactured under a TSCA section 5(h) exemption are not added to the TSCA Inventory. Accordingly, this proposed rule would not require that reporting occur with respect to such substances. This is reflected in the proposed definitions at 40 CFR 710.23, which are drafted in such a manner that if a chemical substance was not on the TSCA Inventory as of June 22, 2016, it would not be subject to reporting.

Naturally occurring chemical substances also are proposed to be excluded from reporting under this proposed rule, so long as the manufacturing and processing of such substances meets the criteria set forth in 40 CFR 710.27(b). When EPA required

manufacturers and processors to submit notices in support of the original compilation of the TSCA Inventory in 1977, EPA made clear that reporting on naturally occurring chemical substances would not be necessary, as these substances would automatically be included in the Inventory as a category: ''Naturally Occurring Chemical Substances,'' 42 FR 64578 (1977). EPA proposes to simply designate the whole category of Naturally Occurring Chemical Substances as active substances, by rule, without the need for reporting to differentiate among such substances.

Finally, this proposed rule would not require manufacturers to report chemical substances that are on both the non-confidential portion of the TSCA Inventory and the interim list of active substances described in TSCA section 8(b)(6). Such reporting would be unnecessary, since EPA already has reporting data to establish that the chemical substance was in active commerce at some time between June 21, 2006 and June 21, 2016. Furthermore, for such substances, there are no existing claims for protection against disclosure of the specific identity of the chemical substance for any party to elect to maintain or not maintain. With respect to chemical substances on the confidential portion of the TSCA Inventory, however, such reporting still serves a statutory function under TSCA sections 8(b)(4)(B)(ii) and 8(b)(4)(C), even where there is already adequate evidence, prior to reporting, that the substance was in active commerce during the lookback period.

Regarding the composition of the interim list of active substances, TSCA section 8(b)(6) requires EPA to compile an interim list of active substances reported under 40 CFR part 711 for the purposes of TSCA section 6(b), before promulgation of the rule. The definition of the interim list is somewhat ambiguous, since it refers to the ''reporting period that most closely preceded June 22, 2016.'' The term ''reporting period'' is not defined under 40 CFR part 711. In light of the definitional ambiguity of TSCA section 8(b)(6) and EPA's weighing of the statutory objectives noted previously, EPA has construed the ''interim list of active substances'' to include 2012 CDR data, which avoids delay of this proposed rule, but would allow for the 2016 CDR data to give rise to a reporting exemption as soon as they are publicly released in final form. Under the proposal, manufacturers and processors of chemical substances on the non-confidential portion of the Inventory would be exempt from reporting if the manufacture of that chemical substance was already reported (by any party) in response to 2012 or 2016 CDR.

iii. Manufacturing or processing for an exempt commercial purpose. TSCA section 8(b) directs EPA to limit reporting obligations to manufacturing and processing for ''nonexempt commercial purpose.'' This phrase had a commonly-accepted usage at the time that TSCA was amended, in 2016. See, for example, ''Certain New Chemicals; Receipt and Status Information'' (referencing TSCA section 5 requirements as applying to manufacture for ''nonexempt commercial purpose'') (Ref. 4), and ''2016 Chemical Data Reporting Frequent Questions'' (associating ''nonexempt commercial purpose'' with exemptions codified at 40 CFR 720.30 and 40 CFR 711.10(a)) (Ref. 5). Since reporting under TSCA section 8(b) is a form of existing chemical reporting, EPA construes the phrase ''nonexempt commercial purpose'' consistent with the manner in which the 40 CFR 720.30 exemptions from pre-manufacture reporting requirements were adapted for use in the CDR at 40 CFR 711.10. Thus, for example, the manufacturing or processing of chemical substances solely in small quantities for research and development would not trigger reporting obligations under this proposed rule. Similarly, the manufacturing or processing of impurities, or byproducts that have no subsequent commercial purpose, would not trigger reporting obligations under this proposed rule. Finally, since the CDR integrates reporting exemptions for persons who import chemical substances solely as part of articles with reporting exemptions for nonexempt commercial purposes (see 40 CFR 711.10), EPA construes the TSCA 8(b) reference to ''nonexempt commercial purpose'' as also encompassing this article exemption. Further supporting this interpretation, EPA believes it would be incongruous to establish a more comprehensive reporting obligation for the import of inactive existing chemical substances under TSCA section 8(b)(5) (*i.e.,* including import as part of an article), than would be applicable to the import of new chemical substances under TSCA section 5 (*i.e.,* excluding import as part of an article).

3. Chemical substances added to the Inventory on or after June 22, 2016. In this proposed rule, chemical substances added to the Inventory on or after June 22, 2016 would be designated as active, without the need for any reporting to establish that the chemical substance is active and without the need for any statement by manufacturers or processors indicating whether such persons wish to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance. Reporting under TSCA section 8(b)(4) is based on manufacturing or processing, for non-exempt commercial purposes, that occurred between June 21, 2006 and June 21, 2016. TSCA section 8(b)(4)(A)(iii) directs EPA to classify a chemical substance as inactive if no notice of manufacturing or processing is received by EPA. A substance added to the Inventory on or after June 22, 2016, however, would be added so recently that it has no manufacturing or processing overlapping with the lookback period. It would be illogical to designate a very recent addition to the Inventory as inactive, on the grounds that the chemical substance was too recently added to the Inventory to be captured in the retrospective reporting of current manufacturing and processing. Furthermore, if a chemical substance was added to the Inventory on or after June 22, 2016, then any claim for the protection against disclosure of the specific chemical identity of such a substance would be a new claim rather than the maintenance of an existing claim for protection of the information. For the reasons presented previously, EPA construes TSCA section 8(b)(4) reporting requirements to be limited to chemical substances that were added to the Inventory prior to June 22, 2016.

B. When would reporting be required?

1. Retrospective reporting period for manufacturers. This proposed rule would require manufacturers to report to the Agency not later than 180 days after the final rule is published in the **Federal Register**. The 180-day time period for this retrospective reporting for manufacturers is the maximum time allowed under TSCA section 8(b)(4)(A). Following this retrospective reporting for manufacturers, EPA would include the active and inactive designations, determined by the notices received, on the TSCA Inventory.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report to the Agency not later than 360 days after the final rule is published in the **Federal Register**. The 360-day time period for this retrospective reporting for processors would allow processors to search EPA's publication of a first draft of the TSCA Inventory with active designations and draft inactive designations, based on retrospective reporting by manufacturers, and to report only those chemical substances

not already reported. This first draft of the TSCA Inventory with active designations and draft inactive designations would not have the legal effect of actually designating any chemical substance as inactive. Processors would have the option to simply not report under TSCA section 8(b)(4) and continue processing until such time when EPA has actually designated a chemical substance as inactive. At such time, any further processing of the chemical substance, without prior notification to EPA, would be prohibited by section 8(b)(5). Prior notification would allow EPA to add the chemical substance to the TSCA Inventory as an active substance.

3. Forward-looking reporting. After EPA completes its review of the notices submitted under TSCA section 8(b)(4)(A), it must designate as inactive any chemical substance (subject to designation) for which no notice was received. TSCA section 8(b)(5)(B) provides that, once a chemical substance has been designated as inactive, any person who intends to manufacture or process that inactive substance for a nonexempt commercial purpose must first notify the Agency before the date on which the inactive substance is manufactured or processed. EPA proposes to furthermore limit the submission period for such notices, so that they may not be submitted more than 30 days before the actual date of manufacturing or processing.

The 30-day time period for forward-looking reporting is based on EPA's experience with Premanufacture Notices (PMNs). Although persons often form the intent to commercially manufacture or process chemical substances several months ahead of time, EPA's experience with processing PMNs is that business decisions, technical difficulties, and other unforeseen circumstances may delay a company's plans to commercialize. EPA believes that a commercial activity notice reflects a more tentative or provisional intent to manufacture or process if it is submitted more than 30 days prior to the actual date of manufacturing or processing of the chemical substance. As such, it is less reliable as evidence that placement as active Inventory is warranted. Reassigning chemical substances from inactive to active status, based on relatively unreliable indicia of intent to manufacture, could affect the reliability of the Inventory designations. Therefore, this proposed rule would require that forward-looking reporting of chemical substances designated as inactive on the TSCA Inventory occur not earlier than 30 days before companies intend to manufacturing or processing for nonexempt commercial purposes.

C. What information would be reported?

1. Retrospective reporting period for manufacturers. This proposed rule would require that manufacturers reporting for the retrospective reporting period provide certain information including chemical identity, type of commercial activity (*i.e.,* whether it is domestic manufacture and/or import), date range of manufacture for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report for the retrospective reporting period, provided that the processor reports timely and consistent with the pertinent reporting requirements, including providing certain information such as chemical identity, date range of processing for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

3. Forward-looking reporting. TSCA section 8(b)(5) requires that manufacturers and processors of inactive substances notify EPA before the date on which they manufacture or process an inactive substance for non-exempt commercial purposes. This proposed rule stipulates that they would do so in the following manner: By reporting certain information including chemical identity, type of commercial activity (*i.e.,* whether it is domestic manufacture, import, and/or processing), actual date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

4. Reporting forms. EPA developed two versions of a Notice of Activity (NOA) reporting form for submitting the information described in this proposed rule for the two reporting scenarios, retrospective and forward-looking (Ref. 6). NOA Form A (EPA Form No. TBD–1) would be used by manufacturers for the retrospective reporting period. It would also be used by processors who report for the retrospective reporting period. NOA Form B (EPA Form No. TBD–2) would be used by manufacturers and processors for forward-looking reporting. The new NOA forms are based on EPA's Notice of Commencement (NOC) form (Ref. 7), since much of the information submitted in an NOC form is the same or similar to the information proposed in the NOA.

Any person required to report under this proposed rule would provide the information identified in the relevant version of the NOA forms to the extent it is known to or reasonably ascertainable by them. Drafts of the two versions of the proposed NOA reporting forms are available in the docket for public review (Ref. 6).

As noted previously, these forms require very basic explanatory information about the type of commercial activity at issue (domestic manufacture, import, or processing) as well as the date range over which the activity occurred or the date when the activity is intended to resume. The collection of this explanatory information is intended to reduce the likelihood of receiving erroneous notices (*e.g.,* notices regarding commercial activity outside the lookback period), to support EPA's capacity to inquire into the accuracy of activity notices, and thus to increase the reliability of commercial activity designations on the TSCA Inventory.

D. How would information be submitted to EPA?

In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d) (Ref. 8). The final rule followed two previous rules requiring similar electronic reporting of information submitted to the Agency for TSCA Chemical Data Reporting and Pre-Manufacture Notifications. This proposed rule would require electronic reporting similar to the requirements established in 2013 for submitting certain other information under TSCA (see 711.35 and 720.40). This proposed rule would require submitters to use EPA's CDX, the Agency's electronic reporting portal, and EPA's Chemical Information Submission System (CISS), a web-based reporting tool, for all reporting under this proposed rule in accordance with section 3.2000 of 40 CFR part 3 (CROMERR) (Ref. 3).

This proposed rule would require persons submitting notices of activity to EPA under TSCA section 8(b) to follow these same electronic reporting procedures used for other TSCA submissions, *i.e.,* to register with EPA's CDX and use CISS to prepare a data file for submission. Registration in CDX

enables CDX to authenticate identity and verify authorization. To register, the CDX registrant (also referred to as ''Electronic Signature Holder'' or ''Public/Private Key Holder'') agrees to the Terms and Conditions, provides information about the submitter and organization, and selects a user name and password. Users who have previously registered with CDX for other submissions would be able to add the ''Submission for Chemical Safety and Pesticide Program'' service to their current registration in CDX and use the CISS web-based reporting tool.

EPA developed the Chemical Information Submission System (CISS) for use in submitting data electronically under TSCA sections 4, 5, 8(a), and 8(d) to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers and uses ''Extensible Markup Language'' (XML) specifications for efficient data transmission across the Internet. CISS works with CDX to secure online communication and provides user-friendly navigation. The NOA forms described in this proposed rule will be included in an e-NOA software module in CISS. Once a user completes entry of the relevant data fields and metadata information in the appropriate NOA form, the CISS reporting tool validates the submission by performing a basic error check. CISS also allows the user to choose ''Preview,'' ''Save,'' or ''Submit.'' When ''Submit'' is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then submits the data via CDX. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as ''Submitted.'' The user can also login to the application and download their Copy of Record.

EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization and more easily save a copy for their records or future use. The resource and time requirements to review, process, store, and retrieve data by the Agency would also be reduced.

Any person submitting a reporting form could claim any part or all of the form as confidential. Except as otherwise provided in this proposed rule, any information that is claimed as confidential would be disclosed by EPA only to the extent and by the means of the procedures set forth in 40 CFR part 2.

E. How would CBI claims and requests be handled?

Notices pursuant to this rulemaking may contain two different types of CBI assertions: Claims for protection of information other than specific chemical identify, and requests to maintain existing claims for protection of specific chemical identify.

1. *Information other than specific chemical identity.* For all new claims for protection (*i.e.,* for all CBI assertions under this rule other than requests to maintain existing claims for protection of specific chemical identity), TSCA section 14(c)(1)(B) and 14(c)(5) require that persons claiming CBI must provide a specific, certification statement regarding the basis for the CBI claims. In addition, this proposed rule would require that all such claims be substantiated at the time of submission, except for claims for information exempted from substantiation under section 14(c)(2). In view of the rapid EPA review of claims required by section 14(g)(1), and in order to reduce the likelihood of unwarranted claims, EPA believes that a concurrent substantiation is required. EPA will review a representative subset of these claims as specified by section 14(g)(1).

2. *Requests to maintain existing CBI claims for chemical identity.* Requests to maintain existing CBI claims for specific chemical identity on Form A are governed in part by TSCA sections 8(b)(4)(C–E). TSCA section 8(b)(4)(C), in particular, requires EPA to issue a rule to establish a review plan for these requests. That review plan must specify a time when the Form A CBI requests for specific chemical identity are to be substantiated. EPA will be conducting a separate rulemaking to establish this review plan. Therefore, this proposal does not include mandatory substantiation requirements for Form A CBI requests for chemical identity. Mandatory substantiation requirements will be part of the review plan promulgated under section 8(b)(4)(C). However, the Agency proposes to allow companies to submit early substantiation at the same time that their Form A is filed, if they so choose. As long as the period between the date these earlier substantiations are received and the due date to be established in the review plan (yet to be proposed) is not more than five years, these early substantiations would exempt the company from the requirement to submit additional substantiation for their Form A under the terms of the review plan. See section 8(b)(4)(D)(i). EPA will review requests to maintain CBI claims for specific chemical identity in accordance with the 8(b)(4)(D) review plan in the timeframe mandated by section 8(b)(4)(E).

Any manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) may seek to maintain an existing CBI claim for specific chemical identity, regardless of whether that person asserted the original claim that caused the specific chemical identity to be treated as confidential. EPA believes this is the correct interpretation of ''a manufacturer or processor . . . that seeks to maintain an existing claim for protection of against disclosure'' of specific chemical identity. A number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, and the initial claimant may no longer exist. EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants no longer manufacture the chemical substances.

Pursuant to TSCA section 8(b)(4)(B)(iv), EPA would move an active chemical substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific identity of that chemical substance. See proposed 710.37(a).

Requests to maintain existing CBI claims for specific chemical identity on Form B are governed by TSCA section 8(b)(5)(B), which provides that the request to maintain the claim must be substantiated not later than 30 days after submitting Form B. See section 8(b)(5)(B)(ii)(II). Proposed substantiation requirements for Form B CBI claims for chemical identity are found in section 710.37(a)(1)(ii).

Although TSCA section 8(b)(5) provides that substantiation for requests to maintain existing CBI claims for specific chemical identity must be provided not later than 30 days after submitting a Form B, persons submitting a Form B may find it more efficient to simply provide the substantiation for a CBI claim for specific chemical identity at the time of filing. Section 8(b)(5)(iii)(II) provides that the Agency shall ''promptly'' review CBI claims for specific chemical identity in Form B. The Agency intends to review these claims within 90 days of receipt of the substantiation.

IV. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule, including specific issues throughout this document, as well as other issues discussed in this Unit.

A. Considerations for the Agency's Economic Impact Analysis

EPA has evaluated the potential costs for manufacturers and processors of chemical substances reportable under this proposed rule (Ref. 1). EPA is specifically seeking additional information and data that the Agency could consider in developing the final economic analysis. In particular, EPA is seeking data that could facilitate the Agency's further evaluation of the potentially affected industry and firms, including data related to potential impacts for those small businesses that would be subject to reporting.

B. Electronic Reporting

Requiring electronic reporting under this proposed rule that is similar to those established in 2013 for other TSCA reporting, EPA expects to save time, improve data quality, and provide efficiencies for both submitters and the Agency. EPA is specifically interested in comments related to the adoption of the existing mechanisms and procedures for use in transmitting the notices proposed in this rule, including comments related to the extent to which potential reporting entities are already familiar with these mechanisms and procedures because of their existing use for other TSCA reporting. EPA is also interested in feedback on how electronic reporting affects potential reporting entities in terms of reporting time, reporting efficiency, and potential burden associated with training to use the electronic systems (*i.e.,* CDX and CISS).

V. References

The following is a listing of the documents that are specifically referenced in this proposed rule. The docket includes these references and other information considered by EPA. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. 2016. EPA. Burden and Cost Report for the Proposed Rule: TSCA Inventory Notification Requirements (RIN 2070–AK24, December 21, 2016).
2. 1977. EPA. Inventory Reporting Requirements; Final Rule. **Federal Register** (42 FR 64572, December 23, 1977) (FRL 817–1).
3. 2005. EPA. Cross-Media Electronic Reporting Rule (CROMERR); Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL 7977–1).
4. 2010. EPA. Certain New Chemicals; Receipt and Status Information; Notice. **Federal Register** (75 FR 71688, November 24, 2010) (FRL 8852–1).
5. 2016. EPA. 2016 Chemical Data Reporting Frequent Questions. *https://www.epa.gov/chemical-data-reporting/2016-chemical-data-reporting-frequent-questions*.
6. 2016. EPA. Notice of Activity Form A and Form B; Draft.
7. 2009. EPA. Notice of Commencement Form; Final.
8. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394–6).
9. 2016. EPA. Information Collection Request for the TSCA section 8(b) Proposed Reporting Requirements for TSCA Inventory Notification Active-Inactive (EPA ICR No. 2517.01).
10. 2016. EPA. Small Entity Analysis Report for the Proposed Rule: TSCA Inventory Notification Requirements (December 16, 2016).

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an Information Collection Request (ICR) to estimate the potential burden and costs associated with the proposed requirements (Ref. 9). The ICR, which is available in the docket, has been assigned the EPA ICR No. 2517.01 (OMB Control No. 2070-[new]). You can find a copy of the ICR in the docket for this proposed rule (Ref. 9), and it is briefly summarized here.

Start-Up Year Burden/Cost (Retrospective). Covers respondents/affected entities, *i.e.,* persons who manufacture chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 4,692.

Frequency of response: Once and on-occasion.

Estimated burden: 86,783 hours. The term ''burden'' is defined at 5 CFR 1320.3(b).

Estimated cost: $6.68 million.

Note that an additional number of respondents (*i.e.,* processors), as high as 161,550, are each assumed to undergo four hours of rule familiarization (about $300 per firm), but would likely not be required to submit information. This is based on an assumption that 100 percent of processor firms would undertake rule familiarization. However, EPA believes that it is unlikely that 100% of processors would initiate rule familiarization and that the actual percentage would be lower. Although this count, and the associated burden and costs, are not included in the estimates, the estimated burden and costs account for the bulk of total start-up costs (88%). In addition, the estimated burden and costs includes 469 CDX registrations in addition to NOA submissions.

Ongoing Annual Burden/Cost (Forward-looking): Covers respondents/affected entities, *i.e.,* persons who manufacture or process chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 20.

Frequency of response: On-occasion.

Total estimated burden: 142 hours.

Total estimated cost: $10,790.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and included on any related collection instrument (*e.g.,* the form).

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov*, Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 13, 2017. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule would not have a significant economic impact on a substantial number of small entities if the rule has a very small level of impact on the small entities subject to the rule.

The small entities subject to the requirements of this action are manufacturers, and processors of chemical substances. As the most burdensome conditions are incurred during the start-up year for manufacturers, these reporters are the subject of the quantitative analysis with other reporters and other years assessed by inference. The detailed analysis is available in the docket (Ref. 10).

The quantitative analysis addresses the ''most affected'' subset of entities who are expected to incur the highest typical burden under the proposed rule as entities manufacturing (or importing) chemicals that must submit NOAs involving an average of seven chemicals per entity in the start-up year. These small entities most directly regulated by this rule are small businesses in NAICS 325: Chemical Manufacturing, and 324: Petroleum and Coal Products Manufacturing reporting during the start-up year. EPA has determined that all of the small entities (comprising about 96% of the total number of entities) within the scope of the quantitative analysis would experience an impact of less than 1% of revenues. This analysis follows EPA guidance on Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act (SBREFA) analyses. Per this guidance document, the preferred measure of economic impacts is the ''sales test:'' Annualized compliance costs as a percentage of sales (or revenue or receipts when sales data are not readily available). This measure is termed ''cost impact percentage'' in the small entity analysis.

Additional groups of small entities may be affected by the rule and are expected to incur similar or lesser impacts, by inference. First, processors submitting NOAs during the start-up year are expected to incur a smaller unit burden with one chemical per NOA, and therefore experience similar or lesser impacts than manufacturers. Secondly, all reporters in future years, with lower counts and relatively smaller unit burdens, would therefore incur much lower impact than entities during the start-up year, Therefore, inferences drawn regarding small entity impacts on the most affected group may be extended to characterize the impacts on processors during the start-up year and all entities for future years.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action is not expected to impose enforceable duty on any state, local or tribal governments, and the requirements imposed on the private sector are not expected to result in annual expenditures of $100 million or more for the private sector. As such, EPA has determined that the requirements of UMRA sections 202, 203, 204, or 205 do not apply to this action.

E. Executive Order 13132: Federalism

This action does not have federalism implications because it would not have any 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications because it is not expected to have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

I. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 710

Environmental protection, Chemicals, Reporting and Recordkeeping, TSCA Inventory.

Dated: December 23, 2016.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 710—[AMENDED]

■ 1. The authority citation for part 710 would continue to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 2. Redesignate §§ 710.1 through 710.4 as subpart A under the following subpart A heading:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

Subpart A—General Provisions

Sec.
710.1 Scope and compliance.
710.3 Definitions.
710.4 Scope of the Inventory.

Subpart B—Commercial Activity Notification

710.23 Definitions.

710.25 Persons subject to the notification requirement.
710.27 Activities for which notification is not required.
710.29 Information required in the notification.
710.30 When to submit notifications.
710.33 Co-manufacturers and co-processors.
710.35 Recordkeeping requirements.
710.37 Confidentiality claims.
710.39 Electronic filing.

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■ 3. Revise § 710.1 paragraph (b) to read as follows:

Subpart A—General Provisions

§ 710.1 Scope and compliance.

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(b) This part applies to the activities associated with the compilation of the TSCA Chemical Substance Inventory (TSCA Inventory) and the designation of chemical substances on the TSCA Inventory as active or inactive in U.S. commerce.

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■ 4. Revise § 710.3 paragraph (d) to read as follows:

§ 710.3 Definitions.

* * * * *

(d) The following definitions also apply to this part:

Act means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his/her authority to carry out his/her functions, or any other person who will by operation of law be authorized to carry out such functions.

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

CASRN means Chemical Abstracts Service Registry Number.

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that ''chemical substance'' does *not* include: (1) Any mixture; (2) any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product, but not including any derivative products; (4) any source material, special nuclear material, or byproduct material; (5) any pistol, firearm, revolver, shells, and cartridges; and (6) any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commerce means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Distribute in commerce and *distribution in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after its introduction into commerce.

Domestic means within the geographical boundaries of the 50 United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

EPA means the U.S. Environmental Protection Agency.

Importer means any person who imports any chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. ''Importer'' includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate, (1) the consignee, (2) the importer of record, (3) the actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20, or (4) the transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR 144.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rate(s) of such chemical reaction(s).

Inventory means the TSCA Chemical Substance Inventory, which is EPA's comprehensive list of confidential and non-confidential chemical substances manufactured or processed in the United States for non-exempt commercial purpose that EPA compiled and keeps current under section 8(b) of the Act.

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is: (1) Produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

Manufacture for commercial purposes means: (1) To manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, among other things, the ''manufacture'' of any amount of a chemical substance or mixture (i) for commercial distribution, including for test marketing, or (ii) for use by the manufacturer, including use for product research and development or as an intermediate. (2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

Manufacturer means a person who manufactures a chemical substance.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that

''mixture'' does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

New chemical substance means any chemical substance which is not included on the Inventory.

Person includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Process means to process for commercial purposes. Process includes the preparation of a chemical substance or mixture, after its manufacture, (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way will be considered one site. More than one manufacturing plant may be located on a single site. (1) For chemical substances manufactured under contract, *i.e.,* by a toll manufacturer, the site is the location where the chemical substance is physically manufactured. (2) The site for an importer who imports a chemical substance described in § 710.25 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

Small quantities solely for research and development (or ''small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product'') means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Technically qualified individual means a person (1) who because of his/her education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his/her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

■ 5. Add a new subpart B to read as follows:

Subpart B—Commercial Activity Notification

§ 710.23 Definitions.

The following definitions also apply to subpart B of this part.

Active substance means any interim active substance, any naturally occurring chemical substance as defined by § 710.27(b), any substance added to the TSCA Inventory on or after June 22, 2016, and any chemical substance subject to commercial activity designation that the Administrator designated as active based on the receipt of a notice under this subpart.

Central Data Exchange or CDX means EPA's centralized electronic document reporting portal, or its successors.

Chemical substance subject to commercial activity designation means a chemical substance that requires a designation as either an active or an inactive substance. A chemical substance is subject to commercial activity designation if it was added to the TSCA Inventory before June 22, 2016, it is not an interim active substance, it is not a naturally occurring chemical substance as defined by § 710.27(b), and it has not yet been designated by the Administrator as either an active or an inactive substance.

Chemical Information Submission System or CISS means EPA's web-based reporting tool for preparing and submitting a Notice of Activity.

e-NOA means EPA's software module within CISS for generating and completing Notice of Activity forms A and B.

Existing claim for protection of specific chemical identity against disclosure is a claim to continue protection of specific chemical identity of a chemical substance that is listed on the confidential portion of the TSCA Inventory.

Inactive substance means any chemical substance subject to commercial activity designation, that the Administrator designates as inactive based on the lack of receipt of a notice under this subpart.

Interim active substance means any chemical substance that was reported, pursuant to 40 CFR part 711, as having been manufactured in either 2010 or 2011. After such time when EPA has made public a compiled list of chemical

substances that were reported, pursuant to 40 CFR part 711, as having been manufactured in either 2012, 2013, 2014, or 2015, the term shall also include any such additional chemical substances that were there reported as having been manufactured in those additional years.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Lookback period means the period beginning on June 21, 2006 and ending on June 21, 2016.

Reportable chemical substance means a chemical substance that is listed on the TSCA Inventory and that is either: (1) A chemical substance subject to commercial activity designation for which notification is required or allowed under § 710.25(a) and § 710.25(b), (2) an interim active substance for which notification is required under § 710.25(a), or (3) an inactive substance for which notification is required under § 710.25(c).

Submission period means the applicable period for submitting a Notice of Activity under § 710.25.

§ 710.25 Persons subject to the notification requirement.

The following persons are subject to the requirements of this subpart.

(a) *Who must submit the Notice of Activity Form A?* Any person who manufactured a chemical substance subject to commercial activity designation or who manufactured an interim active substance that is on the confidential portion of the TSCA Inventory, at any time during the lookback period, except as provided in § 710.27, must submit a Notice of Activity Form A as specified under § 710.29 and § 710.30.

(b) *Who else may submit the Notice of Activity Form A?* Any person who processed a chemical substance subject to commercial activity designation, at any time during the lookback period, except as provided in § 710.27, may submit a Notice of Activity Form A as specified under § 710.29 and § 710.30.

(c) *Who must submit the Notice of Activity Form B?* Any person who intends to manufacture or process an inactive chemical substance, except as provided in § 710.27, after the effective date of the Administrator's designation of such chemical substance as an inactive substance, must submit a Notice of Activity Form B as specified under § 710.29 and § 710.30.

§ 710.27 Activities for which notification is not required.

(a) *In general.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacturing or processing of a chemical substance solely in small quantities for research and development.

(2) The import of a chemical substance as part of an article.

(3) The manufacturing or processing of a chemical substance as described in § 720.30(g) or (h).

(b) *Manufacturing or processing naturally occurring chemical substances.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacture of a naturally occurring chemical substance, as described in § 710.4(b). Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person manufactures a chemical substance by means other than those described in § 710.4(b), this exemption is inapplicable, regardless of whether the chemical substance also could have been produced as described in § 710.4(b). This exemption does not cover the manufacture of a chemical substance from a naturally occurring chemical substance.

(2) The processing of a naturally occurring chemical substance only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water.

§ 710.29 Information required in the notification.

(a) *Reporting information to EPA.* Any person who reports information to EPA, including post-notification substantiation of confidentiality claims under § 710.37(b), must do so using the e-NOA software module, the CISS reporting tool, and the CDX electronic reporting portal provided by EPA at the addresses set forth in § 710.39. For notices of activity under § 710.25(a) and § 710.25(b), the submission must include all information described in paragraph (b) of this section. For a Notice of Activity under § 710.25(c), the submission must include all information described in paragraph (c) of this section. A person must submit a separate form for each chemical substance that the person is required to report. CDX, CISS, and e-NOA allow a person to report multiple chemical substances in one session that will be transmitted to EPA on separate forms. Using e-NOA and registering in CDX are described in instructions available from EPA at the Web sites set forth in § 710.39.

(b) *Information to be reported on the Notice of Activity Form A.* Any person submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b) must submit the information described in this paragraph for each reportable chemical substance during the submission period specified in § 710.30(a). A person submitting information under § 710.25(a) or § 710.25(b) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each chemical substance for which the person is required to report. A person reporting information under § 710.25(a) or § 710.25(b) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of commercial activity for each reportable chemical substance: Whether the chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(3) The first date and the last date that each reportable chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(c) *Information to be reported on a Notice of Activity Form B.* Any person submitting a Notice of Activity Form B under § 710.25(c) must provide the information described in this paragraph for each inactive chemical substance intended to be manufactured or processed at the time specified in § 710.30(b). A person submitting information under § 710.25(c) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each chemical substance that the person intends to manufacture or process. A person submitting a notice of activity under § 710.25(c) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of intended commercial activity for the inactive substance: Whether the inactive substance is intended to be domestically manufactured in the United States, imported into the United States, processed in the United States, or a particular combination of these.

(3) The actual date by which the inactive substance is to be domestically manufactured in the United States, imported into the United States, or processed in the United States.

(d) *Information to be reported on either the Notice of Activity Form A or Form B.*

(1) *Company.* The name of the submitting company.

(2) *Authorized official.* The name and address of the authorized official for the submitting company.

(3) *Technical contact.* The name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to EPA.

(4) *Chemical-specific information.* The correct CA Index name as used to list the chemical substance on the Inventory and the correct corresponding CASRN must be submitted for each reportable chemical substance. Persons who wish to report chemical substances listed on the confidential portion of the TSCA Inventory must report the chemical substances using a TSCA Accession Number and generic name.

(i) If an importer submitting a notice cannot provide the information specified in § 710.29(d)(4) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must ask the supplier to provide the specific chemical identity information directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically, using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other name for the chemical substance or mixture, and a copy of the request to the supplier must be included with the importer's submission with respect to the chemical substance.

(ii) If a manufacturer or processor submitting a notice cannot provide the information specified in § 710.29(d)(4) because the reportable chemical substance is manufactured or processed using a reactant having a specific chemical identity that is unknown to the manufacturer or processor and claimed as confidential by its supplier, the manufacturer or processor must ask the supplier of the confidential reactant to provide the specific chemical identity of the confidential reactant directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the manufacturer's or processor's submission. Contact information for the supplier, a trade name or other name for the chemical substance, and a copy of the request to the supplier must be included with the manufacturer's or processor's submission with respect to the chemical substance.

(iii) EPA will only accept joint submissions that are submitted electronically using e-NOA, CISS, and CDX (see § 710.39) and that clearly reference the primary submission to which they refer.

(5) *Certification statement.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the form are true and correct using the certification statement in this paragraph.

(i) The certification must be signed and dated by the authorized official for the submitting company.

(ii) The following is the required certification language:

''I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge is, true, accurate, and complete. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.''

§ 710.30 When to submit notifications.

(a) *When must a Notice of Activity Form A be submitted?* The Notice of Activity Form A required to be submitted under § 710.25(a) must be submitted during the applicable submission period.

(1) *Manufacturers.* The submission period for manufacturers under § 710.25(a) begins on [date on which the final rule is published in the **Federal Register**] and ends on [180 days after the date on which the final rule is published in the **Federal Register**].

(2) *Processors.* The submission period for processors under § 710.25(b) begins on [date on which the final rule is published in the **Federal Register**] and ends on [360 days after the date on which the final rule is published in the **Federal Register**].

(b) *When must a Notice of Activity Form B be submitted?* The Notice of Activity Form B required to be submitted under § 710.25(c) must be submitted before a person manufactures or processes the inactive substance, but not more than 30 days prior to the actual date of manufacturing or processing.

§ 710.33 Co-manufacturers and co-processors.

(a) *Notice of Activity submitted by co-manufacturers.* When, in a single instance of manufacturing or importing a particular volume of a chemical substance during the lookback period, two or more persons qualify as the manufacturer or importer of that volume, they may determine among themselves who should make the required submission under § 710.25(a). If no notice is submitted as required under this subpart, EPA will hold each such person liable for failure to submit a notice.

(b) *Notice of activity by prospective co-manufacturers or co-processors.* If two or more persons intend to manufacture, import, or process a particular volume of an inactive substance, such that multiple persons would qualify as the manufacturer, importer, or processor of that volume, they may determine among themselves who will submit the required notice under § 710.25(c). If no notice is submitted as required under this subpart, all of the persons remain subject to the reporting requirements, and EPA will hold each such person liable for a failure to submit a notice prior to the date of manufacturing, importing, or processing.

§ 710.35 Recordkeeping requirements.

Each person who is subject to the notification requirements of this part must retain records that document any information reported to EPA. Records relevant to a notice of activity under § 710.25(a) and § 710.25(b) must be retained for a period of 5 years beginning on the last day of the submission period. Records relevant to a notice of activity under § 710.25(c) must be retained for a period of 5 years beginning on the day that the notice was submitted.

§ 710.37 Confidentiality claims.

(a) *Chemical identity.* Any persons submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance only if the identity of the chemical substance is listed on the confidential portion of the TSCA

Inventory as of the time the notice is submitted for that chemical substance under this part. Any such requests to maintain an existing claim of confidentiality must be made at the time the information is submitted. If no person submitting the information specified in § 710.29(d)(4) for a particular chemical substance requests that the claim be maintained, EPA will treat the specific chemical identity of that chemical substance as not subject to a confidentiality claim and will move the chemical substance to the public portion of the TSCA Inventory. Except as set forth in this subsection, information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2. The following steps must be taken to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance.

(1) *Substantiation of requests.*

(i) *Notice of Activity Form A.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity may submit with the notice detailed written answers to the questions in paragraph (1)(iii) of this section, signed and dated by an authorized official. If these early answers are received less than five years before the date on which substantiation is due pursuant to TSCA Section 8(b)(4)(D)(i) the early answers will be deemed to be substantiations made under TSCA Section (8)(b)(4)(D)(i) and the person will be exempt from further substantiation requirements under Section (8)(b)(4)(D)(i). Early answers that do not include the answers to questions in paragraph (1)(iii) of this section will not be deemed to be substantiations made under the TSCA section (8)(b)(4)(D)(i) requirement.

(ii) *Notice of Activity Form B.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity must submit detailed written answers to the questions in paragraph (1)(iii) of this section within 30 days of submitting the notice, signed and dated by an authorized official. If this information is not submitted within 30 days of submitting the notice, EPA will consider the specific chemical identity as not subject to a confidentiality claim and may make the information public without further notice.

(iii) *Substantiation questions.*

(A) What harmful effects to your competitive position, if any, or to your supplier's competitive position, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(B) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured for a commercial purpose by anyone?

(E) Is the fact that the chemical substance is being manufactured for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?

(F) What measures have been taken to prevent undesired disclosure of the fact that the chemical substance is being manufactured for a commercial purpose?

(G) To what extent has the fact that this chemical substance is manufactured for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(H) Does this particular chemical substance leave the site of manufacture in any form, *e.g.,* as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(I) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

(J) For what purpose do you manufacture the chemical substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (a)(1)(iii) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(b) *Information other than specific chemical identity.* Any persons submitting information under this part may assert a claim of confidentiality for information other than specific chemical identity. Any such confidentiality claims must be made at the time the information is submitted. Confidentiality claims will apply only to the information submitted with the claim. Confidentiality claims cannot be made when a response field on a reporting form is left blank or designated as not known or reasonably ascertainable. Except as set forth in this section, information claimed as confidential in accordance with this subsection will be treated and disclosed in accordance with 40 CFR part 2. The following steps must be taken to assert a claim of confidentiality for information other than specific chemical identity. If no claim is asserted at the time the information is submitted, or if the following steps are not taken, EPA will consider the information as not subject to a confidentiality claim and may make the information public without further notice.

(1) *Substantiation of claims.* A person asserting a claim of confidentiality for information other than specific chemical identity must submit detailed written answers to the following questions at the time of submission, signed and dated by an authorized official.

(i) For what period of time do you request that the information be maintained as confidential, *e.g.,* until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.

(ii) Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?

(iii) What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?

(iv) Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.

(v) Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

(vi) Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

(vii) For each item or category of information claimed as confidential, *explain with specificity* why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

(viii) Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

(ix) Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

(x) If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).

(xi) Explain any other issue you deem relevant.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (b)(1) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as ''confidential business information,'' ''proprietary,'' or ''trade secret.''

(3) *Certification statement for claims.* In submitting a claim of confidentiality, a person must certify the truth of the following four statements concerning all information which is claimed as confidential:

(i) My company has taken reasonable measures to protect the confidentiality of the information.

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

§ 710.39 Electronic filing.

(a) EPA will accept information submitted under this subpart only if submitted in accordance with this section. All information must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, Notices of Activity and any associated information must be generated and completed using the e-NOA software module.

(b) Obtain instructions for registering in CDX as follows:

(1) *Web site.* The CDX Registration User Guide is available at *https://www.epa.gov/sites/production/files/documents/cdx_registration_guide_v0_02.pdf.* To register in CDX, go to *https://cdx.epa.gov* and follow the appropriate links.

(2) *Telephone.* Contact the EPA CDX Help Desk at 1–888–890–1995.

(3) *Email.* Email the EPA CDX Help Desk at *HelpDesk@epacdx.net.*

(c) Obtain instructions for using the e-NOA software module as follows:

(1) *Web site.* Go to the EPA New Chemicals under the Toxic Substances Control Act Web site at *https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn* and follow the appropriate links.

(2) *Telephone.* Contact the EPA TSCA Hotline at 1–202–554–1404.

(3) *Email.* Email the EPA TSCA Hotline at *TSCA-Hotline@epa.gov.*

[FR Doc. 2016–31923 Filed 1–12–17; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[IB Docket No. 98–96; FCC 16–179]

1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes to withdraw as an accounting authority and transition its functions and duties to private accounting authorities. The Commission seeks comment on a transition plan and a timetable to implement an orderly transition to the privatization of the accounts-settlement function.

DATES: Comments due on or before March 14, 2017, and reply comments due on or before April 13, 2017.

ADDRESSES: You may submit comments, identified by IB Docket 98–96, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.
- *Email: ecfs@fcc.gov.* Include IB Docket No. 98–96 in the subject line of the message.
- *Mail:* Commercial overnight mail (other than U.S. Postal Service Express Mail, and Priority Mail, must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Dana Shaffer, Office of Managing Director at (202) 418–0832.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Further Notice of Proposed Rulemaking (*Second FNPRM*), FCC 16–179, IB Docket No. 98–96, adopted on December 22, 2016, and released on December 30, 2016. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Room CY–A257, Portals II, Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their Web site, *http://www.bcpi.com,* or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and braille).

Persons with disabilities who need documents in these formats may contact the FCC by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

I. Procedural Matters

A. Ex Parte Rules—Permit-But-Disclose

1. The proceeding this *Second FNPRM* initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules.[1] Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

B. Comment Period and Procedures

2. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

C. Initial Regulatory Flexibility Analysis

3. As required by the Regulatory Flexibility Act of 1980 (RFA),[2] the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules proposed in this *Second FNPRM.* The IRFA is found near the end of this document. We request written public comment on the analysis. Comments must be filed in accordance with the same deadlines as comments filed in response to this *Second FNPRM,* and must have a separate and distinct heading designating them as responses to the IRFA. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this *Second FNPRM,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

4. Copies to Private Accounting Authorities and Governmental Users. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this *Second Further Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Analysis, to the current U.S.-certified private accounting authorities: Mackay Communications, Inc., Astrium Services Business Communications Inc., Seven Seas Communications Inc., Omnet, Inc., KFS World Communications dba GLOBE WIRELESS, GMPCS Personal Communications, Inc., ShipCom, L.L.C. (formerly M M R Radio, L.L.C.), Stratos Mobile Networks Inc., Exxon Communications Company, Vizada, Inc., Raytheon Service Co., Telemar USA LLC, MVS USA Inc., A–N–D Group Plc, Selex ES Ltd, Selex ES Ltd, NSSLGlobal, Airtime Billing Department.

D. Initial Paperwork Reduction Analysis

5. This document does not contain a proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA, Pub. L. 104–13). In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

II. Introduction

6. In this Second Further Notice of Proposed Rulemaking (*2016 Accounting Authority Second FNPRM),* we propose to transition the functions and duties performed by the Commission as an accounting authority to private accounting authorities. In doing so, we seek to revisit findings in the 1999 Report and Order and Further Notice of Proposed Rulemaking *(1999 Accounting Authority Order & FNPRM),*[3] which

[1] 47 CFR 1.1200 *et seq.*

[2] *See* 5 U.S.C. 603.

[3] 1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services and Withdrawal of the Commission as an Accounting Authority in the Maritime Mobile and the Maritime Mobile-Satellite Radio Services, *Report and Order and Further Notice of Proposed Rulemaking,* 15

included the Commission's decision that it should withdraw as an accounting authority in the maritime mobile and maritime mobile-satellite radio services.[4] The Commission tentatively concluded that a three-year transition period following adoption of a Report and Order was appropriate to permit the preparation and implementation of a plan to ensure a smooth, non-disruptive transition to private accounting authorities, and to develop the transition plan.[5] Although in that Order the Commission concluded that ''the Commission shall cease operating as an accounting authority for settling accounts for maritime mobile, maritime satellite, aircraft,[6] and handled terminal radio services,'' and that ''a transition period is necessary to allow for an orderly transition to a full privatization of the accounts-settlement function,'' we stopped short of proscribing a transition plan, instead seeking further comment ''on a number of proposals regarding how best to implement this transition.'' [7]

7. The completion of a plan based on those comments, however, was subsequently delayed. Thus, no definitive timeline for the transition to implement our decision in the Order to withdraw as accounting authority has been established.

8. We continue to believe that it is in the public interest for the Commission to withdraw as an accounting authority. Given the passage of time, we now, in this *2016 Accounting Authority Second FNPRM,* seek further comment on the appropriate transition plan and period to implement our decision in the *1999 Accounting Authority Order & FNPRM* to withdraw as an accounting authority in the maritime mobile and maritime mobile-satellite radio services.

III. Background

9. International maritime mobile communications are HF or VHF radio communications between a ship and a coast station operated by the telecommunications operator in the country in which the station is located, and international maritime mobile-satellite communications services are conducted by satellite. Payment for the services provided by the telecommunications operators involves interaction with an entity known as an ''accounting authority,'' which settles an account between the telecommunications operator and the customer. In practice, the telecommunications operator, the earth or coast station, sends its bill either to the accounting authority that the customer has designated to act for it or to an ''accounting authority of last resort,'' which, as the name implies, settles accounts for customers that have not designated a particular accounting authority. The function of the accounting authority, also referred to as a ''clearinghouse'' or ''settlement authority,'' involves presenting the bill to the customer, accepting payment from the customer, and remitting the collected funds to the telecommunications operator.

10. Historically, most nations required individual ships to settle their accounts with their telecommunications provider; however, since 1934, the Commission has acted as an accounting authority in the United States, to settle accounts for maritime, aircraft, and hand-held terminal radio services to both private users and other U.S. federal government agencies. Over time, the Commission has reduced its accounting authority or clearinghouse function related to the maritime mobile radio services and the satellite-based services, including aeronautical and hand-held terminals. The primary reason for this reduction is that private accounting authorities provide similar account settlement services for U.S. users. Certification and operation of private accounting authorities are governed under part 3 of our rules, which ensure that qualified applicants are authorized as accounting authorities and that such authorities, once approved, have adequate guidance of the standard of conduct required of them by the Commission. We believe that this process has been working effectively.[8] Currently, there are twenty-two entities certified as U.S. private accounting authorities.[9]

11. When the Commission last considered this matter more than fifteen years ago, it found no public policy reason for the Commission's continued function as an accounting authority,[10] and concluded in the Report and Order section of the decision, therefore, that the Commission should withdraw as a clearinghouse for the settlement of accounts in the maritime mobile radio, maritime mobile-satellite, and other satellite-based communications services.[11] The Commission tentatively concluded that it should not designate a new accounting authority of last resort,[12] and that a three year transition plan was sufficient to ensure a smooth transition.[13] The Commission sought further comment on these tentative conclusions.[14]

IV. Discussion

12. In the Order portion of the *1999 R&O and FNPRM,* the Commission announced its decision to withdraw from the accounting authority function. Additionally, it revised section 3.10(e) to make explicit the authorities' obligations not to discriminate,[15] grandfathered the accounting authority of EXXON to permit it to continue to settle accounts only for its ships, and provided guidance to allow applicants to amend their pending applications in light of the change to section 3.10(e). In the *Second FNPRM,* the Commission requested comments on two issues. First, the Commission sought comment on whether to appoint or allow an entity to take over the Commission's function as the accounting authority of last resort, require customers to pre-subscribe to an accounting authority or to designate an accounting authority on every message, or to develop a formula to spread undesignated messages among several private accounting authorities. Second, the Commission tentatively concluded that the appropriate phase-out period was three years following **Federal Register** publication of a final order, and invited comment.

A. Withdrawal by the Commission From the Accounting Authority Function

13. In the *1999 R&O and FNPRM,* the Commission decided to withdraw from performing the functions of an accounting authority, and to leave the settlement of accounts to the private

FCC Rcd 20703 (1999) *(1999 Accounting Authority Order & FNPRM*).

[4] *Id.*

[5] *Id.* at 20717.

[6] The focus of this FNPRM is the effect on maritime communications, as the Commission has not, for several years, settled aeronautical accounts. It is important to note, however, that our withdrawal as accounting authority of last resort would include a cessation in our settling of accounts for maritime mobile, maritime satellite, aircraft, and handled terminal radio services, as we previously concluded.

[7] *Id.*

[8] *See* Letter from Bruce Henoch, Inmarsat, to Accounting Authority Certification Office, Federal Communications Commission (dated April 20, 2015); Letter from Robert Swanson, Airbus Defense and Space, to Marlene Dortch, Federal Communications Commission (dated January 30, 2015); Letter from Steven Chernoff, Lukas, Nace, Gutierrez, and Sachs, LLP, to Accounting Authority Certification Officer, Federal Communications Commission (April 15, 2015) (providing inventories of accounting authority settlements).

[9] Some of these private accounting authorities may not currently settle accounts for maritime services; however, our certification does not limit any certified U.S. accounting authority to the settlement of accounts for only one class of service.

[10] *1999 Accounting Authority Order & FNPRM* at 20709.

[11] *Id.* at 20723.

[12] *Id.* at 20715.

[13] *Id.* at 20718.

[14] *Id.* at 20715, 20723.

[15] 47 CFR 3.10(e).

accounting authorities subject to part 3 of our rules. Although the Commission never implemented a transition plan, many users of the Commission's services subsequently have transitioned to one of these accounting authorities. We continue to believe that it is in the public interest for the Commission to withdraw as an accounting authority and seek comment on our proposals to do so below. The function of an accounting authority is not necessarily a governmental function, but can be performed equally well by privately owned entities, subject to Commission oversight under our part 3 rules.[16] Since the Commission last visited this issue, U.S. private accounting authorities have continued to succeed in providing these functions.[17] We anticipate that our action to step away from the functions of an accounting authority will create further competition for the settlement of maritime and satellite accounts, and may thereby encourage the industry to provide the public with more choices in obtaining settlement of their accounts.

14. Since 1999, the number of users relying on the Commission to provide accounting authority services has decreased,[18] even as the activity handled by other accounting authorities, in general, appears to have increased in scope. We recognize that an immediate departure of the Commission as an accounting authority will require those U.S. international ship and satellite operators currently handled by the Commission to select an alternative accounting authority. We also believe, unlike in 1999 when we suggested a three-year transition period, that maritime operators are far better prepared to adjust to the departure of the Commission as the accounting authority. First, the Commission possesses the ability to contact current users and thereby their expedite transition. Second, through outreach and coordination with the maritime industry, Commission staff have learned that many of those entities using the Commission's accounting authority services have anticipated the change, and they have initiated a transition process in contracting with other accounting authorities. Consequently, we believe that most maritime mobile satellite users will be able to accommodate this change, and that they will act promptly to select an alternative accounting authority. We therefore, recommend a one year transition period and seek comment on this recommendation.

15. We continue to believe that we should not designate a new accounting authority of last resort, but, rather, customers should designate an accounting authority for each call or should presubscribe for the services of an accounting authority.[19] We seek further comment on this tentative conclusion.

B. Government Agencies

16. In the *1999 R&O and FNPRM* we acknowledged that the Commission at that time acted as the accounting authority for the maritime and satellite communications of a majority of U.S. governmental agencies.[20] At the time, because we anticipated that Government agency users might have special needs that differ from other users, we requested the agencies to address this issue in their comments.[21]

17. In their 1998 comments, the United States Coast Guard urged the Commission to maintain a default accounting authority, provide ample notice to affected users and small vessel organizations, provide a smooth transition process to a new default accounting authority, and ensure the economic impact on small entities is non-significant.[22] The National Telecommunications and Information Administration (NTIA), in coordination with the Interdepartment Radio Advisory Committee (which includes the Coast Guard), expressed concern that the Commission's withdrawal might lead to disruption or curtailment of communication services to federal users, as well as increased cost to the taxpayer.[23] They requested that the FCC retain its accounting authority, or, in the alternative, noted that most government agencies operate on a three year budget cycle, and asked that the FCC defer termination of its accounting authority responsibility ''until an [sic] alternative billing and payment arrangements ensuring uninterrupted service can be established.[24] NTIA further urged that the FCC either retain its accounting authority, or designate an authority of last resort that would ''not charge more than the Commission currently charges its accounts until users are notified and given a chance to select their own accounting authority or accept the terms offered.'' [25]

18. We agree that, as part of an effective plan for the Commission to withdraw as an accounting authority, U.S. Government agencies must have in place alternate arrangements upon the Commission's withdrawal to ensure that critical communications are not disrupted. In the more than fifteen years, since our 1999 decision, Commission staff have contacted the various government agencies informing them of the Commission's intent to terminate its accounting authority; as a result, many of these various agencies, have moved to alternative accounting authorities for some or all of their services.[26] In light of this trend, and the more than fifteen years impacted entities have had to transition to a new accounting authority, we seek comment on the appropriate time period to complete the Commission's transition from serving as accounting authority for government agencies. Movement of government agencies anticipating our change in function suggests that a transition period shorter than the three-year period previously proposed is appropriate to accommodate these particular changes, including anticipated government budget planning changes. We propose that the transition period for government and non-government entities be the same. We seek comment on whether one year suffices for government agencies to transition to an alternative accounting authority. Alternatively, we invite comment on whether this period should be longer or shorter.

C. Accounting Authority of Last Resort

19. The Commission historically has served as the ''accounting authority of last resort'' for the United States, which resulted in the Commission receiving from foreign telecommunications

[16] The FCC's withdrawal as an accounting authority will in no way change the rules by which we certify and monitor private entities serving as accounting authorities for maritime mobile and maritime satellite services. *See* 47 CFR 3.1 *et seq.*

[17] *See 1999 R&O and FNPRM,* 15 FCC Rcd at 20706–09, paragraphs 7–12; *See* Letter from Bruce Henoch, Inmarsat, to Accounting Authority Certification Office, Federal Communications Commission (dated April 20, 2015); Letter from Robert Swanson, Airbus Defense and Space, to Marlene Dortch, Federal Communications Commission (dated January 30, 2015); Letter from Steven Chernoff, Lukas, Nace, Gutierrez, and Sachs, LLP, to Accounting Authority Certification Officer, Federal Communications Commission (dated April 15, 2015) (providing inventories of accounting authority settlements).

[18] *See supra* n.5.

[19] *See id.* at 20715 (tentatively concluding not to designate a new accounting authority of last resort).

[20] *See 1999 R&O and FNPRM,* 15 FCC Rcd at 20709, para. 13.

[21] *See 1999 R&O and FNPRM,* 15 FCC Rcd at 20709, para. 13.

[22] Letter from J.D. Hersey, Jr., Chief, Spectrum Management Division, to Magalie Roman Salas, FCC Secretary, August 21, 1998.

[23] *See* Comments of the National Telecommunications and Information Administration, filed August 24, 1998, at page 2.

[24] *Id.*

[25] Letter from William T. Hatch, Acting Associate Administrator, National Telecommunications and Information Administration, to Magalie Roman Salas, FCC Secretary, October 29, 1998.

[26] Commission staff have confirmed the removal of many of the terminals once billed to these agencies from the FCC as the accounting authority.

operators all accounts for which the customer did not designate a specific accounting authority.[27] In 1999, we tentatively concluded that we should not designate a new accounting authority of last resort.[28] Instead, we found that customers should designate an accounting authority for each call or should presubscribe for the services of an accounting authority.[29] We noted, however, that in order to prevent a deleterious effect on safety communications, the Commission must take care to ensure a seamless transition to new accounting authorities.[30]

20. We continue to believe that, although the functions of an accounting authority of last resort may still be necessary to address infrequent situations where an authority is or cannot be designated due to circumstances beyond the control of the user, it remains the basic responsibility of the user, whether a private or governmental entity, to provide for an accounting authority to handle its calls. However, as we withdraw as an accounting authority, we tentatively conclude, based on the commenters' urging us, in 1998, to either retain our accounting authority or ensure an alternative is in place before withdrawing,[31] that it will be necessary to have an alternative arrangement in place that will eliminate the possibility of messages being sent without having an accounting authority necessary to settle accounts. We seek comment on possible approaches to ensure an alternative is in place: (1) Requiring all customers to pre-subscribe to an accounting authority or to designate an accounting authority on every message; (2) developing a formula to spread undesignated messages among several private accounting authorities; and/or (3) appointing through comparative selection one of the private accounting authorities as the new authority of last resort.

Table 1—Government Agencies Who Use the Commission as an Accounting Authority

Defense Information Systems Agency
Department of Agriculture
Department of Air Force
Department of the Army
Department of Commerce
Department of Defense—Office of Secretary of Defense
Department of Energy
Department of Health and Human Services
Department of Homeland Security—United States Coast Guard
Department of Justice
Department of Justice—Federal Bureau of Investigation
Department of Justice—U.S. Drug Enforcement Administration
Department of the Interior
Department of the Navy
Department of State
Department of Transportation
Department of Treasury
Department of Veteran Affairs
Federal Aviation Administration
Federal Emergency Management Agency
National Aeronautics and Space Administration
National Science Foundation
On-Site Inspection Agency
U.S. Environmental Protection Agency
U.S. General Services Administration
United States Information Agency
U.S. Postal Service

21. Given the reduction of reliance on the FCC as an accounting authority and the resulting lower volume of customers[32] who will be affected when we withdraw as accounting authority (see Table 1 above), we tentatively conclude that the best alternative is the first option noted above, to require all customers to pre-subscribe to an accounting authority or to designate an accounting authority on every message. We seek comment on this tentative conclusion as well as the merits of each of the three proposals. For example, is it technically feasible, for U.S. maritime and satellite radio traffic for which no accounting authority is designated and for which the customer is not able or willing to designate an accounting authority on every message, to allow the provider to bill for such traffic through a certified accounting authority of its choice? Is this feasible for a ship-to-shore radiotelephone call made through a foreign coast station? In the alternative, is it feasible to allow public coast stations to designate their own ''default'' accounting authority in order to send bills to mariners who have not chosen/designated a private accounting authority?[33] Is there a need for the Commission to adopt additional qualifying criteria for an existing accounting authority to serve as a designated accounting authority of last resort? If so, what should the additional criteria be? We also seek comment on any potential enforcement or authority issues that may arise from each of the proposed alternatives for providing an accounting authority of last resort. We also request that commenting parties propose any other viable alternatives that help ensure a smooth transition while relieving the Commission from performing this function.

22. We note that withdrawal of the Commission as an accounting authority without an effective transition plan could leave a gap for some U.S. maritime and satellite radio traffic for which no accounting authority is designated. Thus, during any transition period and subsequently, we intend to conduct outreach to make users aware of our decision and their options for ensuring that they continue to receive the services of an accounting authority.

23. In any event, we believe that an accounting authority, whether selected by the ship, the provider, or a competent default accounting authority, must be in place for distress and safety telecommunications on board ships, particularly when a maritime mobile satellite system is being used. We therefore seek comment on whether, if we decline to designate an accounting authority, we should designate an accounting authority of last resort specifically for Global Maritime Distress and Safety System (GMDSS) mobile satellite communications.[34] Although maritime distress and certain safety communications are provided at no charge, other types of safety communications do incur a charge. If neither the designated nor a competent default accounting authority exists, then foreign earth stations may have no way to bill the U.S. satellite user. As a result, the user may, through no fault of its

[27] *See 1999 R&O and FNPRM,* 15 FCC Rcd at 20715, paragraph 25.

[28] *Id.* at para. 26.

[29] *Id.*

[30] *Id.* at para. 27 (citing Coast Guard Comments at 1).

[31] Letter from J.D. Hersey, Jr., Chief, Spectrum Management Division, to Magalie Roman Salas, FCC Secretary, August 21, 1998. *See, also* Comments of the National Telecommunications and Information Administration, filed August 24, 1998, at page 2 and Letter from William T. Hatch, Acting Associate Administrator, National Telecommunications and Information Administration, to Magalie Roman Salas, FCC Secretary, October 29, 1998.

[32] We note that, for 2016, traffic billed by the FCC as accounting authority to private and/or third parties is exclusively satellite traffic, and ask commenters to address whether that fact, coupled with the potential to allow providers to choose a U.S. accounting authority to bill traffic for which no accounting authority has been designated by the customer, mitigates any concerns regarding a potential gap in service once the FCC withdraws as accounting authority of last resort.

[33] There are few users of maritime public coast stations now due to the closure worldwide of public coast stations; however, ensuring the safety of such users is important. We, therefore, seek comment on what different approaches may be necessary for radio communications via a foreign public coast station versus satellite communications via a mobile satellite communications provider.

[34] INMARSAT continues to be the only worldwide maritime mobile satellite system providing these safety communications. INMARSAT will commission a new ship terminal intended to carry distress and safety communications only if the application designates an accounting authority.

own, find that its ship earth station has been barred for non-payment of bills. We understand that, although a ship mobile device has been ''barred'' from the network provider (*e.g.,* foreign earth station), a ship can still initiate a ship-to-shore distress alert. In such a situation, however, it could not communicate further with the Coast Guard, even if those further communications are safety related. A ship on the high seas that has been barred from such communications may be a danger to itself and others, as well as a potential problem for the Coast Guard. We agree with commenters that any change in accounting authorities must ensure that critical communications are not disrupted. First, during any transition period that we adopt, we will notify users of GMDSS mobile satellite communications of our decision to withdraw as an accounting authority and of their need to select a new accounting authority. Moreover, we seek comment, not only on designation of an accounting authority of last resort for all users, including GMDSS mobile satellite and GMDSS maritime mobile communications, but also on whether there are other options to ensure that the Commission's withdrawal as accounting authority would not cause ship stations to become barred because they were unaware that they need to choose a new accounting authority.

24. We also invite comment whether advancements in technology and the business community could reduce the burdens associated with our proposal to withdraw as accounting authority of last resort. Technological changes may mitigate concerns that stem from the fact that the Commission's service as the accounting authority of last resort has made it unnecessary for users to be aware that they may select a private accounting authority. We can promptly notify users which relied on the Commission as accounting authority of last resort for the need to select an alternative accounting authority. In doing so, we seek comment on notifying users from the past seven years. Alternatively, should we make the period of users which relied on the Commission as carrier of last resort shorter or longer? In addition, the Commission could review on a periodic basis the plan it adopts to ensure that the need for accounting authority services is being met, including distress and safety communications on board ships, and determine whether further modifications are appropriate.

Initial Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act (RFA),[35] the Commission prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this *Second Further Notice of Proposed Rulemaking* (*Second FNPRM*). Written comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments on this *Second FNPRM.* The Commission will send a copy of this *Second FNPRM,* including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[36] In addition, this *Second FNPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.[37]

A. Need for and Objectives of, the Notice

2. In this Second Further Notice of Proposed Rulemaking (*Second FNPRM),* we propose to transition the functions and duties performed by the Commission as an accounting authority to private accounting authorities. In doing so, we seek to revisit findings in the 1999 Report and Order and Further Notice of Proposed Rulemaking (*1999 Accounting Authority Order & FNPRM*),[38] which included the Commission's decision that it should withdraw as an accounting authority in the maritime mobile and maritime mobile-satellite radio services. The Commission tentatively concluded that a three-year transition period following adoption of a Report and Order was appropriate to permit the preparation and implementation of a plan to ensure a smooth, non-disruptive transition to private accounting authorities, and to develop the transition plan.[39] The completion of the plan was subsequently delayed and until now, the proceeding has been inactive.

3. In this *2016 Accounting Authority Second FNPRM,* we now seek comment on whether the findings in the *1999 Accounting Authority Order & FNPRM* remain in the public interest. As such, we seek input on whether the Commission should withdraw as an accounting authority in the maritime mobile and maritime mobile-satellite radio services. In doing so, we seek information on whether interested parties continue to support the Commission's 1999 decision and if not, why that decision should be revisited or amended.

B. Legal Basis

4. This *Second Further Notice of Proposed Rulemaking* is adopted pursuant to Sections 1, 4(i), 4(j), 11, 201–205, 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 161, 201–205, and 303(r).

C. Description and Estimate of the Number of Small Entities To Which the Rules Will Apply

5. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted.[40] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[41] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[42] A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[43]

6. The rules proposed in this *Second Notice of Proposed Rulemaking* apply to entities providing account-settlement services for maritime mobile and maritime mobile-satellite radio services.

[35] 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612 has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 847 (1996).

[36] 5 U.S.C. 603(a).

[37] *Id.*

[38] 1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services and Withdrawal of the Commission as an Accounting Authority in the Maritime Mobile and the Maritime Mobile-Satellite Radio Services, *Report and Order and Further Notice of Proposed Rulemaking,* 15 FCC Rcd 20703 (1999) (*1999 R&O and FNPRM*). The Commission as part of its *Further Notice of Proposed Rulemaking* sought comments to be filed by comments August 23, 1999, and replies by September 8, 1999.

[39] 1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services and Withdrawal of the Commission as an Accounting Authority in the Maritime Mobile and the Maritime Mobile-Satellite Radio Services, Order, 14 FCC Rcd 13504 (1999). The order extended the deadline for filing comments to October 25, 1999 and reply comments to November 29, 1999. The extension of time was made to allow for a fuller record.

[40] 5 U.S.C. 603(b)(3).

[41] 5 U.S.C. 601(6).

[42] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small-business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[43] 15 U.S.C. 632.

Small businesses may be able to become accounting clearinghouses, as the establishment of such a function does not appear to involve high implementation costs. The rules also apply to existing maritime mobile and maritime satellite customers who have not presubscribed to a U.S. accounting authority and are, therefore, billed through the FCC as the accounting authority of last resort. An estimated thirty small entities have been billed for traffic by the FCC as an accounting authority in 2016. The proposed action in this *Second Notice of Proposed Rulemaking* does not appear to involve high implementation costs for such entities.

D. Reporting, Recordkeeping, and Other Compliance Requirements

7. The proposed action in this *Second Further Notice of Proposed Rulemaking* would affect those entities already certified and those applying for certification as a private accounting authority in the maritime mobile, maritime mobile-satellite, aeronautical and other satellite-based radio services. The amended rule, however, merely clarifies an existing requirement imposed on accounting authorities. It, therefore, does not alter the reporting, recordkeeping or other compliance requirements of certified accounting authorities.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered

8. As stated above, we propose to transition the functions and duties performed by the Commission as an accounting authority to private accounting authorities. In doing so, we seek to revisit findings in *1999 Accounting Authority Order & FNPRM*),[44] which included the Commission's decision that it should withdraw as an accounting authority in the maritime mobile and maritime mobile-satellite radio services. We seek comment on the impact of our proposals on small entities and on any possible alternatives that could minimize the impact of our rules on small entities.

[44] 1998 Biennial Regulatory Review—Review of Accounts Settlement in the Maritime Mobile and Maritime Mobile-Satellite Radio Services and Withdrawal of the Commission as an Accounting Authority in the Maritime Mobile and the Maritime Mobile-Satellite Radio Services, *Report and Order and Further Notice of Proposed Rulemaking,* 15 FCC Rcd 20703 (1999) (*1999 R&O and FNPRM*). The Commission as part of its *Further Notice of Proposed Rulemaking* sought comments to be filed by comments August 23, 1999, and replies by September 8, 1999.

F. Federal Rules That Overlap, Duplicate or Conflict With These Proposed Requirements

9. None.

V. Ordering Clauses

10. *It is ordered* that pursuant to sections 4(i), 4(j), 11, 201–205 and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 161, 201–205 and 303(r), this *Second Further Notice of Proposed Rulemaking is adopted.*

11. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Second Further Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2017–00597 Filed 1–12–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 10–90; FCC 16–178]

Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on whether to expand the Alternative Connect America Cost Model (A–CAM) budget for rate-of-return carriers to provide additional funding with an associated increase in broadband deployment obligations.

DATES: Comments are due on or before February 13, 2017 and reply comments are due on or before February 27, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this document, you should advise the contact listed below as soon as possible.

ADDRESSES: You may submit comments, identified by WC Docket No. 10–90, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/. Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*
  - *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Because more than one docket number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket number.
- Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
  - All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.
  - Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
  - U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th St. SW., Washington, DC 20554.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Further Notice of Proposed Rulemaking (FNPRM) in WC Docket No. 10–90; FCC 16–178, adopted on December 19, 2016 and released on December 20, 2016. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th St. SW., Washington, DC 20554 or at the following Internet address: *http://transition.fcc.gov/Daily_Releases/Daily_Business/2016/db1220/FCC-16-178A1.pdf.*

I. Further Notice of Proposed Rulemaking

1. In this Further Notice of Proposed Rulemaking, the Commission seeks

comment on whether to allocate additional high-cost funding to the voluntary path to the model. Rate-of-return carriers that accept the second offer of model-based support will do so on the condition that they commit to meet the deployment obligations of the original offer if authorized no later than December 31, 2017 to receive additional A–CAM funding equivalent to the original offer. The Commission therefore seeks comment on whether the Commission should further increase the budget for A–CAM to provide the full amount of the original offer for some or all of those carriers that accepted the second offer of model-based support.

2. The Commission seeks comment on increasing the budget by a lesser amount. If the increased budget for A–CAM were insufficient to cover all participants, should the Wireline Competition Bureau (Bureau) prioritize funding to those with the least broadband deployment using the same data set as that utilized for the adjusted offer? Alternatively, if the Commission increases the budget by a smaller amount, should the Bureau revise the offers to an amount less than the original offer? In that latter situation, the Commission expects that the Bureau would make a new offer, limited to the carriers that originally elected the first offer and accepted the revised offer; those carriers would be free to choose whether to accept that new offer and the associated broadband deployment obligations.

3. The Commission notes that commenters responding to the Bureau's *A–CAM Election Results Public Notice* uniformly support increasing the A–CAM budget by more than $50 million. The Commission would need to increase the overall high-cost budget by an additional $110 million per year if all carriers elect the second offer, and by a lesser amount if fewer do. The Commission invites comment from all interested stakeholders on whether to enlarge the budget for A–CAM support, including the costs and benefits of allocating limited funding for this particular purpose.

II. Procedural Matters

4. This document does not contain new information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

5. In the *April 2014 Connect America FNPRM,* 79 FR 39196, July 9, 2014, the Commission proposed a framework for a voluntary election by rate-of-return carriers to receive model-based support and tentatively concluded that such a framework could achieve important universal service benefits by creating incentives for deployment of voice and broadband-capable infrastructure. The Commission sought written comment on the proposal, including comment on the Initial Regulatory Flexibility Analysis (IRFA). The Commission did not receive any comments on the *April 2014 Connect America FNPRM* IRFA. In the *Rate-of-Return Reform Order,* 81 FR 24282, April 25, 2016, the Commission adopted a voluntary path under which rate-of-return carriers may elect to receive model-based support for a term of 10 years in exchange for meeting defined build-out obligations. The Commission issued a Final Regulatory Flexibility Analysis (FRFA) that conforms to the Regulatory Flexibility Act of 1980 (RFA), as amended. This present Report and Order and Further Notice of Proposed Rulemaking implements the framework previously adopted by the Commission and seeks comment on additional funding to implement that framework. The Commission promulgates no additional final rules, and our present action is, therefore, not an RFA matter.

6. The proceeding this Notice initiates shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

7. *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

III. Ordering Clauses

8. *It is further ordered,* pursuant to the authority contained in sections 1, 2, 4(i), 5, 10, 201–206, 214, 218–220, and 254 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 160, 201–206, 214, 218–220, 254, and 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429, that this Further Notice of Proposed Rulemaking *is adopted*, effective thirty (30) days after publication of the text or summary thereof in the **Federal Register**.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2017–00598 Filed 1–12–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

RIN 0648–XF080

Endangered and Threatened Species; Petition for Rulemaking To Establish a Whale Protection Zone for Southern Resident Killer Whales

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of receipt of petition; request for comments.

SUMMARY: This document announces receipt by the National Marine Fisheries Service (NMFS) of a petition for rulemaking to establish a whale protection zone in the San Juan Islands, Washington, to support recovery of endangered Southern Resident killer whales. NMFS is requesting comments on the petition and will consider all comments and available information when determining whether to accept the petition and proceed with the suggested rulemaking.

DATES: The closing date for comments on the petition is April 13, 2017.

ADDRESSES: You may submit information on this document identified by NOAA–NMFS–2016–0152 and the petition by either of the following methods:

• *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*. To submit comments via the Federal e-Rulemaking Portal, go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0152*, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail or hand-delivery:* Lynne Barre, NMFS West Coast Region, 7600 Sand Point Way NE., Seattle, WA 98115.

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: Lynne Barre, West Coast Regional Office, 206–526–4745.

SUPPLEMENTARY INFORMATION: In 2009, NMFS proposed vessel traffic regulations to minimize vessel impacts to Southern Resident killer whales, including a 200-yard approach rule, a prohibition on parking vessels in the path of the whales, and a protected area (no-go zone) in Puget Sound along the west side of San Juan Island, Washington (74 FR 37674; July 29, 2009). In 2011, we finalized vessel traffic regulations that included an approach rule and path prohibitions but did not finalize a protected area (76 FR 20870; April 14, 2011). In deciding not to move forward with a protected area in the final rule, we noted the degree of public opposition to the concept and concluded a no-go zone required further analysis. We further noted that to be effective, regulations must be understood by the public and have a degree of public acceptance. We stated that we would evaluate the enacted regulations, gather additional information and conduct further analysis and public outreach on the concept of identifying a protected area or no-go zone as a future protective measure. Since 2011, we have conducted a public workshop in 2013, continued communicating with a variety of interested groups (including the petitioners) on this topic, and are currently completing a review of the 2011 vessel traffic regulations. NOAA's Northwest Fisheries Science Center has also conducted further research on the impacts of vessels on Southern Resident killer whales.

On November 10, 2016, NMFS received a petition pursuant to the Administrative Procedure Act (APA) from the Orca Relief Citizen's Alliance, Center for Biological Diversity, and Project Seawolf requesting that we utilize our authorities under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) to establish a whale protection zone to reduce noise and disturbance of Southern Resident killer whales. The petitioners identify threats to the whales, discuss alleged insufficiencies with existing protections, and describe NMFS' authority under the ESA and MMPA to establish a whale protection zone with regulations. The petition describes the features of a whale protection zone and cites information from our evaluation of the benefits of a protected area supporting our 2009 proposed rule. The area proposed for a protection zone is similar to, but wider and longer than the zone originally considered by NMFS in 2009 (74 FR 37674; July 29, 2009).

To ensure our decision about whether to accept the petition and move forward with the petitioned action to establish a whale protection zone is based on the best available scientific and commercial information, we are soliciting information from the public, governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the petitioned action. In particular we request information and comments on: (1) The advisability of and need for regulations to establish a whale protection zone; (2) the geographic scope of regulations; (3) alternative management options for regulating vessel interactions with killer whales, including but not limited to the option in the petition; (4) scientific and commercial information regarding the effects of vessels on killer whales and their habitat; (5) information regarding potential economic effects of regulating vessel interactions; and (6) any additional relevant information that NMFS should consider should it accept the petition. To inform your comments, information on the previous vessel regulations, the petition and other supporting documents is available at: *http://www.westcoast.fisheries.noaa.gov/protected_species/marine_mammals/killer_whale/vessel_regulations.html.*

You may submit your information and materials electronically or via mail (see **ADDRESSES** section). We request that all information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications. We also would appreciate the submitter's name, address, and any association, institution, or business that the person represents; however, anonymous submissions will also be accepted.

If NMFS decides to accept the petition and initiate rulemaking, we will notify the petitioners and publish a notice of our decision in the **Federal Register**. If NMFS decides not to proceed with the petitioned action, we will notify the petitioners, provide a brief statement of the grounds for the decision, and publish notice of our decision in the **Federal Register**.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: January 6, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–00437 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 070719377–2189–01]

RIN 0648–AV81

Confidentiality of Information; Magnuson-Stevens Fishery Conservation and Management Reauthorization Act

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

ACTION: Proposed rule; withdrawal.

SUMMARY: The National Marine Fisheries Service (NMFS) withdraws a proposed rule to revise existing regulations governing the confidentiality of information submitted in compliance with any requirement or regulation under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). NMFS published the proposed rule on May 23, 2012. After careful consideration, NMFS has decided that the proposed changes discussed in the proposed rule are not warranted at this time.

DATES: The proposed rule published on May 23, 2012 (77 FR 30486) is withdrawn as of January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Karl Moline at 301–427–8225.

SUPPLEMENTARY INFORMATION:

Background

The Magnuson-Stevens Act sets forth information confidentiality requirements at section 402(b), 16 U.S.C. 1881a(b). Section 402(b)(3) of the Act provides that the ''Secretary shall, by regulation, prescribe such procedures as may be necessary to preserve the confidentiality of information submitted in compliance with any requirement or regulation under this Act . . .''. Id. 1881a(b)(3). Accordingly, NMFS has promulgated confidentiality of information regulations, which are set forth at 50 CFR part 600, subpart E. Certain terms used in these regulations are defined under 50 CFR part 600, subpart A. NMFS last revised the regulations under subpart E in February 1998 (63 FR 7075).

On May 23, 2012, NMFS proposed revisions to its regulations at 50 CFR part 600 subpart A, subpart B, and subpart E, in order to implement confidentiality requirements amendments, which were included in the 1996 Sustainable Fisheries Act (SFA) and the 2006 Magnuson Stevens Fishery Conservation and Management Reauthorization Act (MSRA) (77 FR 30486). In the proposed rule, NMFS proposed three types of changes: (1) Changes related to broadening the scope of the confidentiality requirements, (2) changes concerning exceptions authorizing the disclosure of confidential information, and lastly, (3) non-substantive changes intended to improve the clarity and accuracy of the regulations.

During the proposed rule's comment period, NMFS received several requests from fishery management councils and representatives of fishing and environmental organizations to extend the comment period to allow the councils and other organizations to review the proposed rule and prepare comments. On June 13, 2012, NMFS published a notice in the **Federal Register** extending the comment period end date of the proposed rule from June 22, 2012 to August 21, 2012 (77 FR 35349). Subsequently, NMFS received requests to extend the comment period beyond August 21, 2012. In response, NMFS published a notice in the **Federal Register** extending the comment period an additional 60 days, from August 21, 2012 to October 21, 2012 (July 26, 2012, 77 FR 43803).

NMFS would like to reevaluate the proposed revisions to the existing regulations governing the confidentiality of information submitted in compliance with the Magnuson-Stevens Act. As a result, NMFS has decided that the changes covered in the proposed rule from 2012 are not warranted at this time. Therefore, NMFS is withdrawing the proposed rule published in the **Federal Register** on May 23, 2012 (77 FR 30486).

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

Dated: January 5, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–00307 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 82, No. 9

Friday, January 13, 2017

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

Agricultural Research Service

Notice of Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to Huvepharma, Inc. of Peachtree City, Georgia, an exclusive license to U.S. Patent Application Serial No. 15/108,725, ''MUTATED SALMONELLA ENTERIACA'', filed on June 28, 2016.

DATES: Comments must be received on or before February 13, 2017.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Rm. 4–1174, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: Mojdeh Bahar of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights in this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as Huvepharma, Inc. of Peachtree City, Georgia has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Mojdeh Bahar,

Assistant Administrator.

[FR Doc. 2017–00746 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 10, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by February 13, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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

Rural Utilities Service

Title: 7 CFR 1783, Revolving Fund Program.

OMB Control Number: 0572–0138.

Summary of Collection: Section 6002 of the Farm Security and Rural Investment Act of 2002 amended the Consolidated Farm and Rural Development Act by adding a grant program that established the Revolving Fund Program (RFP) to assist communities with water or wastewater systems. Qualified private non-profit organizations will receive RFP grant funds to establish a revolving loan fund. Loans will be made to eligible entities to finance predevelopment costs of water or wastewater projects, or short-term small capital projects not part of the regular operation and maintenance of current water and wastewater systems.

Need and Use of the Information: Non-profit organizations applying for the RFP grant(s) must submit an application package that includes an application form, narrative proposal (work plan), various other forms, certifications, and supplemental information. The Rural Development State Offices and the Rural Utilities Service National Office staff will use the information collected to determine applicant eligibility, project feasibility, and the applicant's ability to meet the grant and regulatory requirements. Grant recipients will set up a revolving loan fund to provide loans to finance predevelopment costs of water or wastewater projects, or short-term small capital projects not part of the regular operation and maintenance of current water and wastewater systems.

Description of Respondents: Not-for-profit institutions.

Number of Respondents: 4.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 376.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–00641 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Privacy Act of 1974: Notice of Computer Matching Agreement Between Food Nutrition Service (FNS) and State Agencies Administering the Supplemental Nutrition Assistance Program (SNAP)

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice of proposed new Computer Matching Agreement.

SUMMARY: In accordance with the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100503), Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818 published June 19, 1989), and OMB Circular No. A130, revised November 28, 2000, the USDA, Food and Nutrition Service is publishing notice of its intent to conduct a computer matching program with the State agencies of all 50 States and the State agencies of the District of Columbia and the territories of Guam and the Virgin Islands administering the Supplemental Nutrition Assistance Program (SNAP). Under this matching program, FNS will provide records from the Electronic Disqualified Recipient System (eDRS) to State agencies to verify SNAP recipient (applicants and individuals being certified or recertified for eligibility) eligibility for SNAP benefits.

DATES: The effective date of this Computer Matching Agreement will begin 30 days from the publication date in the **Federal Register** or 30 days from the date copies of the approved agreement and the notice of the matching program are sent to the Congressional committee of jurisdiction under subsections (0)(2)(B) and (r) of the Privacy Act, as amended, or 30 days from the date the approved agreement is sent to the Office of Management and Budget, whichever is later, provided no comments are received which result in a contrary determination.

ADDRESSES: State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, 3101 Park Center Drive, Room 818, Alexandria, Virginia 22302.

FOR FURTHER INFORMATION CONTACT: Jane Duffield, (703) 605–4385.

SUPPLEMENTARY INFORMATION:

FNS Computer Matching Program Subject to the Privacy Act

The purpose of this FNS Computer Matching Program is to provide and disclose information about individuals disqualified from the program to the State agency in order to allow the State agency to assist the State agency in determining eligibility status of individuals applying for or receiving program benefits and to assign the correct disqualification periods for individuals determined to be disqualified from the program.

Notice of Computer Matching Program

The States will match SNAP recipient records with eDRS to verify the recipient's eligibility for SNAP benefits.

A. Participating Agencies

The U.S. Department of Agriculture FNS and the State agencies of all 50 States, including the State agencies of the District of Colombia and the territories of Guam and the Virgin Islands.

B. Purpose of the Matching Program

The State agencies shall use eDRS to conduct matches as specified in 7 CFR 273.16 on initial program applications prior to certification and to ascertain the appropriate penalty to impose based on past disqualifications in a case under consideration.

C. Authority for Conducting the Matching Program

The legal authority for conducting the matching program is the Food and Nutrition Act of 2008, as amended. Section 6(b) of the Act, 7 U.S.C. 2015(b), prescribes mandatory periods of ineligibility for persons found on one or more occasions to have committed fraud, misrepresentation, or other violation of statute or regulation in connection with SNAP eligibility and use of benefits. Section 6(b)(4), prescribes regulations to ensure that appropriate State and Federal entities forward information concerning determinations rising out of such proscribed activity by a specific individual. The States agencies shall also use eDRS to conduct matches as specified in 7 CFR 273.16 on initial program application prior to certification.

D. Categories of Records and Individuals Covered

The State agency agrees to the following:

1. To update eDRS at least monthly with information on individuals disqualified from the program. The specific data elements that will be reported on such individuals are full name, Social Security Number, date of birth, sex, State and locality in which the disqualification was either determined or implemented, disqualification number, disqualification length, decision date, disqualification start date, and a State case identification number if used. The State will also provide the title, organization, and phone number of the contacts which will verify the information submitted for each locality identified in the records it submits. This information is supplied with the initial eDRS record and is updated if the contact information changes or if additional localities are added.

2. To obtain information from eDRS on the disqualification status of individuals against whom a disqualification period will be assessed in accordance with the provisions of 7 CFR 273.16.

3. To determine the eligibility of individuals applying for program benefits or to verify the continuing eligibility of individuals already participating.

FNS agrees to provide records from the eDRS to all State agencies.

E. Effective Dates of the Matching Program

The effective date of this Computer Matching Agreement will begin 30 days from the publication date in the **Federal Register** or 30 days from the date copies of the approved agreement and the notice of the matching program are sent to the Congressional committee of jurisdiction under subsections (0)(2)(B) and (r) of the Privacy Act, as amended, or 30 days from the date the approved agreement is sent to the Office of Management and Budget, whichever is later, provided no comments are received which result in a contrary determination.

F. Address for Receipt of Public Comments

Individuals wishing to comment on this matching program should send comments to Jane Duffield, Chief, State Administration Branch, Program Accountability and Administration Division, Supplemental Nutrition Assistance Program, Room 818, Alexandria, Virginia 22302, (703) 605–4385, *Jane.Duffield@fns.usda.gov.*

Dated: January 5, 2017.

Thomas J. Vilsack,

Secretary.

[FR Doc. 2017–00596 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request; General Program Administration

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection associated with FSA's Farm Loan Programs (FLP) General Program Administration. The information collected is used to ensure that applicants meet statutory eligibility requirements, loan funds are used for authorized purposes, and the Government's interest in security is adequately protected.

DATES: We will consider comments that we receive by March 14, 2017.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal Rulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Niki Chavez, Senior Loan Officer, USDA/FSA/FLP, STOP 0521, 1400 Independence Avenue SW., Washington, DC 20250–0521.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. Copies of the information collection may be requested by contacting Niki Chavez at the above address.

FOR FURTHER INFORMATION CONTACT: Niki Chavez, (202) 690–6129.

SUPPLEMENTARY INFORMATION:

Title: Farm Loan Programs, General Program Administration.

OMB Control Number: 0560–0238.

Expiration Date of Approval: 05/31/2017.

Type of Request: Extension with a revision.

Abstract: General Program Administration, as specified in the 7 CFR 761, contains requirements that are applicable to making and servicing direct loans. The information collections are necessary to ensure that applicants meet statutory eligibility requirements, loan funds are used for authorized purposes, and the Federal Government's interest in security is adequately protected. Specific information collection requirements include financial information in the form of a balance sheet and cash flow projection used in loan making and servicing decisions; information needed to establish joint bank accounts in which loan funds, proceeds derived from the sale of loan security and insurance proceeds, may be deposited; collateral pledges from financial institutions when the balance of a supervised bank account will exceed the maximum amount insurable by the Federal Government; and documents that construction plans and specifications to comply with state and local building standards.

Since the introduction of Microloan Loan (ML) Program certain forms are being used less in this request and there are fewer farmers and businesses reporting information resulting in a total program changes decrease of 6,997 respondents; 16,392 responses; and 19,678 burden hours.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Estimated Respondent Burden: Public reporting burden for this collection of information is estimated to average 1.12 hours per response. The average travel time, which is included in the total annual burden, is estimated to be 1 hour per respondent.

Type of Respondents: Individuals or households, businesses or other for profit and farms.

Estimated Number of Respondents: 84,833.

Estimated Number of Responses per Respondent: 2.40.

Estimated Total Annual Number of Responses: 204,438.

Estimated Average Time per Response: 1.12 hours.

Estimated Total Annual Burden on Respondents: 229,203 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of the 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.

All responses to this notice, including name and addresses when provided, will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Val Dolcini,

Administrator, Farm Service Agency.

[FR Doc. 2017–00650 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Administrative Reviews in the School Nutrition Programs; Approval of Information Collection Request

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice of approval of Information Collection Request (ICR).

SUMMARY: The final rule titled Administrative Reviews in the School Nutrition Programs was published on July 29, 2016 (81 FR 50170). The Office of Management and Budget (OMB) cleared the associated information collection requirements (ICR) on September 12, 2016. This document announces approval of the ICR.

DATES: The ICR associated with the final rule published in the **Federal Register** on July 29, 2016, at 81 FR 50170, was approved by OMB on September 12, 2016, under OMB Control Number 0584–0006.

FOR FURTHER INFORMATION CONTACT: Sarah Smith-Holmes, Child Nutrition Monitoring and Operations Support Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, Virginia 22302; telephone: (703) 605–3223.

Dated: December 23, 2016.

Richard Lucas,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2016–31955 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Initiating the Assessment Phase of the Forest Plan Revision for the Salmon-Challis National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The Salmon-Challis National Forest, located in east central Idaho, is initiating the first phase of the forest planning process pursuant to the 2012 National Forest System Land Management Planning rule. This process will result in a revised forest land management plan (Forest Plan) which describes the strategic direction for management of forest resources on the Salmon-Challis National Forest for the next ten to fifteen years. The planning process encompasses three-stages: assessment, plan revision, and monitoring. The first stage of the planning process involves assessing ecological, social, and economic conditions of the planning area, which is documented in an assessment report.

The Forest is inviting the public to contribute in the development of the Assessment. The Forest will be hosting public forums near the end of February into early March 2017 with a second set of meetings forthcoming in June 2017. We will invite the public to share information relevant to the assessment including existing information, current trends, and local knowledge. Public engagement opportunities associated with the development of the Assessment will be announced on the Web site cited below.

DATES: From January 2017 through August 2017, the public is invited to participate in the development of the Assessment. The draft assessment report for the Salmon-Challis National Forest is being initiated and is expected to be available in August 2017 on the Forest Web site at: *http://www.fs.usda.gov/scnf/.*

Following completion of the assessment, the Forest will initiate procedures pursuant to the National Environmental Policy Act (NEPA) to prepare and evaluate a revised forest plan.

ADDRESSES: Written correspondence can be sent to Salmon-Challis National Forest, 1206 S. Challis Street, Salmon, ID 83467, or sent via email to *jmilligan@fs.fed.us.* All correspondence, including names and addresses when provided, are placed in the record and are available for public inspection and copying.

FOR FURTHER INFORMATION CONTACT: Josh Milligan, Forest Plan Revision Team Leader at 208–756–5560. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m. (Eastern time), Monday through Friday.

More information on the planning process can also be found on the Salmon-Challis National Forest Planning Web site at *http://www.fs.usda.gov/detail/scnf/home/?cid=FSEPRD522039.*

SUPPLEMENTARY INFORMATION: The National Forest Management Act (NFMA) of 1976 requires that every National Forest System (NFS) unit develop a land management plan (LMP). On April 9, 2012, the Forest Service finalized its land management planning rule (2012 Planning Rule, 36 CFR part 291), which describes requirements for the planning process and the content of the land management plans. Forest plans describe the strategic direction for management of forest resources for ten to fifteen years, and are adaptive and amendable as conditions change over time. Pursuant to the 2012 Forest Planning Rule (36 CFR part 219), the planning process encompasses three-stages: assessment, plan revision, and monitoring. The first stage of the planning process involves assessing social, economic, and ecological conditions of the planning area, which is documented in an assessment report. This notice announces the start of the initial stage of the planning process, which is the development of the assessment report.

The second stage, formal plan revision, involves the development of our Forest Plan in conjunction with the preparation of an Environmental Impact Statement under the NEPA. Once the plan revision is completed, it will be subject to the objection procedures of 36 CFR part 219, subpart B, before it can be approved. The third stage of the planning process is the monitoring and evaluation of the revised plan, which is ongoing over the life of the revised plan.

The assessment rapidly evaluates existing information about relevant ecological, economic, cultural and social conditions, trends, and sustainability and their relationship to land management plans within the context of the broader landscape. This information builds a common understanding prior to entering formal plan revision. The development of the assessment will include public engagement.

With this notice, the Salmon-Challis National Forest invites other governments, non-governmental parties, and the public to contribute in assessment development. The intent of public engagement during development of the assessment is to identify as much relevant information as possible to inform the upcoming plan revision process. We encourage contributors to share material about existing conditions, trends, and perceptions of social, economic, and ecological systems relevant to the planning process. The assessment also supports the development of relationships with key stakeholders that will be used throughout the plan revision process

As public meetings, other opportunities for public engagement, and public review and comment opportunities are identified to assist with the development of the forest plan revision, public announcements will be made, notifications will be posted on the Forest's Web site at: *http://www.fs.usda.gov/scnf/* and information will be sent out to the Forest's mailing list. If anyone is interested in being on the Forest's mailing list to receive these notifications, please contact Josh Milligan at the address identified above, or by sending an email *jmilligan@fs.fed.us.*

Responsible Official

The responsible official for the revision of the land management plan for the Salmon-Challis National Forest is Charles Mark, Forest Supervisor, Salmon-Challis National Forest.

Dated: January 4, 2017.

Charles A. Mark,

Forest Supervisor.

[FR Doc. 2017–00684 Filed 1–12–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Superior National Forest; Minnesota; Application for Withdrawal

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The United States Forest Service (USFS) has submitted an application to the Secretary of Interior proposing a withdrawal of approximately 234,328 acres of National Forest System (NFS) lands, for a 20-year term, within the Rainy River Watershed on the Superior National Forest from disposition under United States mineral and geothermal leasing laws, subject to

valid existing rights. This proposal will also include an amendment to the Superior National Forest Land and Resource Management Plan to reflect this withdrawal.

The purpose of the withdrawal request is protection of the natural resources and waters located on NFS lands from the potential adverse environmental impacts arising from exploration and development of fully Federally-owned minerals conducted pursuant to the mineral leasing laws within the Rainy River Watershed that flow into the Boundary Waters Canoe Area Wilderness (BWCAW) and the Boundary Waters Canoe Area Wilderness Mining Protection Area (MPA) in northeastern Minnesota. The USFS acknowledges this proposed request subjects these NFS lands to temporary segregation for up to 2 years from entry under the United States mineral and geothermal leasing laws. The lands have been and will remain open to such forms of use and disposition as may be allowed by law on National Forest System lands including the disposition of mineral materials. The USFS recognizes that any segregation or withdrawal of these lands will be subject to valid existing rights and therefore inapplicable to private lands owned in fee, private mineral estates, and private fractional minerals interests. This notice also gives the public an opportunity to comment on the proposed request for withdrawal, and announces the opportunity for a future public meeting.

DATES: Comments concerning the proposed request for withdrawal and the scope of the environmental analysis must be received by April 13, 2017. This Notice coincides with the Bureau of Land Management's (BLM) ''Notice of Application for Withdrawal and Notification of Public Meeting'' announced today in the **Federal Register**. The USFS comment period for the EIS is commensurate with the BLM's 90-day comment period associated with the consideration of the USFS application to propose a withdrawal of approximately 234,328 acres of NFS lands from disposition under United States mineral and geothermal leasing laws (subject to valid existing rights) within the Rainy River Watershed on the Superior National Forest.

The draft environmental impact statement is expected June 2018 and the final environmental impact statement is expected January 2019. The USFS and BLM will hold a public meeting within the initial 90-day comment period to gather public input on the proposed request for withdrawal. This meeting will be held at the Duluth Entertainment and Convention Center on March 16, 2017 from 5:00 to 7:30 p.m. CT (350 Harbor Drive, Duluth, MN 55802). The USFS will publish a notice of the meeting location and time in a local newspaper at least 30 days before the scheduled date of the meeting.

ADDRESSES: Address written comments regarding the environmental effects associated with this proposed request for withdrawal to Connie Cummins, Forest Supervisor, Superior National Forest. Written comments are to be mailed to 8901 Grand Avenue Place, Duluth, MN 55808–1122. Comments may also be sent via email to *comments-eastern-superior@fs.fed.us* or via facsimile to 218–626–4398.

FOR FURTHER INFORMATION CONTACT: Matt Judd, Superior National Forest (218–626–4382). The Superior National Forest Web site (*https://www.fs.usda.gov/projects/superior/landmanagement/projects*) also contains information relative to this proposed request for withdrawal.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday. This relay service is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The USFS has submitted an application on January 5, 2017 to the Secretary of the Interior proposing to withdraw the identified lands from disposition under United States mineral and geothermal leasing laws (subject to valid existing rights) for a period of 20 years.

All the NFS Lands identified in this application are described in Appendix A and displayed on a map in Appendix B. This application is available upon request at the Superior National Forest office (8901 Grand Ave Place, Duluth, MN 55808) or their Web site (*https://www.fs.usda.gov/projects/superior/landmanagement/projects*). The lands depicted on this map include NFS lands in the townships below, and all non-Federal lands within the exterior boundaries described below that are subsequently acquired by the Federal government to the boundary of the Boundary Waters Canoe Area Wilderness (BWCAW) and the Boundary Waters Canoe Area Wilderness Mining Protection Area (MPA).

National Forest System Lands

Superior National Forest

4th Principal Meridian, Minnesota

Tps. 61 and 62 N., Rs. 5 W.,
Tps. 60 to 62 N., Rs. 6 W.,
Tps. 59 and 61 N., Rs. 7 W.,
Tps. 59 to 61 N., Rs. 8 W., to the boundary of the BWCAW
Tps. 58 to 61 N., Rs. 9 W., to the boundary of the BWCAW
Tps. 57 to 62 N., Rs. 10 W.,
Tps. 57 to 63 N., Rs. 11 W.,
Tp. 59 N., R. 12 W.,
Tps. 61 to 63 N., Rs. 12 W.,
Tps. 61 to 63 N., Rs. 13 W.,
Tp. 63 N., R. 15 W.,
Tp. 63 N., R. 16 W.,
Tps. 65 to 67 N., Rs. 16 W.,
Tp. 64 N., R. 17 W.,

The areas described contain approximately 234,328 acres of NFS lands that overlay Federally-owned minerals in Cook, Lake, and Saint Louis Counties, Minnesota located adjacent to the BWCAW and the MPA.

Purpose and Need for Action

The purpose of this withdrawal request is protection of NFS lands located in the Rainy River Watershed, and preservation of NFS lands within the BWCAW, from the potential adverse environmental impacts arising from exploration and development of fully Federally-owned minerals conducted pursuant to the Federal mineral leasing laws.

The 234,328 acres of Federal land in this proposed request for withdrawal are located within the Rainy River watershed on the Superior National Forest and are adjacent to the BWCAW and MPA. There is known interest in the development of hardrock minerals that have been found—and others that are thought to exist—in sulfide-bearing rock within this portion of the Rainy River Watershed. Any development of these mineral resources could ultimately result in the creation of permanently stored waste materials and other conditions upstream of the BWCAW and the MPA with the potential to generate and release water with elevated levels of acidity, metals, and other potential contaminants. Additionally, any failure of mitigation measures, containment facilities or remediation efforts at mine sites and their related facilities located upstream of the BWCAW and the MPA could lead to irreversible impacts upon natural resources and the inability to meet the purposes for the designation of the BWCAW and the MPA specified by Sec. 2 of Public Law 95–495, 92 Stat. 1649 (1978) and the inability to comply with Section 4(b) of the 1964 Wilderness Act. These concerns are exacerbated by the likelihood that perpetual maintenance

of waste storage facilities along with the perpetual treatment of water discharge emanating from the waste storage facilities and the mines themselves would likely be required to ameliorate these adverse effects. Yet, it is not at all certain that such maintenance and treatment can be assured over many decades.

Proposed Action

The United States Forest Service (USFS) has submitted an application to the Secretary of Interior proposing a withdrawal, for a 20-year term, of approximately 234,328 acres of NFS lands within the Rainy River Watershed on the Superior National Forest from disposition under United States mineral and geothermal leasing laws, subject to valid existing rights. This proposal will also include an amendment to the Superior National Forest Land and Resource Management Plan to reflect this withdrawal.

Possible Alternatives

In addition to the USFS proposal, a ''no action'' alternative will be analyzed, and no additional alternatives have been identified at this time. No alternative sites are feasible because the lands subject to the withdrawal application are the lands for which protection is sought from the impacts of exploration and development under the United States mineral and geothermal leasing laws.

Lead and Cooperating Agencies

The USFS will be the lead agency. The USFS will designate the BLM as a cooperating agency. The BLM shall independently evaluate and review the draft and final environmental impact statements and any other documents needed for the Secretary of Interior to make a decision on the proposed withdrawal.

Responsible Official

Forest Supervisor, Superior National Forest.

Nature of Decision To Be Made

The Responsible Official will complete an environmental impact statement, documenting the information and analysis necessary to support a decision on withdrawal, and to support an amendment to the Superior National Forest Land and Resource Management Plan.

The Secretary of Interior is the authorized official to approve a proposal for withdrawal.

The Responsible Official is the authorized official to approve an amendment to the Superior National Forest Land and Resource Management Plan to reflect the proposed withdrawal.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. The USFS and Bureau of Land Management (BLM) will hold a public meeting within the initial 90-day comment period to gather public input on the proposed request for withdrawal. This meeting will be held at the Duluth Entertainment and Convention Center on March 16, 2017 from 5:00 to 7:30 p.m. CT (350 Harbor Drive, Duluth, MN 55802). Further opportunities for public particpation will be provided upon publication of the Draft EIS, including a minimum 45-day public comment period. A plan amendment is subject to pre-decisional objection procedures at 36 CFR 219, Subpart B.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however.

Dated: January 6, 2017.

Richard Periman,

Deputy Forest Supervisor.

[FR Doc. 2017–00506 Filed 1–12–17; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

Census Bureau

Generic Clearance for Proposed Information Collection; Comment Request; Generic Clearance for Internet Nonprobability Panel Pretesting and Qualitative Survey Methods Testing

AGENCY: U.S. Census Bureau, 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: To ensure consideration, written comments must be submitted on or before March 14, 2017.

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(s) and instructions should be directed to Jennifer Hunter Childs, U.S. Census Bureau, 4600 Silver Hill Road, Center for Survey Measurement, Washington, DC 20233 or (202)603–4827.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau is committed to conducting research in a cost efficient manner. Prior to this generic clearance, several stages of testing occurred in research projects at the Census Bureau. As a first stage of research, the Census Bureau pretests questions on surveys or censuses and evaluates the usability and ease of use of Web sites using a small number of subjects during focus groups, usability and cognitive testing. These projects are in-person and labor-intensive, but typically only target samples of 20 to 30 respondents. This small-scale work is done through another existing OMB generic clearance. Often the second stage is a larger-scale field test with a split-panel design of a survey or a release of a Census Bureau data dissemination product with a feedback mechanism. The field tests often involve a lot of preparatory work and often are limited in the number of panels tested due to the cost considerations. They are often targeted at very large sample sizes with over 10,000 respondents per panel. These are typically done using stand-alone OMB clearances.

Cost efficiencies can occur by testing some research questions in a medium-scale test, using a smaller number of participants than what we typically use in a field test, yet a larger and more diverse set of participants than who we recruit for cognitive and usability tests. Using Internet panel pretesting, we can answer some research questions more thoroughly than in the small-scale testing, but less expensively than in the large-scale field test. This clearance established a medium-scale (defined as having sample sizes from 100–2000 per study), cost-efficient method of testing

questions and contact strategies over the Internet through different types of nonprobability samples.

This research program will be used by the Census Bureau and survey sponsors to test alternative contact methods, including emails and text messages (via an opt-in strategy), improve online questionnaires and procedures, reduce respondent burden, and ultimately increase the quality of data collected in the Census Bureau censuses and surveys. We will use the clearance to conduct pretesting of decennial and demographic census and survey questionnaires prior to fielding them as well as communications and/or marketing strategies and data dissemination tools for the Census Bureau. The primary method of identifying measurement problems with the questionnaire or survey procedure is split panel tests. This will encompass both methodological and subject matter research questions that can be tested on a medium-scale nonprobability panel.

This research program will also be used by the Census Bureau for remote usability testing of electronic interfaces and to perform other qualitative analyses such as respondent debriefings. An advantage of using remote, medium-scale testing is that participants can test products at their convenience using their own equipment, as opposed to using Census Bureau-supplied computers. A diverse participant pool (geographically, demographically, or economically) is another advantage. Remote usability testing would use click through rates and other paradata, accuracy and satisfaction scores, and written qualitative comments to determine optimal interface designs and to obtain feedback from respondents.

The public is currently offered an opportunity to participate in this research remotely, by signing up for an online research panel. If a person opts in, the Census Bureau will occasionally email (or text, if applicable) the person an invitation to complete a survey for one of our research projects. Invited respondents will be told the topic of the survey, and how long it will take to complete it. Under this clearance, we will also conduct similar-scale and similarly designed research using other email lists to validate preliminary findings and expand the research.

II. Method of Collection

Split sample experiments. This involves testing alternative versions of questionnaires, invitations to questionnaires (*e.g.,* emails or text messages), or Web sites, at least some of which have been designed to address problems identified in draft versions or versions from previous waves. The use of multiple questionnaires, invitations, or Web sites, randomly assigned to permit statistical comparisons, is the critical component here; data collection will be via the Internet. Comparison of revised questionnaires (or invitations) against a control version, preferably, or against each other facilitates statistical evaluation of the performance of alternative versions of the questionnaire (or invitation or Web site).

The number of versions tested and the number of cases per version will depend on the objectives of the test. We cannot specify with certainty a minimum panel size, although we would expect that no questionnaire versions would be administered to less than fifty respondents.

Split sample tests that incorporate methodological questionnaire design experiments will have a larger maximum sample size (up to several hundred cases per panel) than other pretest methods. This will enable the detection of statistically significant differences, and facilitate methodological experiments that can extend questionnaire design knowledge more generally for use in a variety of Census Bureau data collection instruments.

Usability Interviews: This method involves getting respondent input to aid in the development of automated questionnaires and Web sites and associated materials. The objective is to identify problems that keep respondents from completing automated questionnaires accurately and efficiently with minimal burden, or that prevent respondents from successfully navigating Web sites and finding the information they seek. Remote usability testing may be conducted under this clearance, whereby a user would receive an invitation to use a Web site or survey, then answer targeted questions about that experience.

Qualitative Interviews: This method involves one-on-one (or sometimes group) interviews in which the respondent is typically asked questions about survey content areas, survey questions or the survey process. A number of different techniques may be involved, including cognitive interviews and focus groups. The objective is to identify problems of ambiguity or misunderstanding, or other difficulties respondents may have answering survey questions in order to improve the information ultimately collected in large scale surveys and censuses.

Data collection for this project is authorized under the authorizing legislation for the questionnaire being tested. This authorization may be Title 13, United States Code (U.S.C.), Sections 131, 141, 161, 181, 182, 193, and 301 for Census Bureau-sponsored surveys, and Title 13 and 15 for surveys sponsored by other Federal agencies. We do not now know what other titles will be referenced, since we do not know what survey questionnaires will be pretested during the course of the clearance.

Literature on and considerations about the use of nonprobability samples for this type of work have recently been thoroughly covered by a Task Force commissioned by the American Association for Public Opinion Research and are well documented there (Baker, et al., 2013).

The information collected in this program of developing and testing questionnaires will be used by staff from the Census Bureau and sponsoring agencies to evaluate and improve the quality of the data in the surveys and censuses that are ultimately conducted. Because the questionnaires being tested under this clearance are still in the process of development, the data that result from these collections are not considered official statistics of the Census Bureau or other Federal agencies. Data will be included in research reports prepared for sponsors inside and outside of the Census Bureau. The results may also be prepared for presentations related to survey methodology at professional meetings or publications in professional journals.

III. Data

OMB Control Number: 0607–0978.
Form Number(s): TBD.
Type of Review: Extension of a Currently Approved Collection.
Affected Public: Individuals and households.
Number of Respondents: 60,000.
Average Hours per Response: 0.167
Burden Hours: 10,000.
Estimated Total Annual Cost to Public: None.
Respondent's Obligation: Voluntary.
Legal Authority: Data collection for this project is authorized under the authorizing legislation for the questionnaire being tested. This may be Title 13, U.S.C., Sections 131, 141, 161, 181, 182, 193, and 301 for Census Bureau-sponsored surveys, and Title 13 and 15 for surveys sponsored by other Federal agencies. We do not now know what other titles will be referenced, since we do not know what survey questionnaires will be pretested during the course of the clearance.

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.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2017–00584 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request; Report of Requests for Restrictive Trade Practice or Boycott

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: Bureau of Industry and Security.

Title: Report of Requests for Restrictive Trade Practice or Boycott.

Form Number(s): BIS–621P, BIS–6051P, BIS–6051 P–a.

OMB Control Number: 0694–0012.

Type of Request: Regular.

Burden Hours: 482.

Estimated Number of Respondents: 412.

Estimated Time per Response: 1 hour to 1 hour and 30 minutes.

Needs and Uses: This information is used to monitor requests for participation in foreign boycotts against countries friendly to the U.S. The information is analyzed to note changing trends and to decide upon appropriate action to be taken to carry out the United States' policy of discouraging its citizens from participating in foreign restrictive trade practices and boycotts directed against friendly countries.

Affected Public: Business or other for-profit organizations.

Frequency: On Occasion.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *reginfo.gov http://www.reginfo.gov/public/*. 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.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2017–00702 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–003–2017]

Foreign-Trade Zone (FTZ) 122—Corpus Christi, Texas, Notification of Proposed Production Activity, Superior Weighting Products LLC, (Barite/Calcium Carbonate/Bentonite), Corpus Christi, Texas

The Port of Corpus Christi, grantee of FTZ 122, submitted a notification of proposed production activity to the FTZ Board on behalf of Superior Weighting Products LLC (Superior Weighting), located in Corpus Christi, Texas. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on January 3, 2017.

A separate application for subzone designation at the Superior Weighting facility was submitted and will be processed under Section 400.38 of the Board's regulations. The facility will be used to process raw barite into ground barite, and to further process calcium carbonate (limestone) and bentonite. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Superior Weighting from customs duty payments on the foreign-status components used in export production. On its domestic sales, Superior Weighting would be able to choose the duty rate during customs entry procedures that applies to natural barium sulfate (barite) ground, processed calcium carbonate (limestone) and processed bentonite (duty rates 0.0%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: natural barium sulfate (raw barite) not ground (duty rate ranging from $0.00 to $1.25/t-CN); calcium carbonate (limestone) (duty rate 0.0%); bentonite (duty rate 0.0%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is February 22, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita H. Chen at *Juanita.Chen@trade.gov* or (202) 482–1378.

Dated: January 6, 2017.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2017–00750 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–61–2016]

Foreign-Trade Zone (FTZ) 79—Tampa, Florida; Authorization of Production Activity; Givaudan Flavors Corporation(Flavor Products); Lakeland, Florida

On September 12, 2016, Givaudan Flavors Corporation submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within Subzone 79E, in Lakeland, Florida.

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 (81 FR 64870, September 21, 2016). 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: January 9, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00739 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–64–2016]

Foreign-Trade Zone (FTZ) 21—Dorchester County, South Carolina, Authorization of Limited Production Activity, Volvo Car US Operations, Inc., (Motor Vehicles and Related Parts), Ridgeville, South Carolina

On September 9, 2016, Volvo Car US Operations, Inc. (Volvo) submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within FTZ 21, in Ridgeville, South Carolina.

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 (81 FR 66257–66259, September 27, 2016). The FTZ Board has determined that further review of part of the proposed activity is warranted at this time. The production activity described in the notification is authorized on a limited basis, subject to the FTZ Act and the Board's regulations, including Section 400.14, and further subject to a restriction requiring that the following foreign-status materials/components be admitted to the subzone in privileged foreign status (19 CFR 146.41): upholstery leather (HTSUS 4107.99); leather cases/bags (HTSUS 4202.11); felt strips (HTSUS 5602.10); manmade fiber felt shapes (HTSUS 5602.90); felt damping strips (HTSUS 5602.90); netting of twines or ropes (HTSUS 5608.19); manmade fiber twine/cordage/rope nettings (HTSUS 5608.90); nylon carpets (HTSUS 5703.20); tufted other manmade textile carpets/mats (HTSUS 5703.30); felt carpets (HTSUS 5704.90); manmade fiber tufted and non-tufted carpets/mats (HTSUS 5705.00); velcro straps (HTSUS 5806.10); vent pads of polyester fleece (HTSUS 5911.90); textile child seat protector covers (HTSUS 8708.99); textile sun shade curtains (HTSUS 8708.99); manmade fiber cargo nets (HTSUS 8708.99); textile seats/arm rests/head rests/seat belts and related parts (HTSUS 9401.90 and HTSUS 9403.90); and, textile child safety seat covers (HTSUS 9401.90).

Dated: January 9, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00751 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–153–2016]

Approval of Expansion of Subzone 100D; Thor Industries, Inc.; Jackson Center, Ohio

On November 1, 2016, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Greater Dayton Foreign-Trade Zone, Inc., grantee of FTZ 100, requesting an expansion of Subzone 100D subject to the existing activation limit of FTZ 100, on behalf of Thor Industries, Inc., in Jackson Center, Ohio.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (81 FR 78773–78774, November 9, 2016). 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 Executive Secretary (15 CFR Sec. 400.36(f)), the application to expand Subzone 100D is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 100's 2,000-acre activation limit.

Dated: January 9, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–00741 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 170106032–7037–01]

RIN 0694–XC035

Increase of Controls: Infrared Detection Items

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry with request for comments.

SUMMARY: On October 12, 2016, the Bureau of Industry and Security (BIS) published a final rule entitled ''Revisions to the Export Administration Regulations (EAR): Control of Fire Control, Laser, Imaging, and Guidance Equipment the President Determines No Longer Warrant Control Under the United States Munitions List (USML).'' This notice of inquiry is published to request comments from the public on the impact of further increasing certain controls implemented by that final rule.

DATES: Comments must be received by BIS no later than March 14, 2017.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking portal (*www.regulations.gov*). The regulations.gov ID for this rule is: BIS–2017–0001. Please refer to RIN 0694–XC035 in all comments.

FOR FURTHER INFORMATION CONTACT: For questions regarding the ECCNs included in this rule, contact Christopher Costanzo at 202–482–0718 or Email *Chistopher.Costanzo@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

On October 12, 2016, the Bureau of Industry and Security (BIS) published a final rule entitled ''Revisions to the Export Administration Regulations (EAR): Control of Fire Control, Laser, Imaging, and Guidance Equipment the President Determines No Longer Warrant Control Under the United States Munitions List (USML)'' (81 FR 70320), hereafter referred to as the ''October 12 final rule.'' This final rule was preceded by two proposed rules published on May 5, 2015 (80 FR 25798) (''May 5, 2015 proposed rule'') and February 19, 2016 (81 FR 8421) (''February 19, 2016 proposed rule''). Revisions made by the October 12 final rule became effective on December 31, 2016. During the course of public comment and interagency discussion on the rule that became effective at the end of 2016, several ideas for new types of controls under the ITAR arose. Because these controls were not proposed earlier and not subject to public comment, they were not included in the October 12 final rule. Thus, the Department of State is publishing a notice of inquiry addressing those controls. Along with those possible new controls under the ITAR, this notice of inquiry requests comments from the public on the potential impact of increasing certain EAR controls established in the October 12 final rule. Items controlled in certain Export Control Classification Numbers (ECCNs) in Category 6 of the Commerce Control List (CCL) can be incorporated into foreign military commodities. To provide greater visibility into exports, reexports, and in-country transfers of such items, the October 12 final rule increased the scope of controls described in § 744.9 (Restrictions on

exports, reexports, and transfers of certain cameras, systems, or related components) and the scope of Export Control Classification Number (ECCN) 0A919 (''Military Commodities'' Located and Produced Outside the United States . . . .). This Notice of Inquiry seeks public comment on the impact of imposing additional license requirements for certain transactions, including the effect such controls would have on: The national security or foreign policy interests of the United States; the export performance of the United States; the competitive position of the United States in the international economy; the international reputation of the United States as a supplier of goods and technology; or the economic well-being of individual United States companies. This includes comments addressing the competitive advantage of U.S. companies vis-à-vis non-U.S. companies, any impacts to the technological edge of U.S. companies, and whether these changes would influence assembly and integration activities inside and outside of the United States. Public comments should also state whether or not foreign availability exists for items subject to potential additional controls and, to the extent such foreign availability exists, describe such foreign availability in detail.

Section 734.4 ''De Minimis U.S. Content'' for 0A919 Foreign Military Commodities

Prior to December 31, 2016. Section 734.4(a)(5) of the EAR provided that there is no *de minimis* level for non-U.S. made military commodities, as described in ECCN 0A919, that incorporate uncooled thermal imaging cameras controlled in 6A003.b.4.b. The May 5, 2015 proposed rule maintained that standard in § 734.4(a)(5), but proposed to increase the scope of incorporated infrared detection items in ECCN 0A919 to include ECCNs 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4). The February 19, 2016 proposed rule maintained the change in scope to ECCN 0A919 but narrowed the destinations subject to the no *de minimis* provision in § 734.4(a)(5) to Group D:5 countries. This was done to treat foreign-made products using such dual-use items the same as foreign-made products using items previously subject to the ITAR (*i.e.,* 600 series and 9x515 items)

As of December 31, 2016. Consistent with the February 19, 2016 proposed rule, the October 12 final rule broadened the scope of ECCN 0A919 to include incorporated infrared detection items in ECCNs 6A002, 6A003, 6A990, or 6A993.a (having a maximum frame rate equal to or less than 9 Hz and thus meeting the criterion of Note 3.a to 6A003.b.4) and limited the destinations subject to the no *de minimis* provision to Group D:5 countries.

Potential Revision. Expand the destinations subject to the no *de minimis* provision to ''any destination, except Canada,'' for non-U.S. military commodities (0A919) to those that incorporate any of the following: (1) Image intensifier tubes having a figure of merit (FOM) exceeding 1,400 lp/mm (line pairs per millimeter); (2) an infrared focal plane array (FPA) with format exceeding 75,000 detector elements, or (3) related infrared focal plane array read-out integrated circuit having more than 75,000 unit cells. FOM would be defined as the product of the tube's signal to noise ratio (SNR) and limiting resolution (FOM = SNR (unitless) × Limiting Resolution (lp/mm) and is a term of art regularly associated with exports of image intensifier tubes and related devices subject to the ITAR.

Rationale. With no *de minimis* control level for commodities controlled by ECCN 0A919.a.1 only for countries listed in Country Group D:5 of Supplement No. 1 to part 740 of the EAR, there could be reexports, without U.S. Government review, of certain foreign-made military commodities incorporating items subject to the EAR to countries not in Country Group D:5. Examples of military commodities that would not reach the generally applicable 25 percent *de minimis* level, absent other controlled EAR content, and thus would not require a U.S. reexport license to countries outside of Country Group D:5, include: (1) Thermal Weapon Sights (320 × 256 bolometer (VOx or alpha Si)): Approximate cost: >$4,000. Incorporated microbolometer core camera: Approximate cost: $400 − $700; (2) Multi-sensor targeting turrets (640x480 InSb): Approximate cost: >$250,000. Incorporated Integrated Detector Cooler Assembly: Approximate cost: $25,000. (3) Airborne Targeting Pods (640 x 480 MW HgCdTe): Approximate cost: >$1,000,000. Incorporated Integrated Detector Cooler Assembly: Approximate cost: $25,000. (4) Airborne Infrared Search and Track (640 x 480 InSb): Approximate cost: >$1,000,000. Incorporated Integrated Detector Cooler Assembly: Approximate cost: $25,000.

The absence of U.S. controls over the reexport of such military commodities could result in potentially high performance systems incorporating U.S. components being exported to a wide range of destinations outside of Country Group D:5 without U.S. Government review.

Section 740.20, License Exception Strategic Trade Authorization (STA) for Certain Night Vision Equipment To Be Embedded

Prior to December 31, 2016. Section 740.20(b)(2)(x) restricted the use of License Exception STA for specific commodities controlled by ECCN 6A002, as well as related technology controlled by 6E001 or 6E002. The May 5, 2015 proposed rule expanded that restriction to also include ECCNs 0E987; 6A002; 6A990; 6D002 (for the use of commodities controlled under ECCN 6A002.b); 6D003.c; 6D991 (for the development, production, or use of commodities controlled under ECCNs 6A002, 6A003, or 6A990); 6E001 (for the development of commodities controlled under ECCNs 6A002 or 6A003); 6E002 (for the production of commodities controlled under ECCNs 6A002 or 6A003); 6E990; and 6E994. The February 19, 2016 proposed rule maintained those restrictions, but did not include the restriction for ECCN 6E994 since that proposed ECCN was removed.

As of December 31, 2016. Consistent with the February 19, 2016 proposed rule, the October 12 final rule expanded that restriction to include all items in the following ECCNs: 0E987; 6A002; 6A990; 6D002 (for the use of commodities controlled under ECCN 6A002.b); 6D003.c; 6D991 (for the development, production, or use of commodities controlled under ECCNs 6A002, 6A003, or 6A990); 6E001 (for the development of commodities controlled under ECCNs 6A002 or 6A003); 6E002 (for the production of commodities controlled under ECCNs 6A002 or 6A003); and 6E990.

Potential Revision. Remove STA eligibility for infrared imaging cameras controlled in ECCN 6A003.b.4 that:

(i) Are being exported to be embedded into a higher level assembly, system or equipment; and

(ii) incorporate two dimensional FPAs specified in either ECCN 6A002.a.3.c or ECCN 6A002.a.3.f, and that have more than 328,000 detector elements.

Rationale. Removing STA eligibility for such items will ensure that those infrared imaging cameras to be embedded (*e.g.,* kits, cores, modules) that could exceed the size of those incorporated in military fielded systems, receive U.S. Government review when exported for incorporation into commercial/civil equipment and systems.

ECCN 6A993

Prior to December 31, 2016. The export, reexport or in-country transfer of cameras in ECCN 6A993.a (meeting the criteria of Note 3 to ECCN 6A003.b.4) require a license if destined to a country designated as a state sponsor of terrorism (Country Group E:1). The May 5, 2015 and February 19, 2016 proposed rules expanded the license requirement in § 744.9 to include those cameras when destined to a military end-user or to be incorporated into a military commodity.

As of December 31, 2016. Consistent with those proposed rules, the October 12 final rule expanded the license requirement to those cameras when destined to a military end-user or to be incorporated into a military commodity.

Potential Revision. Require a license for the export, reexport or in-country transfer, to or in a D:5 country, of cameras that meet the criteria of Note 3 to ECCN 6A003.b.4 and incorporate a microbolometer FPA with greater than 75,000 detector elements and that are being exported to be incorporated into a higher level assembly, equipment or system.

Rationale: Section 744.9 does not cover camera cores to be incorporated in imaging cameras for civil end-users or civil commodities. These cores could be incorporated into night vision thermal monoculars that are not regarded as weapon sights but that could be used as such. These cores can also be incorporated into civil UAVs that could provide day and night surveillance of U.S. and coalition forces.

Supplement No. 1 to Part 774 (Commerce Control List)

ECCN 3C001

Current control status. ECCN 3C001 has NS Column 2 and AT Column 1 controls. ECCN 3C001 is not eligible for License Exceptions GBS and CIV. Neither the May 5, 2015 nor the February 19, 2016 proposed rules included changes to the control status of ECCN 3C001.

Potential Revision. Add RS Column 1 controls (worldwide except Canada) to items in 3C001 that are III–V compounds of gallium or indium, and aluminum, antimony, or arsenic, forming a strained layer superlattice having a photoluminescence signal maxima originating from the superlattice in the wavelength range exceeding 3,000 nm but not exceeding 15,000 nm at a temperature less than 200 K. License review policy for RS:1 controls are found in § 742.6 of the EAR.

Rationale: Materials meeting these parameters are necessary for the production of FPAs controlled in ECCN 6A002, which are subject to an RS:1 control.

ECCN 3E001

Current control status. ECCN 3E001 has the following controls: NS Column 1 applies to ''technology'' for items controlled by 3A001, 3A002, 3A003, 3B001, 3B002, or 3C001 to 3C006; MT Column 1 applies to ''technology'' for equipment controlled by 3A001 or 3A101 for MT Reasons; NP Column 1 applies to ''technology'' for equipment controlled by 3A001, 3A201, or 3A225 to 3A234 for NP reasons; and AT Column 1 applies to the entire entry.

Potential Revision. Add RS Column 1 to ''technology'' for items in 3C001 that are III–V compounds of gallium or indium, and aluminum, antimony, or arsenic forming a strained layer superlattice having a photoluminescence signal maxima originating from the superlattice in the wavelength range exceeding 3,000 nm but not exceeding 15,000 nm at a temperature less than 200 K. RS Column 1 controls apply to all destinations except Canada. License review policy for RS:1 controls are found in § 742.6 of the EAR. Note that License Exceptions CIV and TSR would no longer be eligible for these specified items in ECCN 3E001, because of the addition of RS Column 1 controls.

Rationale: Technology for the production of materials meeting these parameters is necessary for the production of FPAs controlled in ECCN 6A002, which are subject to an RS:1 control.

ECCNs 6E001, 6E002 and 6E990

Prior to December 31, 2016 and current control status. The May 5, 2015 proposed rule included a new worldwide RS control for commodities controlled under ECCNs 6A002 and 6A990, as well as for related software and technology controlled under 6D002, 6D003.c, 6D991, 6E001, and 6E002. The proposed worldwide RS control would have introduced a new license requirement for such items for exports or reexports to Canada. After receiving extensive public comments opposing the inclusion of the worldwide RS control, the February 19, 2016 proposed rule did not retain that proposal, and as such, the final rule maintained the current controls in place for such items.

Proposed Revision. Add a worldwide RS control for specific technology related to components controlled under ECCN 6A002 or 6A990, as follows:

(i) 6E001 development technology or 6E002 production technology for image intensifier tubes controlled in 6A002.a.2.a or 6A002.a.2.b and their specially designed components controlled in 6A002.a.2.c, except those tubes having a multialkali photocathode.

(ii) 6E001 development technology or 6E002 production technology for microbolometer infrared focal plane arrays controlled in 6A002.a.3.f and two-dimensional infrared focal plane arrays controlled in 6A002.a.3.c.

(iii) 6E990 development and production technology for read-out integrated circuits specially designed for those focal plane arrays specified in ii, above (*i.e.,* microbolometer infrared focal plane arrays controlled in 6A002.a.3.f and two-dimensional infrared focal plane arrays controlled in 6A002.a.3.c).

Rationale. This proposed revision, while similar to proposals from the May 5, 2015 proposed rule, would add new license requirements for Canada for a narrower range of items than those previously proposed. Thus, this one potential revision would be limited to that development or production technology required for the most sensitive items controlled in ECCNs 6A002 or 6A990. Given the close relationship between the U.S. and Canadian industrial bases and the very limited license requirements for exports of dual-use items to Canada in the EAR, BIS also requests comments on how this potential change would affect the U.S.-Canada trade and defense relationship and whether this potential revision would further the collective North American security.

Request for Comments

BIS is seeking comments on foreign availability, as well as the impact these potential revisions may have on: The national security or foreign policy interests of the United States; the export performance of the United States; the competitive position of the United States in the international economy; the international reputation of the United States as a supplier of goods and technology; or on the economic well-being of individual United States companies. As stated under the **DATES** caption to this notice, comments should be received no later than March 14, 2017.

Dated: January 9, 2017.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2017–00652 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–918]

Steel Wire Garment Hangers From the People's Republic of China; 2015–2016; Partial Rescission of the Eighth Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On December 16, 2016, the Department of Commerce (''Department'') published a notice of initiation of an administrative review of the antidumping duty order on steel wire garment hangers from the People's Republic of China (''PRC''). Based on M&B Metal Products Co., Ltd.'s (''Petitioner'') timely withdrawal of the requests for review of certain companies, we are now rescinding this administrative review with respect to 42 companies.

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Jessica Weeks, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–4877.

SUPPLEMENTARY INFORMATION:

Background

On October 3, 2016, the Department published a notice of ''Opportunity to Request Administrative Review'' of the antidumping order on steel wire garment hangers from the PRC.[1] In October 2016, the Department received multiple timely requests to conduct an administrative review of the antidumping duty order on steel wire garment hangers from the PRC.[2] Based upon these requests, on December 16, 2016, the Department published a notice of initiation of an administrative review of the *Order* covering the period October 1, 2015, to September 30, 2016.[3] The Department initiated the administrative review with respect to 46 companies.[4] On December 22, 2016, Petitioner withdrew its request for an administrative review on 42 companies.[5]

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. Petitioner timely withdrew its review request and no other party requested a review of the companies for which the petitioner requested a review. All requests for administrative reviews on the 42 companies listed in the Appendix were withdrawn.[6] Accordingly, we are rescinding this review, in part, with respect to these entities, in accordance with 19 CFR 351.213(d)(1).

This administrative review will continue with respect to Hangzhou Yingqing Material Co., Ltd., Hangzhou Qingqing Mechanical Co., Ltd., Shanghai Wells Hanger Co., Ltd., and Hong Kong Wells Ltd.

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Notification to Importers

This notice serves as the only reminder to importers for whom this review is being rescinded, as of the publication date of this notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751 and 777(i)(l) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: January 9, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

1 Da Sheng Hanger Ind. Co., Ltd.
2 Feirongda Weaving Material Co. Ltd.
3 Hangzhou Yinte
4 Hongye (HK) Group Development Co. Ltd.
5 Liaoning Metals & Mineral Imp/Exp Corp.
6 Nantong Eason Foreign Trade Co., Ltd.
7 Ningbo Bingcheng Import & Export Co. Ltd.
8 Ningbo Dasheng Daily Products Co., Ltd.
9 Ningbo Dasheng Hanger Ind. Co. Ltd.
10 Ningbo Peacebird Import & Export Co. Ltd.
11 Shang Zhou Leather Shoes Plant
12 Shanghai Bao Heng Relay Making Co., Ltd.
13 Shanghai Ding Ying Printing & Dyeing Co. Ltd.
14 Shanghai Ganghun Beddiry Clothing Factory
15 Shanghai Guangwei Shoes Co., Ltd.
16 Shanghai Guoxing Metal Products Co. Ltd.
17 Shanghai Jianhai International Trade Co. Ltd.
18 Shanghai Lian Development Co. Ltd.
19 Shanghai Shuang Qiang Embroidery Factory Co. Ltd.
20 Shanghai Tonghui
21 Shangyu Baoli Electro Chemical Aluminum Products Co., Ltd.
22 Shangyu Baoxiang Metal Manufactured Co. Ltd.
23 Shangyu Tongfang Labour Protective Articles Co., Ltd.

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 81 FR 67968 (October 3, 2016).

[2] *See Notice of Antidumping Duty Order: Steel Wire Garment Hangers from the People's Republic of China,* 73 FR 58111 (October 6, 2008) (''*Order*'').

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 91122 (December 16, 2016).

[4] *Id.*

[5] *See* Letter to the Secretary of Commerce from Petitioner ''Re: Eighth Administrative Review of Steel Wire Garment Hangers from China-Petitioner's Withdrawal of Review Requests for Specific Companies'' (December 22, 2016).

[6] As stated in *Change in Practice in NME Reviews,* the Department will no longer consider the non-market economy (''NME'') entity as an exporter conditionally subject to administrative reviews. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

24 Shaoxing Andrew Metal Manufactured Co. Ltd.
25 Shaoxing Dingli Metal Clotheshorse Co. Ltd.
26 Shaoxing Gangyuan Metal Manufactured Co. Ltd.
27 Shaoxing Guochao Metallic Products Co., Ltd.
28 Shaoxing Liangbao Metal Manufactured Co. Ltd.
29 Shaoxing Meideli Hanger Co. Ltd.
30 Shaoxing Shunji Metal Clotheshorse Co., Ltd.
31 Shaoxing Shuren Tie Co. Ltd.
32 Shaoxing Tongzhou Metal Manufactured Co. Ltd.
33 Shaoxing Zhongbao Metal Manufactured Co. Ltd.
34 Shaoxing Zhongdi Foreign Trade Co. Ltd.
35 Tianjin Innovation International
36 Tianjin Tailai Import and Export Co. Ltd.
37 Wahfay Industrial (Group) Co., Ltd.
38 Wesken International (Kunshan) Co. Ltd.
39 Xia Fang Hanger (Cambodia) Co., Ltd.
40 Zhejiang Hongfei Plastic Industry Co. Ltd.
41 Zhejiang Jaguar Import & Export Co. Ltd.
42 Zhejiang Lucky Cloud Hanger Co. Ltd.

[FR Doc. 2017–00667 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–703]

Granular Polytetrafluoroethylene Resin From Italy: Rescission of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is rescinding the administrative review of the antidumping duty order on granular polytetrafluoroethylene (PTFE) resin from Italy, for the period of review (POR) August 1, 2015, through July 18, 2016, based on the timely withdrawal of request for review by Polis S.r.l., (Polis).

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Aimee Phelan, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0697.

SUPPLEMENTARY INFORMATION:

Background

On August 5, 2016, the Department published the notice of opportunity to request an administrative review of the antidumping order on granular PTFE resin from Italy for the POR August 1, 2015, through July 31, 2016.[1] On August 31, 2016, Polis, an Italian exporter of granular PTFE resin requested that the Department conduct an administrative review of itself.[2] On October 14, 2016, the Department initiated an administrative review for the POR August 1, 2015, through July 18, 2016, pursuant to Polis' request.[3] On October 14, 2016, Polis timely withdrew its request for an administrative review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. As noted above, Polis withdrew its request for review within the 90-day period. No other party requested a review and, therefore, the Department is rescinding this administrative review.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of granular PTFE resin from Italy. For Polis, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notifications

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under an 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 terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(l) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 35l.213(d)(4).

Dated: January 9, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–00736 Filed 1–12–17; 8:45 am]

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[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 81 FR 51850, 51851 (August 5, 2016) (*Opportunity Notice*). On August 11, 2016, the Department revoked the antidumping duty order on *Granular Polytetrafluoroethylene Resin from Italy,* effective July 18, 2016. *See Granular Polytetrafluoroethylene Resin from Italy: Final Results of Sunset Review and Revocation of Antidumping Duty Order,* 81 FR 53119 (August 11, 2016). Although the *Opportunity Notice* identified the POR as August 1, 2015, through July 31, 2016, in light of the revocation of the order, effective July 18, 2016, the POR would be August 1, 2015, through July 18, 2016. *See* Memorandum to the File, re: ''Administrative Review of the Antidumping Duty Order on Granular Polytetrafluoroethylene Resin (PTFE) From Italy'' dated September 8, 2016.

[2] *See* letter from Polis, re: ''Polis Srl Request for Administrative Review of the Antidumping Duty Order on Granular Polytetrafluoroethylene Resin (PTFE) From Italy (A–475–703)'' dated August 31, 2016.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 71061 (October 14, 2016).

[4] *See* letter from Polis, re: ''Polis Srl Withdrawal of Administrative Review Request of the Antidumping Duty Order on Granular Polytetrafluoroethylene Resin (PTFE) From Italy (A–475–703)'' dated October 14, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–818; C–475–819]

Certain Pasta From Italy: Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 22, 2016, the Department of Commerce (the Department) published its initiation and preliminary results in these changed circumstances reviews. Based on our analysis of the comments submitted by interested parties, our final results remain unchanged from the preliminary results.

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Jennifer Shore, Office I for AD/CVD Operations, at (202) 482–2778; George McMahon, Office III for AD/CVD Operations, at (202) 482–1167; or Renee D'Antonio, Customs Liaison Unit for AD/CVD Operations, at (202) 482–1318, AD/CVD Operations, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On June 22, 2016, the Department published a notice of *Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews* [1] on certain pasta from Italy (1) in furtherance of the International Trade Data System (ITDS) initiative and U.S. Customs and Border Protection's (CBP) efforts to modernize the electronic submission of import documents using the Automated Commercial Environment (ACE), and (2) to align the scope language regarding certifications accompanying imports of organic pasta across the *AD/CVD Italy Pasta Orders.*[2]

Specifically, the Department preliminarily determined to: (1) Convert the organic pasta certification submission requirement to a record-keeping requirement and to adjust the scope exclusion language to reflect this change, (2) authorize electronic submission of the certification when the certificate is requested by CBP or the Department, (3) update the scope language to remove the reference to the National Organic Program certificate, and (4) to align the certification language across the *AD/CVD Italy Pasta Orders* to reflect that the same certification authority (or authorities) is acceptable for purposes of both orders. Since the publication of the *Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* the Department received a single case brief, filed on July 6, 2016, on behalf of American Italian Pasta Company, Dakota Growers Pasta Company and New World Pasta Company (Petitioners). No interested party submitted a rebuttal brief.

Scope of the Orders

The scope of these orders covers shipments of certain non-egg dry pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by the scope of these Orders is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.[3]

The merchandise subject to the *AD/CVD Italy Pasta Orders* is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise subject to these Orders is dispositive.

Analysis of Comments Received

In their July 6, 2016, case brief, Petitioners agree with the Department's revision of the organic pasta exclusion to harmonize the scope language regarding certifications concerning imports of organic pasta across the *AD/CVD Italy Pasta Orders.* Petitioners, however, express concern regarding the Department's proposal to replace the requirement to file the organic certification at entry with a record-keeping requirement. Petitioners argue that because organic pasta is an excluded product, an exporter or importer dealing exclusively with organic pasta might never become subject to the Department's jurisdiction in an administrative review or other segment and would therefore, never be required to produce the certification. Additionally, Petitioners note that, at the outset of the *Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* the Department indicated it was initiating a changed circumstances review to change the requirement to submit an organic certification at entry to a record-keeping requirement and to allow for electronic submission of the document. However, the Department did not further discuss the possible electronic submission requirement or how it would work.

Petitioners suggest that in lieu of, or in addition to, the record-keeping requirement, the Department should require importers to scan electronically and submit the organic certification using the Document Imaging System (DIS) in ACE so that the certification will be attached to each relevant entry. Petitioners conclude that the Department would have access to the certifications if the Department obtained copies of entry packages from CBP.

Department's Position

The Department considered the comments submitted by Petitioners and continues to find that it is appropriate to convert the current requirement to submit the organic certification at entry to a record-keeping requirement. Petitioners have not provided any information to indicate that enforcement of the *AD/CVD Italy Pasta Orders* would be compromised by such a change. Under the record keeping requirement described in the preliminary results, both the exporter and the importer would be required to maintain a copy of the original certification in their respective records, as well as documentation supporting the certification, that would be subject to verification by the U.S. Government.[4]

With respect to our statement in the summary of the *Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews* regarding authorization for electronic submission of the certification, this was meant to refer to one manner through which a party could submit a certification, once requested by the Department or CBP. CBP or the Department may request that the certification and/or supporting documentation be submitted electronically, through the DIS component of ACE or in some other form or manner as required by the requesting agency. As further discussed in the *Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* should the Department or CBP have concerns about entries of pasta, either agency, or both agencies, may require submission of the certifications to substantiate a party's claim that the imported pasta meets the requirements of the organic pasta exclusion. As such, the importer, or the party filing on its behalf, would be required to submit the organic pasta certification upon request by CBP or the Department.

Absent evidence that the organic pasta certification record-keeping requirement undermines the enforcement of the *AD/CVD Italy Pasta Orders,* and because this change furthers the ITDS initiative and CBP's efforts to modernize the electronic submission of import documents using ACE, we find that it is appropriate to adopt the organic pasta certification record-keeping requirement. However, this Notice should not be construed as an indication that the Department relinquishes its ability to require the

[1] *See Certain Pasta from Italy: Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* 81 FR 40659 (June 22, 2016) (*Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews*).

[2] *See Notice of Antidumping Duty Order and Amended Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy,* 61 FR 38547 (July 24, 1996); and *Notice of Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination: Certain Pasta (''Pasta'') from Italy,* 61 FR 38544 (July 24, 1996) (collectively, *AD/CVD Italy Pasta Orders*).

[3] For a full description of the scope of these *AD/CVD Italy Pasta Orders,* see the Appendix to this Notice.

[4] *See Initiation and Preliminary Results of Antidumping and Countervailing Duty Changed Circumstances Reviews,* 81 FR at 40660.

filing of the organic certification for each entry of pasta subject to the *AD/CVD Italy Pasta Orders.* If, at any time, either CBP or the Department becomes aware of evidence indicating that the elimination of the requirement to file the organic certification with each entry is undermining the enforcement of the *AD/CVD Italy Pasta Orders,* the Department can reconsider whether to require that the organic certification be filed with each entry, using the DIS for entries filed in ACE or through other means as appropriate.

Final Results of Changed Circumstances Review

After an analysis of the comments submitted, we continue to find that the organic pasta certification submission requirement should be converted to a record-keeping requirement. Under this record-keeping requirement, both the exporter and the importer are required to maintain a copy of the original EU authorized body certification in their respective records, as well as documentation supporting the certification, that would be subject to verification by the U.S. Government. Because this certification requirement will now be a record-keeping requirement, the exporter and importer are required to submit the certification in response to a request from CBP or the Department, in the form or manner required by the requesting agency (*i.e.,* electronically or otherwise). Additionally, the certification must be issued, signed, and dated prior to the exportation of the merchandise from Italy. Entries for which an exporter or importer is unable to produce the required certification and/or documentation supporting the certification upon the request of CBP or the Department may be subject to antidumping or countervailing duties.

In addition, we continue to find that the scope language relating to the organic pasta exclusion should be updated to: (1) Reflect the conversion to a record-keeping requirement; (2) remove the reference to the National Organic Program certificate; and (3) align the certification language across the *AD/CVD Italy Pasta Orders* to reflect that the same certification authority is acceptable for purposes of both orders. Based on the foregoing, the Department adopts the revised scope of the *AD/CVD Italy Pasta Orders* to reflect the aforementioned changes. The full text of the revised scopes is found in the Appendix to this document.

Notification to Parties

This notice is the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the 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.

These final results are being issued and published in accordance with sections 751(b)(1) and 777(i) of the Tariff Act of 1930, as amended and 19 CFR 351.216 and 351.221(b)(5).

Dated: January 6, 2017.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the AD Order on Certain Pasta From Italy

Imports covered by this Order are shipments of certain non-egg dry pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by the scope of the Order is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of this Order are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Multicolored pasta, imported in kitchen display bottles of decorative glass that are sealed with cork or paraffin and bound with raffia, is excluded from the scope of the Order. Note 1. Pursuant to the Department's August 14, 2009, changed circumstances review, effective July 1, 2008, gluten free pasta is also excluded from the scope of the Order. Note 2. Effective January 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are also excluded from the scope of the Order. Note 3.

Also excluded are imports of organic pasta from Italy that are certified by an EU authorized body in accordance with the United States Department of Agriculture's National Organic Program for organic products. The organic pasta certification must be retained by exporters and importers and made available to U.S. Customs and Border Protection or the Department of Commerce upon request.

The merchandise subject to this order is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise subject to the Order is dispositive.

Note 1. *See* Memorandum to Richard Moreland, dated August 25, 1997, which is on file in the Central Records Unit.

Note 2. *See Certain Pasta From Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review and Revocation, in Part,* 74 FR 41120 (August 14, 2009).

Note 3. *See Certain Pasta From Italy: Final Results of Antidumping Duty and Countervailing Duty Changed Circumstances Reviews and Revocation, in Part,* 79 FR 58319, 58320 (September 29, 2014).

Scope of the CVD Order on Certain Pasta From Italy

Imports covered by this Order are shipments of certain non-egg dry pasta in packages of five pounds four ounces or less, whether or not enriched or fortified or containing milk or other optional ingredients such as chopped vegetables, vegetable purees, milk, gluten, diastasis, vitamins, coloring and flavorings, and up to two percent egg white. The pasta covered by the scope of the Order is typically sold in the retail market, in fiberboard or cardboard cartons, or polyethylene or polypropylene bags of varying dimensions.

Excluded from the scope of this Order are refrigerated, frozen, or canned pastas, as well as all forms of egg pasta, with the exception of non-egg dry pasta containing up to two percent egg white. Multicolored pasta, imported in kitchen display bottles of decorative glass that are sealed with cork or paraffin and bound with raffia, is excluded from the scope of the Order. Note 1. Pursuant to the Department's May 12, 2011, changed circumstances review, effective January 1, 2009, gluten free pasta is also excluded from the scope of the Order. Note 2. Effective January 1, 2012, ravioli and tortellini filled with cheese and/or vegetables are also excluded from the scope of the Order. Note 3.

Also excluded are imports of organic pasta from Italy that are certified by an EU authorized body in accordance with the United States Department of Agriculture's National Organic Program for organic products. The organic pasta certification must be retained by exporters and importers and made available to U.S. Customs and Border Protection or the Department of Commerce upon request.

The merchandise subject to this order is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and Customs purposes, the written description of the merchandise subject to the Order is dispositive.

Note 1. *See* Memorandum to Richard Moreland, dated August 25, 1997, which is on file in the CRU.

Note 2. *See Certain Pasta From Italy: Final Results of Countervailing Duty Changed Circumstances Review and Revocation, In Part,* 76 FR 27634 (May 12, 2011).

Note 3. *See Certain Pasta From Italy: Final Results of Antidumping Duty and*

Countervailing Duty Changed Circumstances Reviews and Revocation, in Part, 79 FR 58319, 58320 (September 29, 2014).

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DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

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

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Brenda E. Waters, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various antidumping and countervailing duty orders and findings with November anniversary dates.

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

Notice of No Sales

If a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (''POR''), it must notify the Department within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at *http://access.trade.gov* in accordance with 19 CFR 351.303.[1] Such submissions are subject to verification in accordance with section 782(i) of the Tariff Act of 1930, as amended (''the Act''). Further, in accordance with 19 CFR 351.303(f)(1)(i), a copy must be served on every party on the Department's service list.

Respondent Selection

In the event the Department limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, the Department intends to select respondents based on U.S. Customs and Border Protection (''CBP'') data for U.S. imports during the period of review. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 30 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments five days after the deadline for the initial comments.

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

In general, the Department has found that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, the Department will not conduct collapsing analyses at the respondent selection phase of this review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to this review, if the Department determined, or continued to treat, that company as collapsed with others, the Department will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, the Department will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete the Quantity and Value (''Q&V'') Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of this proceeding where the Department considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

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

Separate Rates

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

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, the Department analyzes each entity exporting the subject merchandise under a test arising from the *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991), as amplified by *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the*

[1] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

People's Republic of China, 59 FR 22585 (May 2, 1994). In accordance with the separate rates criteria, the Department assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below. For these administrative reviews, in order to demonstrate separate rate eligibility, the Department requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the ''Instructions for Filing the Certification'' in the Separate Rate Certification. Separate Rate Certifications are due to the Department no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding [2] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,[3] should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Status Application will be available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html* on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Status Application, refer to the instructions contained in the application. Separate Rate Status Applications are due to the Department no later than 30 calendar days of publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Status Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

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

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than November 30, 2017.

	Period to be reviewed
Antidumping Duty Proceedings	
Indonesia: Monosodium Glutamate, A–560–826	11/1/15–10/31/16
PT Cheil Jedang Indonesia	
Mexico: Certain Circular Welded Non-Alloy Steel Pipe, A–201–805	11/1/15–10/31/16
Abastecedora y Perfiles y Tubos, S.A. de C.V.	
Conduit, S.A. de C.V.	
Lamina y Placa Comercial, S.A. de C.V.	
Regiomontana de Perfiles y Tubos S.A. de C.V.	
Maquilacero S.A. de C.V.	
Mueller Comercial de Mexico, S. de R.L. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
Pytco, S.A. de C.V.	
Ternium Mexico, S.A. de C.V.	
Tuberia Nacional, S.A. de C.V.	
Villacero	
Mexico: Steel Concrete Reinforcing Bar, A–201–844	11/1/15–10/31/16
Deacero S.A.P.I. de C.V.	
Grupo Acerero S.A. de C.V.	
Grupo Simec	
Orge S.A. de C.V.	
Industrias CH	
Ternium Mexico, S.A. de C.V.	
ArcelorMittal Lazaro Cardenas S.A. de C.V.	
Cia Siderurgica De California, S.A. de C.V.	
Siderurgica Tultitlan S.A. de C.V.	
Talleres y Aceros, S.A. de C.V	
Grupo Villacero S.A. de C.V.	
AceroMex S.A.	
ArcelorMittal Celaya	
ArcelorMittal Cordoba S.A. de C.V.	

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

[3] Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

	Period to be reviewed
Republic of Korea: Certain Circular Welded Non-Alloy Steel Pipe, A–580–809	11/1/15–10/31/16
AJU Besteel	
Husteel Co., Ltd.	
Hyundai HYSCO	
Hyundai Steel Company [4]	
NEXTEEL	
SeAH Steel Corporation	
The People's Republic of China: Diamond Sawblades and Parts Therof, A–570–900	11/1/15–10/31/16
ASHINE Diamond Tools Co., Ltd.	
Bosun Tools Co., Ltd.	
Chengdu Huifeng Diamond Tools Co., Ltd.	
Danyang City Ou Di Ma Tools Co., Ltd.	
Danyang Hantronic Import & Export Co., Ltd.	
Danyang Huachang Diamond Tools Manufacturing Co., Ltd.	
Danyang Like Tools Manufacturing Co., Ltd.	
Danyang NYCL Tools Manufacturing Co., Ltd.	
Danyang Tsunda Diamond Tools Co., Ltd.	
Danyang Weiwang Tools Manufacturing Co., Ltd.	
Guilin Tebon Superhard Material Co., Ltd.	
Hangzhou Deer King Industrial and Trading Co., Ltd.	
Hangzhou Kingburg Import & Export Co., Ltd.	
Hebei XMF Tools Group Co., Ltd.	
Henan Huanghe Whirlwind Co., Ltd.	
Henan Huanghe Whirlwind International Co., Ltd.	
Hong Kong Hao Xin International Group Limited	
Husqvarna (Hebei) Co., Ltd.	
Huzhou Gu's Import & Export Co., Ltd.	
Jiangsu Fengtai Diamond Tool Manufacture Co., Ltd.[5]	
Jiangsu Fengtai Tools Co., Ltd.[6]	
Jiangsu Huachang Tools Manufacturing Co., Ltd.	
Jiangsu Inter-China Group Corporation	
Jiangsu Youhe Tool Manufacturer Co., Ltd.	
Orient Gain International Limited	
Pantos Logistics (HK) Company Limited	
Pujiang Talent Diamond Tools Co., Ltd.	
Qingdao Hyosung Diamond Tools Co., Ltd.	
Qingdao Shinhan Diamond Industrial Co., Ltd.	
Qingyuan Shangtai Diamond Tools Co., Ltd.	
Quanzhou Zhongzhi Diamond Tool Co., Ltd.	
Rizhao Hein Saw Co., Ltd.	
Saint-Gobain Abrasives (Shanghai) Co., Ltd.	
Shanghai Jingquan Industrial Trade Co., Ltd.	
Shanghai Starcraft Tools Company Limited	
Sino Tools Co., Ltd.	
Weihai Xiangguang Mechanical Industrial Co., Ltd.	
Wuhan Wanbang Laser Diamond Tools Co., Ltd.	
Xiamen ZL Diamond Technology Co., Ltd.	
Zhejiang Wanli Tools Group Co., Ltd.	
The People's Republic of China: Fresh Garlic, A–570–831	11/1/15–10/31/16
China Union Agri. (Qingdao) Co., Ltd.	
Hebei Golden Bird Trading Co., Ltd.	
Jining Alpha Food Co., Ltd.	
Jinan Farmlady Trading Co., Ltd.	
Jining Shengtai Fruits & Vegetables Co., Ltd.	
Jining Shunchang Import & Export Co., Ltd.	
Jining Yifa Garlic Produce Co., Ltd.	
Jining Yongjia Trade Co., Ltd.	
Jinxiang Hejia Co., Ltd.	
Jinxiang Jinma Fruits Vegetables Products Co., Ltd.	
Jinxiang Shengtai Fruits & Vegetables Co., Ltd.	
Jining Shunchang Import & Export Co., Ltd.	
Jinxiang Feiteng Import & Export Co., Ltd.	
Jinxiang Richfar Fruits & Vegetables Co., Ltd.	
Juxian Huateng Food Co., Ltd.	
Juxian Huateng Organic Ginger Co., Ltd.	
Qingdao Hailize (Sea-line) International Trading Co., Ltd.	
Qingdao Jiashan Trading Co., Ltd.	
Qingdao Jiuyihongrun Foods Co., Ltd.	
Qingdao Joinseafoods	
Qingdao Lianghe International Trade Co., Ltd.	
Qingdao Ritai Food Co., Ltd.	
Qingdao Sea-line International Trading Co., Ltd.	
Qingdao Tiantaixing Foods Co., Ltd.	

	Period to be reviewed
Qingdao Xintianfeng Foods Co., Ltd.	
Shandong Helu International Trade Co., Ltd.	
Shandong Jinxiang Zhengyang Import & Export Co., Ltd.	
Shenzhen Bainong Co., Ltd.	
Shenzhen Xinboda Industrial Co., Ltd.	
Shijiazhuang Goodman Trading Co., Ltd.	
Weifang Hongqiao International Logistics Co., Ltd.	
Weifang Wangyuan Food Co., Ltd.	
Zhengzhou Harmoni Spice Co., Ltd.	
Zhengzhou Yudishengjin Agricultural Trade Co., Ltd.	
Zhengzhou Yudishengjin Farm Products Co., Ltd.	
Zhonglian Nongchan Co., Ltd.	
The People's Republic of China: Lightweight Thermal Paper, A–570–920	11/1/15–10/31/16
Sailing International Limited	
Shenzhen Formers Printing Co., Ltd.	
Suzhou Xiandai Paper Production Co	
The People's Republic of China: Monosodium Glutamate, A–570–992	11/1/15–10/31/16
Anhui Fresh Taste International Trade Co., Ltd.	
Baoji Fufeng Biotechnologies Co., Ltd.	
Blu Logistics (China) Co., Ltd.	
Bonroy Group Limited	
Forehigh Trade and Industry Co., Ltd.	
Fujian Province Jianyang Wuyi MSG Co., Ltd.	
Golden Banyan Foodstuffs Industry Co., Ltd.	
Henan Lotus Flower Gourmet Powder Co.	
Hong Kong Sungiven International Food Co., Limited	
Hulunbeier Northeast Fufeng Biotechnologies Co., Ltd.	
K&S Industry Limited	
King Cheong Hong International	
Langfang Meihua Bio-Technology Co., Ltd.	
Liangshan Linghua Biotechnology Co., Ltd.	
Lotus Health Industry Holding Group	
Meihua Group International Trading (Hong Kong) Limited	
Meihua Holdings Group Co., Ltd., Bazhou Branch	
Neimenggu Fufeng Biotechnologies Co., Ltd.	
Pudong Prime Int'l Logistics, Inc.	
Qinhuangdao Xingtai Trade Co., Ltd.	
S.D. Linghua M.S.G. Incorporated Co.	
Shandong Linghua Monosodium Glutamate Incorporated Company	
Shanghai Totole Food Ltd.	
Shijiazhuang Standard Imp & Exp Co., Ltd.	
Sunrise (HK) International Enterprise Limited	
Tongliao Meihua Biological Sci-Tech Co., Ltd.	
Zhejiang Medicines & Health	
The People's Republic of China: Passenger Vehicle and Light Truck Tires, A–570–016	1/27/15–7/31/16
Maxon Int'l Co., Limited [7]	
Nankang International Co., Ltd.[8]	
Nankang Rubber Tire Corp., Ltd.[9]	
The People's Republic of China: Polyethylene Terephthalate Film, and Strip, A–570–924	11/1/15–10/31/16
Fuwei Films (Shandong) Co., Ltd.	
Shaoxing Xiangyu Green Packing Co., Ltd.	
Sichuan Dongfang Insulating Material Co., Ltd.	
Tianjin Wanhua Co., Ltd.	
The People's Republic of China: Seamless Refined Copper Pipe and Tube, A–570–964	11/1/15–10/31/16
China Hailiang Metal Trading	
Foshan Hua Hong Copper Tube Co., Ltd.	
Golden Dragon Precise Copper Tube Group, Inc.	
Golden Dragon Holding (Hong Kong) International Co., Ltd. & Hong Kong GD Trading Co., Ltd.	
Guilin Lijia Metals Co., Ltd.	
Hong Kong Hailing Metal	
Ningbo Jintian Copper Tube Co., Ltd.	
Shanghai Hailing Copper Co., Ltd.	
Shanghai Hailing Metal Trading Limited	
Sinochem Ningbo Ltd. & Sinochem Ningbo Import & Export Co., Ltd.	
Taicang City Jinxin Copper Tube Co., Ltd.	
Zhejang Jiahe Pipe Inc.	
Zhejiang Hailing Co., Ltd.	
Zhejiang Naile Copper Co., Ltd.	
United Arab Emirates: Polyethylene Terephthalate (PET) Film, Sheet and Strip, A–520–803	11/1/15–10/31/16
Flex Middle East FZE	
Uflex Limited	
JBF RAK LLC	

	Period to be reviewed
Countervailing Duty Proceedings	
The People's Republic of China: Aluminum Extrusions [10], C–570–968	1/1/15–12/31/15
Changzhou Jinxi Machinery Co., Ltd.	
The People's Republic of China: Certain Magnesia Carbon Bricks [11], C–570–955	1/1/15–12/31/15
Dashiqiao City Guancheng Refractor Co., Ltd. (aka Dashiqiao City Guancheng Refractory Co., Ltd.)	
Yingkou Dalmond Refractories Co., Ltd.	
The People's Republic of China: Chlorinated Isocyanuates, C–570–991	1/1/15–12/31/15
Hebei Jiheng Chemical Co., Ltd.	
Heze Huayi Chemical Co., Ltd.	
Juancheng Kangtai Chemical Co., Ltd.	
The People's Republic of China: Lightweight Thermal Paper, C–570–921	1/1/15–12/31/15
Sailing International Limited	
Shenzhen Formers Printing Co., Ltd.	
Suzhou Xiandai Paper Production Co	
Turkey: Steel Concrete Reinforcing Bar, C–489–819	1/1/15–12/31/15
Acemar International Limited	
Agir Haddecilik Makina Sanayi Ve Ti	
As Gaz Sinai ve Tibbi Azlar AS.	
Asil Celik Sanayi ve Ticaret AS.	
Colakoglu Dis Ticaret A.S.	
Colakoglu Metalurji A.S.	
Duferco Celik Ticaret Limited	
Duferco Investment Services SA	
Ege Celik Endustrisi Sanayi ve Ticaret AS.	
Ekinciler Demir ve Celik Sanayi Anonim Sirketi	
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S.	
Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S.	
Izmir Demir Celik Sanayi A.S.	
Kaptan Demir Celik Industrisi ve Ticaret A.S.	
Kaptan Metal Dis Tic Ve Nak AS	
Kocaer Haddecilik Sanayi Ve Ticar L	
Mettech Metalurji Madencilik Muhendislik Uretim Danismanlik ve Ticaret Limited Sirketi	
MMZ Onur Boru Profil A.S.	
Ozkan Demir Celik Sanayi A.S.	
Wilmar Europe Trading BV	

Suspension Agreements

None.

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v. *United States,* 291 F.3d 806 (Fed Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period, of the order, if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these

[4] Hyundai Steel Company is the successor-in-interest to Hyundai HYSCO, for which we received a review request. *See Notice of Final Results of Antidumping Duty Changed Circumstances Review: Circular Welded Non-Alloy Steel Pipe From the Republic of Korea,* 81 FR 42653 (June 30, 2016), and *Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 89059 (December 9, 2016), and accompanying Preliminary Decision Memorandum at 1, n. 3.

[5] We treated Jiangsu Fengtai Diamond Tool Manufacture Co., Ltd., Jiangsu Fengtai Tools Co., Ltd., and Jiangsu Fengtai Sawing Industry Co., Ltd., as a single entity. *See Diamond Sawblades and Parts Thereof From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2013–2014,* 81 FR 38673, 38674 (June 14, 2016), and *Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 89045, 89046 n.11 (December 9, 2016).

[6] *Id.*

[7] The company name listed was misspelled in the initiation notice that published on October 14, 2016 (81 FR 71065). The correct spelling is listed above.

[8] The Department should have initiated a review for the company listed above in the initiation notice that published on October 14, 2016 (81 FR 71065).

[9] The Department should have initiated a review for the company listed above in the initiation notice that published on October 14, 2016 (81 FR 71065).

[10] The Department should have initiated a review for the company listed above in the initiation notice that published on July 7, 2016 (81 FR 44260).

[11] The two company names listed were misspelled in the initiation notice that published on November 9, 2016 (81 FR 78778). The correct spellings are listed above.

administrative reviews should ensure that they meet the requirements of these procedures (*e.g.,* the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Revised Factual Information Requirements

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to antidumping and countervailing duty proceedings: The definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all segments initiated on or after May 10, 2013. Please review the final rule, available at *http://enforcement.trade.gov/frn/2013/1304frn/2013-08227.txt,* prior to submitting factual information in this segment.

Any party submitting factual information in an antidumping duty or countervailing duty proceeding must certify to the accuracy and completeness of that information.[12] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives. All segments of any antidumping duty or countervailing duty proceedings initiated on or after August 16, 2013, should use the formats for the revised certifications provided at the end of the *Final Rule.*[13] The Department intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable revised certification requirements.

Revised Extension of Time Limits Regulation

On September 20, 2013, the Department modified its regulation concerning the extension of time limits for submissions in antidumping and countervailing duty proceedings: *Final Rule,* 78 FR 57790 (September 20, 2013). The modification clarifies that parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) Case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning U.S. Customs and Border Protection data; and (5) quantity and value questionnaires. Under certain circumstances, the Department may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, the Department will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This modification also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which the Department will grant untimely-filed requests for the extension of time limits. These modifications are effective for all segments initiated on or after October 21, 2013. Please review the final rule, available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these segments.

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: January 9, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–00674 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

[12] *See* section 782(b) of the Act.

[13] *See Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*''); *see also* the frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Rescission, in Part, of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 11, 2016, the Department of Commerce (Department) initiated an administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished (TRBs) from the People's Republic of China (PRC) for eight companies. Based on timely withdrawal of requests for review, we are now rescinding this administrative review with respect to two of these companies, Changshan Peer Bearing Co. Ltd. (CPZ/SKF) and GGB Bearing Technology (Suzhou) Co., Ltd. (GGB).

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Andrew Medley or Whitley Herndon, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4987 or (202) 482–6274, respectively.

Background

In June 2016, the Department received multiple timely requests to conduct an administrative review of the antidumping duty order on TRBs from the PRC. Based upon these requests, on August 11, 2016, in accordance with section 751(a) of the Tariff Act of 1930,

as amended (the Act), the Department published a notice of initiation of an administrative review covering the period June 1, 2015, through May 31, 2016, with respect to eight companies.[1] On September 29, 2016, and October 11, 2016, CPZ/SKF and GGB, respectively, withdrew their requests for an administrative review.

Partial Rescission

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. CPZ/SKF and GGB timely withdrew their requests for an administrative review of themselves; no other party requested a review of these companies. Accordingly, we are rescinding this review, in part, with respect to these companies, pursuant to 19 CFR 351.213(d)(1).

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. For CPZ/SKF and GGB, the companies for which these reviews are rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issued and published in accordance with sections 751 and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: January 10, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–00682 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 53121 (August 11, 2016).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–955]

Certain Magnesia Carbon Bricks From the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2014

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: On September 13, 2016, the Department of Commerce (the Department) published the preliminary results of the administrative review of the countervailing duty (CVD) order on certain chemically-bonded magnesia carbon bricks (MCBs) from the People's Republic of China (PRC). The period of review (POR) is January 1, 2014, through December 31, 2014. The Department preliminarily found no evidence of any reviewable entries and received no comments on the preliminary results. Therefore, the Department is rescinding the administrative review of the CVD order on MCBs from the PRC.

DATES: Effective January 13, 2017.

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 September 13, 2016, the Department published the *Preliminary Results.*[1] In accordance with 19 CFR 351.309(c)(1)(ii), we invited parties to comment on our *Preliminary Results.* No parties submitted comments.

Rescission

It is the Department's practice to rescind an administrative review of a CVD order, pursuant to CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[2] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate calculated for the review period. *See* 19 CFR 351.212(b)(1). Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that the Department can order CBP to liquidate at the newly calculated CVD assessment rate. Accordingly, in the absence of suspended entries of subject merchandise during the period of this administrative review (January 1, 2014, through December 31, 2014), we are rescinding this administrative review of the CVD order on MCBs from the PRC.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: January 9, 2017.

Gary Taverman,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–00689 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Magnesia Carbon Bricks from the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2014,* 81 FR 62870 (September 13, 2016) (*Preliminary Results*).

[2] *See, e.g., Certain Welded Carbon Steel Standard Pipe and Tube from Turkey: Notice of Final Rescission of Countervailing Duty Administrative Review, In Part,* 77 FR 6542 (February 8, 2012). In the *Preliminary Results* the Department stated ''As is our practice, the Department finds that it is not appropriate to rescind this review, but, rather, to complete this review and to issue appropriate instructions to CBP based on the final results of this review.'' This sentence was included in error. The Department issues preliminary and final results in so-called ''no shipment'' reviews in antidumping proceedings only. *See, e.g., Silicomanganese from India: Preliminary Results of Antidumping Duty Administrative Review; 2014–2015,* 81 FR 28826 (May 10, 2016) and accompanying Decision Memorandum at 3.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–910]

Circular Welded Carbon Quality Steel Pipe From the People's Republic of China: Rescission of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') is rescinding the administrative review of the antidumping duty order on circular welded carbon quality steel pipe from the People's Republic of China (''PRC'') for the period July 1, 2015, through June 30, 2016.

DATES: Effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Howard Smith or Jonathan Hill, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5193 or (202) 482–3518, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 12, 2016, based on a timely request for review by Wheatland Tube Company (''Wheatland''), the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on circular welded carbon quality steel pipe from the PRC with respect to 20 companies covering the period July 1, 2015, through June 30, 2016.[1] On December 12, 2016, Wheatland withdrew its request for an administrative review of all of the companies listed in its review request.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation of the requested review. In this case, Wheatland timely withdrew its review request by the 90-day deadline, and no other party requested an administrative review of the antidumping duty order.[2] As a result, we are rescinding the administrative review of circular welded carbon quality steel pipe from the PRC for the period July 1, 2015, through June 30, 2016.

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. Because the Department is rescinding this administrative review in its entirety, the entries to which this administrative review pertained shall be assessed antidumping duties at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a final reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: January 9, 2017.

Gary Taverman,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2017–00668 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 62720 (September 12, 2016) (''*Initiation Notice*'').

[2] The 90-day deadline to withdraw a request for review was December 11, 2016. However, as December 11, 2016 was a Sunday, the deadline to withdraw a request for review was the next business day, December 12, 2016. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF157

Caribbean Fishery Management Council; Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The Caribbean Fishery Management Council's Scientific and Statistical Committee (SSC) will hold a five-day meeting in San Juan, Puerto Rico.

DATES: The meetings will be held on February 6–10, 2017. The meeting will begin at 1 p.m. on February 6, 2017 and adjourn at 5 p.m. on February 10, 2017.

ADDRESSES: The meetings will be held at the Council Office, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903, telephone (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Caribbean Fishery Management Council's SSC will hold a five-day meeting to discuss the items contained in the following agenda:

—Call to Order
—Adoption of Agenda
—SEDAR 46 US Caribbean Data Limited Species—Southeast Fisheries Science Center (SEFSC)
  Complete and final review of the revisions to the SEDAR 46 and its potential for OFL and/or ABC advice
—Island Based Fishery Management Plans (IBFMPs)

The Caribbean Fishery Management Council is developing an Island Based FMP to manage fisheries in each Puerto Rico, St. Thomas/St. John and St. Croix. There are 5 Actions contained in the Draft documents but the SSC will be discussing Action 2 and 3 at this meeting. The Draft Document of Actions and Alternatives presented at the 158th

CFMC meeting is available at *www.caribbeanfmc.com.*

Finalize Action 2: Establish Stock or Stock Complexes for each Puerto Rico, St. Thomas/St. John and St. Croix Fishery Management Plan (FMP)

—Review Consolidated List of Stocks and Stock Complexes/Species Complexes—NMFS Southeast Regional Office (SERO) Update

—SSC final recommendations to the CFMC on species/stock complexes groupings, and recommendations on the use of indicator species in Action 2 of the IBFMPs

Review/Finalize Action 3: Management Reference Points for Stocks/Stock for each Puerto Rico, St. Thomas/St. John and St. Croix Fishery Management Plan (FMP)

Action 3(a): Time Series: Select a time series of landings data to establish management reference points for a stock/stock complex, as applicable.

Action 3(b): Maximum Sustainable Yield (MSY) Proxy for a Stock/Stock Complex for each Puerto Rico, St. Thomas/St. John and St. Croix FMP

Action 3(c): Overfishing Limit (OFL) for Stocks/Stocks Complexes for each Puerto Rico, St. Thomas/St. John and St. Croix FMP

Action 3(d): Acceptable Biological Catch (ABC) Control Rule for Stocks/Stocks Complexes for each Puerto Rico, St. Thomas/St. John and St. Croix FMP.

Action 3(e): Optimum Yield (OY) and Annual Catch Limit (ACL) for Stocks/Stocks Complexes for each Puerto Rico, St. Thomas/St. John and St. Croix FMP.

—SSC final recommendations to the Council on Action 3 of the IBFMPs: Process for setting Reference Points, MSY proxies, OFL, ABC for species/species complexes/groupings

—Other Business

—Next Meeting

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone (787) 766–5926, at least 5 days prior to the meeting date.

Dated: January 10, 2017.

Jeffrey N. Lonergan,

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

[FR Doc. 2017–00738 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Monterey Peninsula Water Supply Project; Notice of Availability of a Draft Environmental Impact Report/Environmental Impact Statement

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA).

ACTION: Notice of availability of a draft environmental impact report/environmental impact statement; request for public comments; announcement of public meetings.

SUMMARY: A permit application has been submitted by California American Water Company (CalAm) to NOAA's Monterey Bay National Marine Sanctuary (MBNMS) to construct and operate a reverse osmosis (RO) desalination facility project (Project) in Monterey County, California. The permit review process is being conducted concurrently with a public process conducted pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and California Environmental Quality Act (CEQA, Cal. Pub. Res. Code § 21000 *et seq.*). NOAA has prepared, in cooperation with the California Public Utilities Commission (CPUC), a joint draft environmental impact review/environmental impact statement (EIR/EIS) that analyzes the potential effects on the physical and human environment related to the Project proposed within MBNMS boundaries. NOAA is soliciting public comment on the draft EIR/EIS.

DATES: Comments must be received on or before February 27, 2017. Public meetings will be on the following dates:

(1) Wednesday, February 15, 11:00 a.m. to 1:00 p.m., Marina, CA

(2) Wednesday, February 15, 6:00 p.m. to 8:00 p.m., Seaside, CA

(3) Thursday, February 16, 4:00 p.m. to 8:00 p.m., Carmel, CA

ADDRESSES: Comments may be submitted by either of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0156,* click the ''Comment Now!'' icon, complete the required fields and enter or attach your comments.

• *Mail:* MBNMS Project Lead for CalAm Desalination Project, 99 Pacific Ave, BLDG 455a, Monterey, CA 93940.

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 NOAA. 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. ONMS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of the DEIR/EIS can be downloaded or viewed on the internet at *www.regulations.gov* (search for docket # NOAA–NOS–2016–0156), or at *www.regulations.gov/#!docketDetail;D=NOAA-NOS-2016-0156.* Copies can also be obtained by contacting the person identified under **FOR FURTHER INFORMATION CONTACT.**

The public meeting locations are:

(1) Marina, CA: Marina Public Library, Community Meeting Room, 188 Seaside Ave., Marina, CA 93933 (February 15, 2017)

(2) Seaside, CA: Oldemeyer Center, Seaside Room, 986 Hilby Ave., Seaside, CA 93955 (February 15, 2017)

(3) Carmel, CA: Sunset Center, Carpenter Hall, San Carlos Street, Carmel, CA 93921 (February 16, 2017)

FOR FURTHER INFORMATION CONTACT: Karen Grimmer at 99 Pacific Ave, BLDG 455a, Monterey, CA 93940 or *mbnms.comments@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background Information

I. Background

A permit application has been submitted by CalAm for construction and operation of its proposed Monterey Peninsula Water Supply Project (MPWSP or Project). The purpose of the MPWSP is to supplement existing water supplies for CalAm's Monterey District service area.

The MPWSP comprises various facilities and improvements, including: A sub-surface seawater intake system; a 9.6-million-gallons-per-day (mgd) reverse osmosis (RO) desalination plant; desalinated water storage and conveyance facilities; and expanded

Aquifer Storage and Recovery (ASR) facilities.

The desalination facility would be capable of producing 9.6 million gallons per day (MGD) of potable water on a 46-acre site located north of the City of Marina on unincorporated Monterey County property. The MPWSP proposes ten subsurface slant wells (nine new wells and conversion of an existing test well) to draw seawater from beneath the ocean floor in Monterey Bay to produce the source water for the desalination plant. The subsurface slant wells would be located primarily within the City of Marina, in the active mining area of the CEMEX sand mining facility. The slant wells would be approximately 700 to 1000 feet in length and extend beneath the coastal dunes, sandy beach, and the surf zone, terminating approximately 161 to 356 feet seaward of the Mean High Water line and at a depth of 190 to 210 feet below the seafloor. Up to 24.1 mgd of source water would be needed to produce 9.6 mgd of desalinated product water.

Under the proposed project, the desalination plant would generate approximately 13.98 mgd of brine, including 0.4 mgd of decanted backwash water. The brine would be discharged into Monterey Bay via a 36-inch diameter pipeline to a new connection with the existing Monterey Regional Water Pollution Control Agency's (MRWPCA) outfall and diffuser located offshore.

II. NOAA Proposed Action

NOAA is releasing for public comment a draft EIR/EIS that was prepared in accordance with: Section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended; and the White House Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA (CEQ NEPA Regulations). NOAA's proposed action would be whether to approve the installation of a subsurface seawater intake system, the discharge of brine into MBNMS via an existing outfall pipe, and the continued presence of pipelines in MBNMS to transport seawater to a desalination facility.

The Project was subject to a Draft Environmental Impact Report (EIR), under the provisions of the California Environmental Quality Act (CEQA), published by the California Public Utilities Commission (CPUC) in April 2015. The NEPA environmental documentation includes an Environmental Impact Statement (EIS), which is issued as a joint draft CEQA/NEPA (EIR/EIS) document with the CPUC.

The EIR/EIS identifies and assesses potential environmental impacts associated with the proposed Project, and identifies 6 alternatives, plus a no action alternative. Federal agencies would use the EIR/EIS to consider related permits or other approvals for the Project as proposed. NOAA's preferred alternative (Alternative 5a) is the environmentally preferred alternative. Alternative 5a would be implemented in conjunction with the Pure Water Monterey Groundwater Replenishment Project (GWR), which would offer the same amount of freshwater as the proposed project but result in a larger footprint than the proposed action alone, yet the pairing of Alternative 5a and the GWR project would result in reduced operational energy use and reduced GHG emissions compared to the proposed project. In addition, the combination of Alternative 5a and the GWR Project result in reduced effects on groundwater levels influenced by fewer slant wells and less volume of pumping, and the GWR project would provide water to the Castroville Seawater Intrusion Project that would benefit the groundwater basin. Lastly, Alternative 5a paired with the GWR project would be consistent with the 2016 California Action Plan seeking integrated water supply solutions, the Governor's drought proclamations, the CPUC Water Action Plan goal of promoting water infrastructure investment, the California Ocean Plan, and MBNMS Desalination Guidelines.

III. Process

This NOA is published by NOAA, the lead federal agency. NOAA, along with the CPUC, as CEQA lead agency, have determined that a joint CEQA/NEPA document is appropriate, and the two agencies have prepared a joint draft EIR/EIS after completion of a federal scoping process. In accordance with Section 102(2)(C) of NEPA, NOAA published a Notice of Intent (NOI) to prepare an EIS for the proposed project on August 26, 2015 (80 FR 51787). During the EIS scoping meeting held on September 10, 2015, five participants commented publically on the proposed project. Twelve written comments were received throughout the public comment period. The complete written comments are available for review at: *https://www.regulations.gov/docket?D=NOAA-NOS-2015-0105.*

IV. Federal Consultations

This notice also advises the public that NOAA is coordinating its consultation responsibilities under section 7 of the Endangered Species Act, Essential Fish Habitat under the Magnuson Stevens Fishery Conservation and Management Act, section 106 of the National Historic Preservation Act, and Federal Consistency review under the Coastal Zone Management Act, along with its ongoing NEPA process including the use of NEPA documents and public and stakeholder meetings to also meet the requirements of other federal laws.

NOAA is seeking public comment on the DEIR/DEIS, which is available at *http://montereybay.noaa.gov* or may be obtained by contacting the individual listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Authority: 16 U.S.C. 1431 *et seq.*

Dated: January 4, 2017.

John Armor,

Director for the Office of National Marine Sanctuaries.

[FR Doc. 2017–00505 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF129

Addition of Species to the Annexes of the Protocol Concerning Specially Protected Areas and Wildlife in the Wider Caribbean Region

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

ACTION: Notice; request for public comments.

SUMMARY: During a meeting of the Scientific and Technical Advisory Committee (STAC) under the Protocol to the Cartagena Convention on Specially Protected Areas and Wildlife (SPAW Protocol), held in Miami, Florida in November 2016, twelve species of fauna were nominated and recommended to be added to the Annexes of the SPAW Protocol. The Department of State, U.S. Fish and Wildlife Service, and National Marine Fisheries Service solicit comment on the recommendations to add these twelve species to the Annexes.

DATES: Comments must be received by February 13, 2017.

ADDRESSES: You may submit comments on the recommendations to add the twelve species to the Annexes of the SPAW Protocol, by including NOAA–NMFS–2016–0166, by either of the following methods:

• *Federal e-Rulemaking Portal:* Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0166*. Click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Addition of Species to the Annexes of the SPAW Protocol, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Room 13535, Silver Spring, MD 20910.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. 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: Chelsey Young, NOAA (301) 427–8491; *chelsey.young@noaa.gov;* and Rosemarie Gnam, U.S. Fish and Wildlife Service (703) 358–1708; *rosemarie_gnam@fws.gov*. Persons who use a Telecommunications Device for the Deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION: The SPAW Protocol is a protocol to the Convention for the Protection and Development of the Marine Environment of the Wider Caribbean Region (Cartagena Convention or Convention). There is also a protocol to the Convention addressing land-based sources of pollution and a protocol addressing regional cooperation on oil pollution preparedness and response. The SPAW Protocol was adopted in 1990 and entered into force in 2000. The United States ratified the SPAW Protocol in 2003. There are currently 16 State Parties to the SPAW Protocol from throughout the Wider Caribbean Region.

Participants at the November 2016 meeting of the STAC to the SPAW Protocol included representatives from: Antigua and Barbuda, Bahamas, Belize, Colombia, Dominican Republic, France, Grenada, Guyana, Jamaica, the Netherlands, Saint Lucia, and the United States of America. Representatives of several non-governmental organizations also attended as observers.

The U.S. delegation included representatives from the U.S. Department of State; the National Oceanic and Atmospheric Administration, National Marine Fisheries Service and National Ocean Service. Copies of the official ''Recommendations of the Meeting,'' a full list of participants, and the text of the Cartagena Convention and SPAW Protocol can be obtained at *www.cep.unep.org/meetings/2016-meetings/7th-spaw-stac*.

Convention and Convention Area

The Cartagena Convention is a regional agreement for the protection and development of the marine environment of the wider Caribbean. The Convention was adopted in 1983 and entered into force in 1986. The United States ratified the Convention in 1984. The Convention area includes the marine environment of the Gulf of Mexico, the Caribbean Sea and the adjacent areas of the Atlantic Ocean south of lat. 30° N. and within 200 nautical miles (nmi) of the Atlantic coasts of the Parties. The United States' responsibility within this Convention area includes: U.S. waters off of Puerto Rico, the Virgin Islands, and peninsular Florida, including the Atlantic coast; the waters off of a number of islands including coastal barrier islands and the Florida Keys; and the Gulf of Mexico waters under U.S. jurisdiction. The SPAW Protocol provides that each Party may designate related terrestrial areas over which they have sovereignty and jurisdiction (including watersheds) to be covered by the SPAW Protocol. The United States has not designated any terrestrial areas under the SPAW Protocol and ''does not intend to designate a terrestrial area under the Protocol unless requested to do so by an interested state or territory . . .'' (Senate Executive Report 107–8).

The Annexes and U.S. Obligations Under Each Annex

The SPAW Protocol includes three Annexes. Plant species subject to the highest levels of protection are listed in Annex I, and animal species subject to the highest levels of protection are listed in Annex II. Plants and animals subject to some management, but lesser protections than those afforded to species listed in Annexes I or II, are listed in Annex III.

Annexes I (flora) and II (fauna) are to include endangered and threatened species, or subspecies, or their populations as well as rare species. The SPAW Protocol describes rare species as those ''that are rare because they are usually localized within restricted geographical areas or habitats or are thinly scattered over a more extensive range and which are potentially or actually subject to decline and possible endangerment or extinction.''

For fauna listed in Annex II, Parties ''shall ensure total protection and recovery to the species . . . by prohibiting: (i) The taking, possession or killing (including, to the extent possible, the incidental taking, possession or killing) or commercial trade in such species, their eggs, parts or products; [and] (ii) to the extent possible, the disturbance of such species, particularly during periods of breeding, incubation, estivation or migration, as well as other periods of biological stress.''

For Annex III species, the SPAW Protocol states: ''Each Party shall adopt appropriate measures to ensure the protection and recovery of the species of flora and fauna listed in Annex III and may regulate the use of such species in order to ensure and maintain their populations at the highest possible levels.'' Therefore, some regulated harvest may be permitted for species on Annex III. The protective provisions of this Annex are not intended to be more restrictive than the provisions of Annexes I and II.

The United States ratified the SPAW Protocol, including Annexes, subject to certain reservations, including the following with respect to Article 11(1): ''The United States does not consider itself bound by Article 11(1) of the [SPAW] Protocol to the extent that United States law permits the limited taking of flora and fauna listed in Annexes I and II [ ] which is incidental, or [ ] for the purpose of public display, scientific research, photography for educational or commercial purposes, or rescue and rehabilitation.''

The United States has not designated any terrestrial area under the SPAW Protocol. As the United States explained at the time the SPAW Protocol was ratified, ''The United States does not plan to designate terrestrial area under the Protocol since no state or territory has identified a need or desire to designate terrestrial area. . . .'' (Senate Treaty Document 103–5). In addition, ''Several terrestrial species, *e.g.* bats (*Tadarida brasiliensis* and *Brachyphylla cavernarum*) and falcons (*Falco peregrinus*), are listed in the Annexes. The listing of these species, however, is not intended to describe the relevant terrestrial scope of the Protocol. As the United States has not designated any terrestrial area, the Protocol obligations will not apply with respect to such species.'' *Id.*

Summary of Annexes

Annex I contains a total of 53 plant species. All plant species on Annex I are either: (1) Listed under the U.S. Endangered Species Act (ESA); (2) endemic to Florida and protected under Florida law; (3) occur only on Federal land and are fully protected where they occur; (4) are not native to the United States, and are listed in the Appendices of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) where primarily commercial trade would be prohibited; or (5) are not native to, nor believed to be commercially imported into the United States. 56 FR 12026, 12028 (March 21, 1991). There have been no additions to Annex I since the adoption of the SPAW Protocol.

Annex II currently contains 114 species and 3 groups of species, including all sea turtles and all marine mammals in the region. Most of these animal species are either: (1) Listed under the U.S. Endangered Species Act or the Marine Mammal Protection Act; (2) are not native to the United States and are listed in Appendix I of CITES; (3) are offered complete protection by domestic legislation in all range States (whereby the Lacey Act, among other things, prohibits commercial trade in specimens taken, possessed, transported or sold in violation of foreign law); or (4) are endemic to foreign countries and are not commercially imported into the United States. Six new species were added to Annex II by the SPAW Parties in December 2014. *Id.*

Annex III currently contains 43 species of plants and 32 species of animals in addition to species of corals, mangroves, and sea-grasses that occur in the region.

Composition of the Annexes

The plant and animal species present on each Annex can be found here: *http://www.car-spaw-rac.org/?Annexes-of-the-SPAW-Protocol,83.*

Species Recommended by SPAW STAC To Be Added to the SPAW Protocol Annexes

ANNEX II

Species	Common name
BIRDS	
Passerina ciris	Painted bunting.
FISH	
Pristis pectinata	Smalltooth sawfish.

ANNEX III

Species	Common name
SNAILS	
Liguus fasciatus	Florida tree snail.
SHARKS AND RAYS	
Manta birostris, Manta alfredi, Manta sp. cf. birostris.	Manta rays.
Sphyrna lewini, Sphyrna mokarran, Sphyrna zygaena.	Hammerheads.
Carcharhinus longimanus.	Oceanic whitetip shark.
Rhincodon typus	Whale shark.
Epinephelus striatus ..	Nassau grouper.

Circumstances of SPAW STAC Recommendations

Article 11(4) of the SPAW Protocol details the requirements for amending the Annexes and states, in part, that a Party may submit a nomination of a species for inclusion in or deletion from the Annexes; that the Party shall submit supporting documentation; and that the SPAW STAC shall review the nomination. At the November 2016 meeting in Miami, Florida, the SPAW STAC reviewed the species proposed by Parties for listing under the SPAW Protocol and made recommendations to the ninth SPAW Conference of the Parties (COP9) meeting, expected to be held in March 2017. The STAC determined that the procedures for nominating species and the supporting documentation were satisfactory for positive recommendations to the COP regarding the species identified above.

Species Under the Jurisdiction of the National Marine Fisheries Service

Ten of the twelve species that were recommended by the STAC to be added to the Annexes at the November 2016 meeting fall under the jurisdiction of the National Marine Fisheries Service (NMFS). The majority of the species under NMFS' jurisdiction have been recommended to be added to Annex III and include manta rays (*Manta birostris, M. alfredi,* and *M. c.f. birostris*), hammerhead sharks (*Sphynra lewini, S. mokarran,* and *S. zygaena*), the oceanic whitetip shark (*Carcharhinus longimanus*), the whale shark (*Rhincodon typus*), and the Nassau grouper (*Epinephelus striatus*). The Nassau grouper is listed as a threatened species under the ESA. One species of fish, the smalltooth sawfish (*Pristis pectinata*), has been recommended to be added to Annex II. The smalltooth sawfish is currently listed as endangered under the ESA, and was originally listed under the ESA in 2003.

Species Under the Jurisdiction of the U.S. Fish and Wildlife Service

Two of the twelve species that were recommended by the STAC to be added to the Annexes at the November 2016 Miami meeting fall under the jurisdiction of the U.S. Fish and Wildlife Service (FWS). One bird species, the Painted bunting (*Passerina ciris*) has been recommended to be added to Annex II. One snail species, the Florida tree snail (*Liguus fasciatus*), has been recommended to be added to Annex III.

Both the Painted bunting and the Florida tree snail are terrestrial species. As explained earlier in this Notice, the United States has not designated any terrestrial area under the SPAW Protocol and the obligations under the SPAW Protocol do not apply in the United States with respect to terrestrial species. Accordingly, no obligations under the SPAW Protocol would apply to these two terrestrial species if they are added to the SPAW Annexes.

Comments Solicited

The Department of State, U.S. Fish and Wildlife Service, and National Marine Fisheries Service solicit comments and information that will inform the United States' consideration of the potential listing of these twelve species in the SPAW Annexes.

Dated: January 9, 2017.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2017–00541 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XF159

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of a public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meeting will be held on Tuesday, February 14 through Thursday, February 16, 2017. For

agenda details, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meetings will be held at: Hilton Garden Inn Kitty Hawk, 5353 N. Virginia Dare Trail, Kitty Hawk, NC 27949, telephone: (252) 261–1290.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their Web site at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

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).

Agenda

Tuesday, February 14, 2017

River Herring/Shad Committee Meeting
Discuss criteria to assess progress in river herring/shad conservation

Mackerel, Squid, and Butterfish Meeting as a Committee of the Whole
Review and approve public hearing document Squid Amendment

Law Enforcement Report

Presentation on National Marine Sanctuary Nomination Process

Wednesday, February 15, 2017

Meeting with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Boards

62nd Northeast Regional Stock Assessment Workshop (62nd SAW)
Overview of black sea bass benchmark stock assessment findings and peer review panelist findings

Black Sea Bass 2017–2019 Specifications
Overview and staff recommendation, SSC recommendation, review Monitoring Committee and Advisory Panel recommendations, and adopt recommendations for 2017–2019

Black Sea Bass Research Update

Black Sea Bass Recreational Specifications
Review Monitoring Committee and Advisory Panel recommendations, adopt recommendations for 2017 management measures, review Recreational Working Group recommendations and regional/state proposals (possible Board action)

Black Sea Bass Commercial AM Framework
Review background, issues, and draft alternatives

Summer Flounder Amendment
Update on progress and timeline

Thursday, February 16, 2017

Business Session

The day will conclude with brief reports from the National Marine Fisheries Service's GARFO and the Northeast Fisheries Science Center, NOAA's Office of General Counsel, the ASMFC, the New England and South Atlantic Fishery Council's liaisons and the Regional Planning Body Report. The Council will also receive the Council's Executive Director's Report, the Science Report, Committee Reports, and discuss any continuing and/or new business.

Although other non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal action during this meeting. 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 act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: January 10, 2017.

Jeffrey N. Lonergan,

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

[FR Doc. 2017–00737 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket Number: NOAA–HQ–2016–0145]

RIN 0648–XF137

National Environmental Policy Act Implementing Procedures and Executive Order 12114 Categorical Exclusions

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of availability.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) publishes this notice to notify the public that NOAA has finalized revisions to the agency's procedures for implementing the National Environmental Policy Act (NEPA) and related authorities, as contained in the Companion Manual to NOAA Administrative Order NAO 216–6A (Companion Manual). Included in the Companion Manual are NOAA's revised categorical exclusions (CE) and related extraordinary circumstances. This notice provides a summary of the public comments received and the agency's responses as well as a summary of changes from the draft to the final procedures. The final Companion Manual is available online at *http://www.nepa.noaa.nepa.gov.*

DATES: The revised procedures are effective January 13, 2017.

FOR FURTHER INFORMATION CONTACT: For information regarding NOAA's NEPA procedures, contact Katherine Renshaw, NOAA NEPA Coordinator, at *noaa.nepa@noaa.gov* or 301–713–7380.

SUPPLEMENTARY INFORMATION:

I. Background

On April 22, 2016, NOAA issued NOAA Administrative Order 216–6A (NAO 216–6A), which updated NOAA's policy for compliance with NEPA, the CEQ NEPA regulations, and other related authorities, including Executive Order (EO) 12114, *Environmental Effects Abroad of Major Federal Actions;* EO 11988, *Floodplain Management;* and EO 11990, *Protection of Wetlands.* The NOAA Administrative Order authorized the development of a Companion Manual entitled *Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities* (''Companion Manual''). On November, 17, 2016, NOAA published a notice in the **Federal Register** inviting public comments for a 30-day period on the draft Companion Manual, which included NOAA's revised CEs. After careful consideration of the public comments received in response to that notice, and upon further internal review, NOAA has decided to finalize the Companion Manual and CEs with some minor revisions from the November 17, 2016 draft.

II. Comments Received and NOAA's Responses

NOAA received comments from private citizens, nongovernmental organizations, states and state organizations. All substantive comments received and considered are available online at (*http://noaa.nepa.gov*), and on the *Regulations.gov* Web site (*www.regulations.gov*) at docket ID: [NOAA–HQ–2016–0145]. NOAA has considered all comments received, and

NOAA's response to the comments is contained below.

A. Comments on NOAA's NEPA Process

State commenters raised concerns regarding the process of applying NEPA to the Federal grant application process. State commenters also sought additional criteria for determining whether cumulative and secondary impacts will trigger an Environmental Assessment (EA), specifically requesting a clear flow chart on the process.

NOAA appreciates the concerns expressed by these comments and will continue to seek ways to improve coordination of environmental review requirements as we begin implementing these revised procedures.

B. Comments on Previously Analyzed Activities

State commenters requested that NOAA develop a CE that ''includes projects that have already undergone sufficient environmental review under NEPA.''

NOAA does not agree that a broad CE that would cover all such activities would be appropriate. Instead, NOAA would point the commenters to section 5 of the Companion Manual that provides guidance on how to determine whether existing NOAA NEPA documents adequately analyze the impacts of a proposed action; as well as section 6(H) that provides guidance on adopting other agency NEPA documents. We believe that the processes outlined in those sections that include factors to consider and required documentation (including, for example, the requirement that NOAA issue its own FONSI when adopting another agency EA), are the appropriate processes to use when relying on existing NEPA documents, consistent with the Council on Environmental Quality (CEQ) regulations and guidance.

C. Comments on Definitions Used in the Companion Manual and CEs

State commenters requested that NOAA provide definitions for frequently used terms including ''minor,'' ''small scale,'' ''nondestructive,'' and ''substantial.''

NOAA provided definitions for the terms ''previously disturbed ground,'' ''minor,'' ''small scale,'' and ''negligible'' in the November 17, 2016 **Federal Register** notice (81 FR 81067). In order to ensure consistent application of its procedures, NOAA determined that such definitions should be included in the Companion Manual and will add the definitions included in our initial **Federal Register** notice to the glossary at Appendix A of the Companion Manual. NOAA will also add definitions for the terms ''short term,'' ''long term,'' and ''nondestructive,'' to provide further clarity. These additional terms will be defined as follows:

Short-term—refers to a potential impact of short duration, relative to the proposed project and the environmental resource. Short-term impacts occur while the activity is underway, and do not persist once the activity ends. Noise produced by temporary construction activities is an example of a short-term impact. *Long-term*—refers to a potential impact of long duration, relative to the proposed project and the environmental resources. Long-term impacts continue after the project has ceased. Permanent impacts that remain after the construction phase of a project is an example of a long-term impact.

Nondestructive—this terms refers to actions that do not result in long term or permanent physical alteration of a component of the human environment. Passive acoustics, ground penetrating radar, and air quality sampling are examples of nondestructive methods to collect environmental data.

D. Comments on Individual CEs

A1

One commenter recommended deleting the phrase ''access to fishery resources'' from A1. The commenter notes that actions that change access to fishery resources do not necessarily result in environmental impacts when there are no changes of any of the other actions listed in the CE, *i.e.,* fishing location, timing, effort, authorized gear types, or harvest levels.

We agree, and have removed the phrase ''access to fishery resources'' from the text of CE A1.

A5

State commenters requested that NOAA modify CE A5 so as to include minor five-year updates to National Estuarine Research Reserve (NERR) management plans relative to boundary expansion based on acquisition of property for conservation purposes. The proposed A5 applies to updates to NERR management plans, provided that the update does not change NERR boundaries.

Boundary changes will involve areas that fall outside the geographic scope of the original Environmental Impact Statement (EIS) prepared pursuant to 15 CFR 921.13, and may involve potentially significant impacts to additional species or habitats that were not considered when the reserve was established. For this reason, NOAA will retain the proposed limiting language in the CE in the final procedures.

B4

One comment raised concerns with proposed CE B4. Generally, the comment expresses concern that the application of the CE will result in a failure to consider the cumulative impacts of activities authorized under that CE. Additionally, the commenter is concerned about NOAA's decision to include authorizations under both sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act (MMPA) in the same CE, arguing that doing so ignores the differences in these authorizations. The commenter finally expressed a concern that NOAA has eliminated language from the 1999 procedures that had specifically stated that ''if authorization under 101(a)(5)(A) does not tier from a programmatic environmental review, that action may require an EIS, EA, or CE, based on a case-by-case review.''

NOAA has determined that this CE, by its terms, and in light of the requirement to consider extraordinary circumstances, is appropriate and would not have the potential for significant impacts. In particular, NOAA notes that extraordinary circumstances (l) refers to ''the potential for significant cumulative impacts when the proposed action is combined with other past, present and reasonably foreseeable future actions, even though the impacts of the proposed action may not be significant by themselves.'' *See* Companion Manual for NOAA Administrative Order 216–6A at 4–5.

Additionally, the B4 CE does not ignore the differences between 101(a)(5)(A) and (D); rather it was crafted to apply to incidental take authorizations issued under either provision *if* they meet the criterion of no serious injury or mortality (and are not disqualified under the extraordinary circumstances evaluation). While it is true that criterion will be satisfied with any authorization issued under section 101(a)(5)(D), it is also true that in some cases authorizations issued under section 101(a)(5)(A) could meet that criterion as well, depending on the specified activity. Section 101(a)(5)(A) allows for authorization of take by serious injury or mortality but is not only for activities involving those effects.

Finally, NOAA notes that although language specific to the application of NEPA to the MMPA process was removed in the revised NEPA procedures, generally applicable provisions still apply to MMPA authorizations. For example, section 3 of the Companion Manual explains how, on a case-by-case basis, to

determine the proper level of NEPA analysis for an action.

One comment raises a concern that proposed CE B12 is overly broad and requests that NOAA delete the CE. As proposed, B12 would cover ''issuance of Exempted Fishing Permits (EFP) under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and Scientific Research Permits (SRP) and other permits for research that may impact species regulated under the authority of the MSA and the Atlantic Tunas Convention Act (ATCA). This includes permitted research of limited size, magnitude or duration with negligible individual or cumulative impacts, which requires temporary relief of fishery management regulations.''

NOAA has determined that this CE, by its terms, and in light of the requirement to consider extraordinary circumstances, is appropriate and would not have the potential for significant impacts. We agree, however, that as proposed, CE B12 would benefit from revision for clarity to make clear that the limitations described in the proposed category apply to all activities under the CE. NOAA will revise B12 in the following manner: ''Issuance of Exempted Fishing Permits (EFP), Scientific Research Permits (SRP), and other permits for research that may impact species regulated under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Atlantic Tunas Convention Act (ATCA). This CE is limited to permits that authorize activities of limited size, magnitude or duration, which have no potential for significant individual or cumulative impacts.''

C1

State commenters asked for several areas of clarification regarding the application of CE C1 that addresses habitat restoration activities.

The state commenters requested that NOAA either remove the CE's dredge and fill limitation, or provide additional clarity as to the application of that limitation. As proposed, C1 is limited to projects that ''[do] not require substantial placement of fill or dredging.''

NOAA believes that the limitation of the CE with respect to dredging and placement of fill is appropriate and notes that its application will be context dependent. When considering whether placement of fill or dredging are ''substantial,'' NOAA will consider the volume of the fill to be placed, as well as the context in which it would occur to determine that the placement will not have the potential to cause significant environmental impacts. Thus, NOAA is not proposing any modifications to this CE to address this issue.

Additionally, the states requested that NOAA further limit covered habitat restoration actions to those that transplant only native species. The proposed C1 language would limit actions to those that ''transplant'' only organisms currently or formerly present at the site or in its immediate vicinity (if transplant is a component of the action). The states expressed concern that without limiting transplant to native species that such actions may result in impacts from exotic invasive species.

NOAA has determined that this CE, by its terms, and in light of the requirement to consider extraordinary circumstances, is appropriate and would not have the potential for significant impacts. In particular, NOAA notes that extraordinary circumstance (j) refers to the ''contribution to the introduction, continued existence, or spread of noxious weeds or non-native invasive species known to occur in the area or actions that may promote the introduction, growth, or expansion of the range of the species.'' *See* Companion Manual for NOAA Administrative Order 216–6A at 4–5. Accordingly, if a proposed action to transplant organisms has the potential to result in significant impacts due to the potential spread of exotic invasive species, such an action may require additional analysis.

Finally, the states requested further guidance as to the applicability of C1 to various restoration activities such as living shoreline construction, routine terrestrial restoration activities, and stocking fish and associated activities.

As noted in Appendix E, the examples provided with the CEs are intended to be illustrative, but not exhaustive. Thus, omission of a particular activity does not mean that such activity could not potentially be covered by the CE. In reviewing whether an activity, such as a living shoreline construction project would be potentially included within C1, NOAA would consider the particular elements of that project to determine whether the proposed action fits within the limits of the CE.

F3

State commenters requested clarification as to whether CE F3 applies to the restoration or repair of buildings of cultural or historic significance. Additionally, state commenters sought clarification as to whether the CE applies to small-scale construction of boat ramps, fishing piers, and observation platforms. Commenters note that limitations in F3(b), such as F3(b)(3) that would preclude proposed uses of newly constructed facilities that will substantially increase the number of marine vessels in the area would potentially preclude application to the construction of public access facilities such as boat ramps. Finally, one commenter questioned how NOAA will determine viewshed impacts.

NOAA's extraordinary circumstance (e) would require evaluation of whether a proposed activity would involve adverse effects on properties listed or eligible for listing on the National Register of Historic Places authorized by the National Historic Preservation Act of 1966, National Historic Landmarks designated by the Secretary of the Interior, or National Monuments designated through the Antiquities Act of 1906; Federally recognized tribal and Native Alaskan lands, cultural or natural resources, or religious or cultural sites that cannot be resolved through applicable regulatory processes. *See* Companion Manual for NOAA Administrative Order 216–6A at 4–5.

With respect to the construction of public access facilities, NOAA notes that such activities are covered explicitly under F3(c), and not F3(b). Thus, the limitations that the commenters are concerned with would not be applicable to the construction of public access facilities such as boat ramps, docks, or observation platforms. Those projects are potentially allowable under the CE so long as the proposed activity is (1) small-scale and nondestructive; and (2) is consistent with applicable right-of-way conditions and approved land use plans. NOAA notes that there is a typographical error in the proposed CE that included an ''and'' following F3(c)(2), which may be confusing, and has corrected that error.

As discussed above, NOAA is adding several additional definitions to the handbook, including ''nondestructive.'' NOAA does not believe that it is necessary to make any modifications to the CE to exempt small scale construction of public access facilities such as boat ramps, fishing piers, and observation platforms as such activities are explicitly covered by F3(c), and included as examples of activities covered by the CE. As described in our definitions section, we believe that it is appropriate to define small scale relative to the potential impacts of the project, rather than with respect to the funding level involved.

Finally, with respect to viewshed impact evaluation, NOAA's staff will rely upon their professional expertise

and standard practices and procedures to evaluate potential impacts to viewsheds. Viewshed analysis, through the use of GIS technology, is commonly used by researchers and natural resource managers to assess potential visual impacts of development.

F4

State commenters request that NOAA clarify whether routine grounds keeping and landscaping would include native landscaping installation or rain gardens and other storm water Best Management Practices.

As discussed above, when determining whether a particular proposed action would be potentially included within a CE, NOAA will consider the particular elements of the project to determine its eligibility. NOAA does note however, that activities that involve improvements of real property may be better categorized under CE F3.

G1

State commenters request clarification as to whether CE G1 applies to the development of community development plans, vulnerability assessments, erosion management plans, feasibility studies, and engineering/design plans for restoration projects.

G1 includes routine administrative actions such as development, establishment, and revisions to documents including, but not limited to interagency agreements, memoranda of understanding, memoranda of agreement, cooperative agreements and university agreements. As noted in Appendix E, the examples provided with the CEs are intended to be illustrative, but not exhaustive. Thus, omission of a particular activity does not mean that such activity could not potentially be covered by the CE. NOAA will evaluate proposed actions on a case-by-case basis to determine whether they are appropriately addressed by the CE.

H4

State commenters request clarification as to whether the acquisition of land intended for habitat restoration, including removal of invasive plant species or off-site native plants/trees would be included within CE H4. Commenters additionally request the development of a new CE to explicitly cover tree removal activities.

CE H4 applies to the acquisition of real property that is not acquired through condemnation of a lease interest, and will not result in significant change in use and does involve construction or modification. Accordingly, so long as the acquisition is done in accordance with the terms of the CE, and upon review by NOAA's NEPA professional staff, acquisition of land intended for habitat restoration may potentially be covered. NOAA notes that one of the examples provided of activities covered by the CE includes funding for land acquisition under the Coastal Zone Management Act (CZMA) and Fish and Wildlife Conservation Act (FWCA)to purchase land (submerged or not submerged) or interests in land that includes but is not limited to conservation easements, for purposes that do not involve construction or modification.

With respect to the request for the development of an additional CE to specifically cover tree removal, NOAA does not currently have the experience to support expanding the CE to include such projects, but this may change as NOAA gains experience over time.

III. Additional Changes to Companion Manual and Categorical Exclusions

In addition to revisions to CEs based on its consideration of public comments, NOAA further reviewed the proposed CEs and determined that certain CEs would benefit from revisions that clarified the scope and applicability of the CE, specifically the limitations described in the text of the CE to ensure it is only applied to activities with no potential for significant effects on the environment under normal circumstances. Internal discussions also resulted in many instances in the addition or revision of examples provided for the CEs for the benefit of NOAA NEPA practitioners. Additionally, NOAA identified typographical and grammatical errors and corrected those errors. This section explains the substantive revisions NOAA made to its proposed CEs and the rationale for those revisions.

E3

NOAA is adding two additional examples of activities that fit within this category: ''use of mobile platforms (*e.g.,* ships, aircraft, balloons, vehicles) to study biological, chemical, or physical processes;'' and ''collection of cultural and environmental data to find and assess archaeological resources.''

E4

NOAA has made minor modifications to the text of E4 following internal discussions with subject matter experts in order to ensure that the category of activities is sufficiently limited. The revised text is as follows: ''Activities that remotely survey or observe living resources in the field using non-invasive techniques, which have little to no potential to adversely affect the environment or interfere with organisms or habitat.'' NOAA has also slightly modified one of the examples provided to make clear that electronic monitoring activities under this category are limited to deployment of non animal-borne devices.

E5

NOAA has made minor modifications to the text of E5 following internal discussions with subject matter experts in order to ensure that the category of activities is sufficiently limited. The revised text is as follows: ''Activities involving invasive techniques or methods that are conducted for scientific purposes, when such activities are conducted in accordance with all applicable provisions of the Endangered Species Act, Marine Mammal Protection Act, Migratory Bird Treaty Act, and Magnuson-Stevens Fishery Conservation and Management Act. Such activities will be limited to impacting living resources on a small scale relative to the size of their populations, and limited to methodologies and locations to ensure that there are no long-term, adverse ecosystem impacts.''

E6

NOAA made a minor modification to the text of E6 to improve internal consistency. The text of the revised CE is as follows: ''Research that involves the development and testing of new and modified fishing gear and technology in order to reduce adverse effects from fishing gear on non-target species, and is limited in size, magnitude or duration with no potential for significant individual or cumulative impacts.''

E7

Based on internal discussions on proposed CE E7, NOAA has revised the text of the CE to remove the references to fishing vessels and dockside as locations for the collection of data and biological samples. These terms were intended to be broad and to encompass any number of locations, including, for example, on fishing vessels, on motherships, in processing plants, dockside, and shoreside. However, that broad scope might not have been obvious to readers on the face of the proposed CE, and including the terms ''fishing vessels'' and ''dockside'' may have unintentionally suggested a narrower scope than what was intended. Therefore, we are removing those terms from the text of the CE and leaving the CE to broadly encompass data and biological samples collected as part of

previously authorized commercial and/or recreational fishing activities. This change does not change the intended scope of the proposed CE, but only makes the scope of the CE clearer for users and the public. In addition, we have revised the first example under this CE to add ''Collecting data from'' before ''observer coverage onboard commercial and recreational fishing vessels.'' This change is being made to make it more explicit that the example is referring only to the collection of data through previously authorized observer coverage, and nothing else related to observer coverage. This CE does not cover observer coverage requirements onboard commercial or recreational fishing vessels, which are generally addressed through fishery management plans or regulations for the fishery for which observer coverage is being implemented.

E8

NOAA made a minor modification to the text of E8 following internal discussions with subject matter experts to ensure that the scope of the CE correctly described the activities undertaken and funded by NOAA. The text of the revised CE is as follows: ''Biological, chemical, food production, ecological, or toxicological research conducted in closed system mesocosm/aquaculture facilities that are conducted according to recommended protocols that provide containment and disposal of waste, chemicals, toxins, non-native species, etc., in compliance with established Federal and state regulatory guidelines, and best management practices.''

IV. NOAA Categorical Exclusions

The following series of CEs includes actions that may be implemented either directly by NOAA or by the recipient of a financial assistance award. The activities contemplated in the series of CEs have been evaluated and found not to have individual or cumulative significant impacts on the human environment, whether implemented by a grantee through a financial assistance award or directly implemented by NOAA. These CEs can be found as appendix E to the Companion Manual, along with illustrative examples for many of the categories.

Trust Resource Management Actions

[A1]. ''An action that is a technical correction or a change to a fishery management action or regulation, which does not result in a substantial change in any of the following: fishing location, timing, effort, authorized gear types, or harvest levels.''

[A2]. ''Preparation of a recovery plan pursuant to section 4(f)(1) of the ESA. Such plans are advisory documents that provide consultative and technical assistance in recovery planning and do not implement site-specific or species-specific management actions. However, implementation of specific tasks identified in a recovery plan may require an EA or EIS depending on the nature of the action.''

[A3.] ''Temporary fishery closures or extensions of closures under Section 305(c)(3)(C) of the Magnuson-Stevens Fishery Conservation and Management Act to ensure public health and safety.''

[A4.] ''Minor updates to existing national marine sanctuary management plans. This CE does not apply to sanctuary designations, expansions, changes in terms of designation, or new sanctuary management plans.''

[A5.] ''Updates to existing National Estuarine Research Reserve (NERR) management plans, provided that the update does not change NERR boundaries or add or significantly change allowable uses, uses requiring a permit, or restrictions on uses. This CE does not apply to new NERR management plans, or to the execution of any specific action subsequently funded to support the updated NERR management plan.''

[A6.] ''Review and approval of changes to state coastal management programs under the Coastal Zone Management Act (CZMA) § 306(e) (16 U.S.C. 1455(e)) and NOAA's regulations at 15 CFR part 923.''

Trust Resource Authorization and Permitting Actions

[B1.] ''Issuance of permits or permit modifications under section 10(a)(1)(A) of the ESA for take, import, or export of endangered species for scientific purposes or to enhance the propagation or survival of the affected species, or in accordance with the requirements of an ESA section 4(d) regulation for threatened species.''

[B2.] ''Issuance of permits or permit amendments under section 104 of the MMPA for take or import of marine mammals for scientific research, enhancement, commercial or educational photography or public display purposes; and issuance of Letters of Confirmation under the General Authorization for scientific research involving only Level B harassment.''

[B3.] ''Issuance of, and amendments to, ''low effect'' Incidental Take Permits and their supporting ''low effect'' Habitat Conservation Plans under section 10(a)(1)(B) of the ESA.''

[B4.] ''Issuance of incidental harassment authorizations under section 101(a)(5)(A) and (D) of the MMPA for the incidental, but not intentional, take by harassment of marine mammals during specified activities and for which no serious injury or mortality is anticipated.''

[B5.] ''Issuance of, or amendments to, general permits for activities that are included in established permit categories at 15 CFR pt. 922 and that meet the regulatory review criteria at 15 CFR pt. 922, that limit any potential impacts so that the proposed activity will be conducted in a manner compatible with the National Marine Sanctuaries Act's primary objective of resource protection.''

[B6.] ''Issuance of, or amendments to, special use permits for activities in a national marine sanctuary that are necessary to either establish conditions of access to and use of any sanctuary resource or promote public use and understanding of a sanctuary resource and must be conducted in a manner that does not destroy, cause the loss of, or injure sanctuary resources in accordance with the National Marine Sanctuaries Act.''

[B7.] ''Issuance of or amendments to, authorizations for activities allowed by a valid federal, regional, state, local or tribal government approval (*e.g.,* leases, permits and licenses) issued after the effective date of sanctuary designation or expansion, so long as such authorizations are based upon a consideration of the regulatory review criteria at 15 CFR pt. 922, and will only result in negligible effects to sanctuary resources.''

[B8.] ''Issuance of, or amendments to certifications for pre-existing activities authorized by a valid federal, regional, state, local, or tribal government approval (*e.g.,* leases, permits and licenses) or rights of subsistence use or access in existence on the date of the designation or expansion of any national marine sanctuary where the Office of National Marine Sanctuaries issues terms and conditions that are either ministerial or prescribe avoidance, minimization, or mitigation measures designed to ensure negligible effects to sanctuary resources.''

[B9.] ''Issuance of, or amendments to Papahānaumokuākea Marine National Monument (as originally established by Presidential Proclamation 8031 and named Papahānaumokuākea Marine National Monument by Presidential Proclamation 8112) permits for activities that are included in established permit categories (50 CFR pt. 404) and that meet the regulatory review criteria at (50 CFR 404.11), that

limit any potential impacts so that the proposed activity will be conducted in a manner compatible with the monument's primary objective of resource protection.''

[B10.] ''Issuance of, or amendments to, Papahānaumokuākea Marine National Monument special ocean use permits for activities or use of the monument that are engaged in to generate revenue or profits for one or more of the persons associated with the activity or use, and do not destroy, cause the loss of, or injure monument resources.''

[B11.] ''Issuance of, or amendments to permits or authorizations for activities that are conducted within Marine National Monuments other than Papahānaumokuākea that are limited in scope so that the potential impacts of the proposed activities will be conducted in a manner compatible with a monument's primary objective of resource protection, and do not destroy, cause the loss of, or injure monument resources.''

[B12.] ''Issuance of Exempted Fishing Permits (EFPs), Scientific Research Permits (SRPs), and other permits for research that may impact species under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Atlantic Tunas Convention Act (ATCA). This CE is limited to permits that authorize activities that are limited in size, magnitude or duration with no potential for significant individual or cumulative impacts.''

Habitat Restoration Actions

[C1.] ''Habitat restoration actions, provided that such action: (1) transplants only organisms currently or formerly present at the site or in its immediate vicinity (if transplant is a component of the action); (2) does not require substantial placement of fill or dredging; (3) does not involve any removal of debris, excavation, or conditioning of soils unless such removal of debris, excavation, or conditioning of soils is geographically limited to the impact area such that site conditions will not impede or negatively alter natural processes, is in compliance with all permit and disposal requirements,), and will not impact critical aquifers or recharge areas; and (4) does not involve an added risk of human or environmental exposure to toxic or hazardous substances, pathogens, or radioactive materials.

Notes: If applicable, limitations and mitigation measures identified in the NOAA Restoration Center Programmatic Environmental Impact Statement for Habitat Restoration Actions must be followed. This CE includes, but is not limited to, response or restoration actions under CERLCA, OPA, or NMSA, if such actions help to restore an ecosystem, habitat, biotic community, or population of living resources to a determinable preimpact condition prior to the incident leading to the response or restoration.''

Additional External Funding

[D1.] ''Financial activities for the following financial services: (1) Loans for purchase, refinancing, or reconstruction of fishing vessels and purchase or refinancing of individual fishing quota through the Fisheries Finance Program; (2) Deferred tax program provided to fishermen to construct, reconstruct, or acquire fishing vessels through the Capital Construction Fund Program; and (3) Compensation to fishermen for economic and property losses caused by oil and gas obstructions on the U.S. Outer Continental Shelf under the Fishermen's Contingency Fund.''

[D2.] ''Provision of a grant, a contract or other financial assistance to a State, Fishery Management Council or Marine Fisheries Commission under 16 U.S.C. 1881a(d).''

Research Actions

[E1.] ''Activities conducted in laboratories and facilities where research practices and safeguards prevent environmental impacts.''

[E2.] ''Social science projects and programs, including economic, political science, human geography, demography, and sociology studies, including information collection activities in support of studies.''

[E3.] ''Activities to collect aquatic, terrestrial, and atmospheric data in a non-destructive manner.''

[E4.] ''Activities that remotely survey or observe living resources in the field using non-invasive techniques, which have little to no potential to adversely affect the environment or interfere with organisms or habitat.''

[E5.] ''Activities involving invasive techniques or methods that are conducted for scientific purposes, when such activities are conducted in accordance with all applicable provisions of the Endangered Species Act, Marine Mammal Protection Act, Migratory Bird Treaty Act, and Magnuson-Stevens Fishery Conservation and Management Act. Such activities will be limited to impacting living resources on a small scale relative to the size of their populations, and limited to methodologies and locations to ensure that there are no long-term adverse ecosystem impacts.''

[E6.] ''Research that involves the development and testing of new and modified fishing gear and technology in order to reduce adverse effects from fishing gear on non-target species, and is limited in size, magnitude, or duration with no potential for significant individual or cumulative impacts.''

[E7.] ''Collection of data and biological samples as part of previously authorized commercial and/or recreational fishing activities.''

[E8.] ''Biological, chemical, food production, ecological, or toxicological research conducted in closed system mesocosm/aquaculture facilities that are conducted according to recommended protocols that provide containment and disposal of waste, chemicals, toxins, non-native species, etc., in compliance with established Federal and state regulatory guidelines, and best management practices.''

Real and Personal Property Improvement, Maintenance, and Construction Actions

[F1.] ''Siting, construction (or modification), and operation of support buildings and support structures (including, but not limited to, trailers and prefabricated buildings) within or contiguous to an already developed area (where active utilities and currently used roads are readily accessible).''

[F2.] ''In-kind replacement of personal property and fixtures and other components of real property when such activities do not result in a substantial change in the existing construction footprint. In-kind replacement includes installation of new components to replace outmoded components if the replacement does not result in a substantial change to the design capacity, or function of the facility.''

[F3.] ''(a) Routine repair, maintenance, and improvement of real and personal property, where such activities are required to maintain and preserve buildings, structures, infrastructures, vehicles, and equipment in a condition suitable to be used for its designed purpose.

(b) New construction, expansion and/or improvement of facilities where all of the following conditions are met:

(1) The site is in a developed area and/or a previously disturbed site;

(2) The structure and proposed use are compatible with applicable Federal, Tribal, State, and local planning and zoning standards and consistent with Federally approved State coastal management programs and the National Historic Preservation Act;

(3) The proposed use will not substantially increase the number of motor vehicles, marine vessels, or aircraft at the facility or in the area;

(4) The site and scale of construction or improvement are consistent with those of existing, adjacent, or nearby buildings;

(5) The construction or improvement will not result in uses that exceed existing infrastructure capacities (*e.g.,* electrical, roads, sewer, water, parking);

(6) The construction or improvement will not result in operational uses that adversely affect the surrounding community (*e.g.,* noise); and

(7) The community-valued view sheds are not adversely affected.

(c) Installation, repair, maintenance, and enhancement of public access facilities and infrastructure, if the activity:

(1) Is small-scale and nondestructive; and

(2) Is consistent with applicable right-of-way conditions and approved land use plans.''

[F4]. ''Routine groundskeeping and landscaping activities where ground disturbance is limited to previously disturbed areas (*e.g.,* previously filled paved, or cleared areas).''

[F5.] ''Installation, operation, maintenance, improvements, repair, upgrade, removal, and/or replacement of instruments or instrument systems in or on:

1. An existing structure or object (*e.g.,* tower, antenna, building, pier, buoy, terrestrial vehicle, or bridge) or

2. on previously disturbed (*e.g.,* filled, paved, or cleared) ground, or

3. on undisturbed ground, if the equipment installation, operation, and removal will require no or minimal ground disturbance.''

Microwave/radio communications towers and antennas must be limited to 200 feet in height without guy wires. NOAA proposes a new CE to cover activities of installing, operating, repairing, maintaining, upgrading, removing and/or replacing instruments or instrument systems in or on an existing structure or object, or on previously disturbed ground or on undisturbed ground that involve either no or minimal ground disturbance.

[F6.] ''The determination that real property is excess to the needs of the Agency, when the real property is excessed in conformity with General Services Administration procedures or is legislatively authorized to be excessed.''

[F7.] ''The disposal, demolition or removal of real property and related improvements, buildings and structures, including associated site restoration, and the disposal of personal property and debris in accordance with all applicable agency procedures and legal requirements.''

Operational Actions

[G1.] ''Routine administrative actions such as (1) program planning, direction and evaluation, (2) administrative tasks, services and support including personnel and fiscal management, advisory services, document and policy preparation, and records management, and (3) development, establishment, and revisions to documents including, but not limited to interagency agreements, memoranda of understanding, memoranda of agreement, cooperative agreements, and university agreements. This CE does not include any associated activities proposed in these documents beyond the administrative task of creating and establishing the document. Actions subsequently funded by or undertaken pursuant to the approved documents may require additional NEPA review at the time those actions are proposed.''

[G2.] ''Routine movement of mobile assets, such as vessels and aircraft, for homeport reassignments or repair/overhaul, where no new support facilities are required.''

[G3.] ''Topographic, bathymetric, land use and land cover, geological, hydrologic mapping, charting, and surveying services that do not involve major surface or subsurface land disturbance and involve no permanent physical, chemical, or biological change to the environment.''

[G4.] ''Basic environmental services and monitoring, such as weather observations, communications, analyses, and predictions; environmental satellite operations and services; digital and physical environmental data and information services; air and water quality observations and analysis, and IT operations. All such activities must be conducted within existing facilities.''

[G5.] ''Enforcement operations conducted under legislative mandate such as the MSA, ESA, MMPA, the Lacey Act Amendments of 1981 (Lacey), and/or the National Marine Sanctuaries Act. This does not include bringing judicial or administrative civil or criminal enforcement actions which are outside the scope of NEPA in accordance with 40 CFR 1508.18(a).''

[G6.] ''Actions that change the NEXRAD radar coverage patterns that do not lower the lowest scan elevation and do not result in direct scanning of previously non-scanned terrain by the NEXRAD main beam.''

[G7.] ''Preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature, or for which the environmental effects are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or on a case-by-case basis.''

[G8.] ''Activities that are educational, informational, or advisory to other agencies, public and private entities, visitors, individuals, or the general public, including training exercises and simulations.''

[G9.] ''Actions taken to identify, determine sources of, assess, prevent, reduce, remove, dispose, or recycle marine debris when removal is undertaken in a non-destructive manner and actions are in accordance with Federal, State, and local laws and regulations for environmental protection, and where all relevant regulatory consultation, and/or permit requirements have been satisfied.''

Acquisition and Real Property Actions

[H1.] ''Procurement of labor, equipment, materials, data and software needed to execute mission requirements in accordance with applicable procurement regulations, executive orders, and policies. This includes, but is not limited to, procurement of mobile and portable equipment that is stored in existing structures or facilities.''

[H2.] ''Procurement of space by purchase or lease of or within an existing facility or structure in accordance with applicable procurement regulations, executive orders, and policies when there is no change in the general type of use, no new construction of buildings or utilities, and minimal change in design from the previous occupancy level.''

[H3.] ''Outgranting of government-controlled property in accordance with applicable regulations, executive orders, and policies to a Federal entity for any purpose consistent with the existing land or facility use or to a non-Federal entity, when the use will remain substantially the same.''

[H4.] ''Acquisition of real property (including fee simple estates, leaseholds, and easements) that is not acquired through condemnation of a lease interest, and will not result in significant change in use and does not involve construction or modification.''

[H5.] ''Granting easements or rights of entry to use NOAA controlled property for activities that, if conducted by NOAA, could be categorically excluded. Grants of easements or rights-of-way for the use of NOAA controlled real

property complementing the use of existing rights-of-way or real property use for use by vehicles (not to include significant increases in vehicle loading); electrical, telephone, and other transmission and communication lines; water, wastewater, stormwater, and irrigation pipelines, pumping stations, and facilities; and similar utility and transportation uses.''

[H6.] ''Relocation of employees into existing Federally-owned or commercially leased office space within the same metropolitan area not involving a substantial increase in the number of motor or other vehicles at a facility.''

[H7.] ''Transferring real property to a non-Federal entity, an agency other than GSA, as well as to States, local agencies and Indian Tribes, including return of public domain lands to the Department of the Interior.''

Dated: January 6, 2017.

Lois J. Schiffer,

General Counsel for the National Oceanic and Atmospheric Administration.

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DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 170105023–7023–01]

RIN 0660–XC033

The Benefits, Challenges, and Potential Roles for the Government in Fostering the Advancement of the Internet of Things

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice, request for public comment.

SUMMARY: Recognizing the vital importance of the Internet to U.S. innovation, prosperity, education, and civic and cultural life, the Department of Commerce (Department) has made it a top priority to encourage growth of the digital economy and ensure that the Internet remains an open platform for innovation. Thus, as part of the Department's Digital Economy Agenda, the National Telecommunications and Information Administration (NTIA) issued a green paper ''Fostering the Advancement of the Internet of Things'' that lays out an approach and areas of engagement for the Department's possible future work on the Internet of Things (IoT). Through this Notice, NTIA seeks broad input from all interested stakeholders—including the private industry, researchers, academia, and civil society—on the issues and proposed approach, current initiatives, and next steps laid out in this paper. These comments will help inform Department leadership on possible future Department action regarding IoT.

DATES: Comments are due on or before 5 p.m. Eastern Time on February 27, 2017.

ADDRESSES: Written comments may be submitted by email to *iotrfc2017@ntia.doc.gov.* Comments submitted by email should be machine-readable and should not be copy-protected. Written comments also may be submitted by mail to the National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Attn: IOT RFC 2017, Washington, DC 20230. Responders should include the name of the person or organization filing the comment, as well as a page number on each page of their submissions. All comments received are a part of the public record and will generally be posted on the NTIA Web site, *http://www.ntia.doc.gov/,* without change. All personal identifying information (for example, name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NTIA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: Travis Hall, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone (202) 482–3522; email *thall@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002, or at *press@ntia.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background: As part of the Department's Digital Economy Agenda, the National Telecommunications and Information Administration (NTIA) is requesting comment on the benefits, challenges, and potential roles for the government in fostering the advancement of the Internet of Things (IoT).

The Internet of Things—in which connected devices are proliferating at an unprecedented rate—is transforming the way we live and do business. IoT continues the decades-long trend of increasing connectivity among devices and the Internet, bringing online everything from refrigerators to automobiles to factory inventory systems. At the same time, IoT encompasses a widening scope of industries and activities and a vastly increasing scale and number of devices being connected, thus raising the stakes and impacts of broad connectivity. Due to its expertise and experience with the issues raised by IoT, as well as its economy-wide perspective, the Department is well placed to meet the challenges of IoT and to champion the development of a robust IoT environment that benefits consumers, the economy, and society as a whole.

With an April 2016 Request for Comment, ''The Benefits, Challenges, and Potential Roles for the Government in Fostering the Advancement of the Internet of Things,'' the Department sought to review the current technological and policy landscape relating to IoT.[1] A broad array of stakeholders—from the private sector, academia, government, and civil society—offered perspectives in response to the request.[2] In September 2016, the Department hosted a workshop to delve deeper into the questions raised by the Request for Comment, and to explore some of the related issues arising from the public comments.[3] The Department issued a green paper entitled ''Fostering the Advancement of the Internet of Things,'' which represents the Department's analysis of those comments.[4] The green paper also identifies key issues that can impact the deployment of IoT technologies, highlights potential benefits and challenges, and discusses what role, if any, the U.S. Government, particularly the Department, should play in this evolving landscape. With this Request for Comment, the Department is asking for a response to the issues raised by the green paper, as well as the proposed approach, current initiatives, and next steps.

[1] *Request for Comments on the Benefits, Challenges, and Potential Roles for the Government in Fostering the Advancement of the Internet of Things,* 81 FR 19956 (April 16, 2016), *available at https://ntia.doc.gov/federal-register-notice/2016/rfc-potential-roles-government-fostering-advancement-internet-of-things.*

[2] All comments are publicly available at: *https://ntia.doc.gov/federal-register-notice/2016/comments-potential-roles-government-fostering-advancement-internet-of-things.*

[3] ''Fostering the Advancement of the Internet of Things Workshop Webcast,'' September 1, 2016, *available at https://ntia.doc.gov/other-publication/2016/09012016-fostering-advancement-internet-things-workshop-webcast* (In addition to the webcast, also available are the Workshop agenda, transcript, and various presentations).

[4] The IOT green paper is available at: *https://www.ntia.doc.gov/other-publication/2017/green-paper-fostering-advancement-internet-things.*

Request for Comment

Instructions for Commenters: The Department invites comment on the full range of issues that may be presented by this inquiry, including issues that are not specifically raised in the following questions. Commenters are encouraged to address any or all of the following questions. Comments that contain references to studies, research, and other empirical data that are not widely published should include copies of the referenced materials with the submitted comments.

(1) Is our discussion of IoT presented in the green paper regarding the challenges, benefits, and potential role of government accurate and/or complete? Are there issues that we missed, or that we need to reconsider?

(2) Is the approach for Departmental action to advance the Internet of Things comprehensive in the areas of engagement? Where does the approach need improvement?

(3) Are there specific tasks that the Department should engage in that are not covered by the approach?

(4) What should the next steps be for the Department in fostering the advancement of IoT?

For any response, commenters may wish to consider describing specific goals or actions that the Department, or the U.S. Government in general, might take (on its own or in conjunction with the private sector) to achieve those goals; the benefits and costs associated with the action; whether the proposal is agency-specific or interagency; the rationale and evidence to support it; and the roles of other stakeholders.

Dated: January 10, 2017.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2017–00720 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2016–0046]

Reopening of the Period for Comments on a Preliminary Draft Convention on the Recognition and Enforcement of Foreign Judgments Currently Being Negotiated at The Hague Conference on Private International Law

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Reopening of the comment period.

SUMMARY: The United States Patent and Trademark Office is publishing this notice to reopen the comment period provided in its notice of November 18, 2016, entitled Request for Comments and Notice of Public Meeting on a Preliminary Draft Convention on the Recognition and Enforcement of Foreign Judgments Currently Being Negotiated at the Hague Conference on Private International Law. The new deadline for public comments is January 18, 2017.

DATES: *Written Comments:* Written comments must be received on or before January 18, 2017.

ADDRESSES: *Written Comments:* Interested parties are encouraged to file written comments electronically by email to *judgmentsproject@uspto.gov.* Comments submitted by email should be machine-searchable and should not be copy-protected. Written comments also may be submitted by mail to the Office of Policy and International Affairs, United States Patent and Trademark Office, Mail Stop International Affairs, P.O. Box 1450, Alexandria, Virginia 22313–1450. Responders should include the name of the person or organization filing the comment, as well as a page number, on each page of their submissions. Paper submissions should also include a CD or DVD containing the submission in MS Word®, WordPerfect®, or pdf format. CDs or DVDs should be labeled with the name and organizational affiliation of the filer, and the name of the word processing program used to create the document. All personally identifiable information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. The USPTO will accept anonymous written comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

All comments received are part of the public record and will be available for public inspection without change via the USPTO's Web site at *www.uspto.gov/learning-and-resources/ip-policy/hague-conference-private-international-law* and at the Office of the Director, Policy and International Affairs, located in Madison West, Tenth Floor, 600 Dulany Street, Alexandria, Virginia 22314, upon request. Because comments will be available for public inspection, information that is not desired to be made public, such as name, an address or phone number, etc., should not be included in the written comments.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the attention of Michael Shapiro, Senior Counsel, Office of Policy and International Affairs, USPTO, by telephone at 571–272–9300, or by email to *judgmentsproject@uspto.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Hague Conference on Private International Law (''The Hague Conference''), an international organization in the Netherlands, is sponsoring negotiations for a convention on the recognition and enforcement of foreign judgments in civil and commercial matters. In February 2016, the Council on General Affairs and Policy of The Hague Conference created a Special Commission on the Recognition and Enforcement of Foreign Judgments (''the Special Commission'') to prepare a preliminary draft text of the convention, which is subject to a formal diplomatic negotiation open to member States of The Hague Conference. At its first session in June 2016, the Special Commission produced a Preliminary Draft Convention that includes general and specific provisions that would apply to the recognition and enforcement of judgments arising from transnational intellectual property disputes.

On November 18, 2016, the United States Patent and Trademark Office (USPTO) requested public comments on the June 2016 Preliminary Draft Convention (the ''Preliminary Draft'') as it relates to intellectual property matters (81 FR 81741 (Nov. 18, 2016)), with the comment period ending on January 9, 2017. The USPTO is now reopening the comment period to ensure that all stakeholders have sufficient opportunity to submit comments. The new deadline for submitting public comments is January 18, 2017. Any comments received between the close of the previous deadline of January 9, 2017, and January 13, 2017 will be treated as timely and given full consideration.

Further information about the Preliminary Draft, as well as questions about the draft that the USPTO presented for consideration, are set forth in the earlier notice requesting comments (81 FR 81741 (Nov, 18, 2016)).

Dated: January 9, 2017.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2017–00671 Filed 1–12–17; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the procurement list.

SUMMARY: The Committee is proposing to add 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 previously furnished by such agencies.

DATES: Comments must be received on or before: 2/12/2017.

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 and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN(s)—Product Name(s): 8920–00–SAM–0169—Super Cereal Plus
Mandatory Source(s) of Supply: Transylvania Vocational Services, Inc., Brevard, NC
Mandatory for: An additional 10% of the requirement of the U.S. Agency for International Development's World Food Program, as aggregated by the USDA Farm Service Agency, IPD Packaged, Kansas City, MO. Total requirement on the U.S. AbilityOne Commission Procurement List will be 30%.
Contracting Activity: USDA, Farm Service Agency, IPD Packaged
Distribution: C-List

NSN(s)—Product Name(s):
7510–00–NIB–0823—Tab, Self-Stick, Durable, 1″, Assorted Colors
7510–00–NIB–0824—Tabs, Self-Stick, Filing, Repositionable, 2″, Red/Yellow
7510–01–421–4751—Tabs, Self-Stick, Page Makers Repositionable, .5″ x 2″, Assorted Colors
Mandatory Source(s) of Supply: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY
Mandatory for: Total Government Requirement
Contracting Activity: General Services Administration, New York, NY
Distribution: A-List

NSN(s)—Product Name(s):
6530–00–NIB–0209—Hot Pack, Instant, Disposable, 6″ x 8″
6530–00–NIB–0217—Cold Pack, Instant, Disposable, 5″ x 6″
6530–00–NIB–0219—Cold Pack, Instant, Disposable, 5″ x 7″
6530–00–NIB–0221—Cold Pack, Instant, Disposable, 6″ x 8.75″
6530–00–NIB–0222—Hot Pack, Instant, Disposable, 5″ x 6″
6530–00–NIB–0223—Hot Pack, Instant, Disposable, 5″ x 7″
Mandatory Source(s) of Supply: Central Association for the Blind & Visually Impaired, Utica, NY
Mandatory for: Total Government Requirement
Contracting Activity: Defense Logistics Agency Troop Support
Distribution: B-List

NSN(s)—Product Name(s):
9905–00–NIB–0376—Flag, Marking, 2–½″ x 3–½″, 21″ Staff, Fluorescent Orange
9905–00–NIB–0377—Flag, Marking, 2–½″ x 3–½″, 21″ Staff, Fluorescent Pink
9905–00–NIB–0378—Flag, Marking, 2–½″ x 3–½″, 21″ Staff, Orange
9905–00–NIB–0379—Flag, Marking, 2–½″ x 3–½″, 21″ Staff, Red
9905–00–NIB–0380—Flag, Marking, 2–½″ x 3–½″, 21″ Staff, Yellow
9905–00–NIB–0384—Flag, Marking, 2–½″ x 3–½″, 15″ Staff, Yellow
9905–00–NIB–0386—Flag, Marking, 2–½″ x 3–½″, 15″ Staff, Red
9905–00–NIB–0387—Flag, Marking, 2–½″ x 3–½″, 15″ Staff, Orange
9905–00–NIB–0389—Flag, Marking, 4″ x 5″, 21″ Staff, Fluorescent Orange
9905–00–NIB–0390—Flag, Marking, 4″ x 5″ 21″ Staff, Fluorescent Pink
9905–00–NIB–0392—Flag, Marking, 4″ x 5″, 21″ Staff, Red
9905–00–NIB–0393—Flag, Marking, 4″ x 5″ 21″ Staff, Yellow
9905–00–NIB–0391—Flag, Marking, 4″ x 5″, 21″ Staff, Orange
Mandatory Source(s) of Supply: West Texas Lighthouse for the Blind, San Angelo, TX
Mandatory for: Total Government Requirement
Contracting Activity: General Services Administration, Fort Worth, TX
Distribution: B-List

Service

Service Type: Janitorial Service
Mandatory for: U.S. Department of Justice, Robert F. Kennedy Building, 950 Constitution Avenue NW., Washington, DC
Mandatory Source(s) of Supply: Melwood Horticultural Training Center, Upper Marlboro, MD
Contracting Activity: Dept of Justice, Offices, Boards and Divisions Washington, DC

Deletions

The following products are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Name(s):
8415–01–503–0761—Shirt, Cold Weather 100 Weight Fleece, Army, Coyote Brown, S
8415–01–503–0762—Shirt, Cold Weather 100 Weight Fleece, Army, Coyote Brown, M
8415–01–503–0763—Shirt, Cold Weather 100 Weight Fleece, Army, Coyote Brown, L
8415–01–503–0766—Shirt, Cold Weather 100 Weight Fleece, Army, Coyote Brown, XL
Mandatory Source(s) of Supply: Peckham Vocational Industries, Inc., Lansing, MI
Contracting Activity: Defense Logistics Agency Troop Support

NSN(s)—Product Name(s):
7530–01–578–9300—Label, File Folder, Recycled, Laser and Inkjet, Assorted Color Stripes, 1 5/16″ x 3–7/16″
Mandatory Source(s) of Supply: North Central Sight Services, Inc., Williamsport, PA
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7510–01–519–4362—Binder, Round Ring, Clear Overlay, Pockets, Cinnamon, 1½″ Capacity, Letter Size
Mandatory Source(s) of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: Department of Veterans Affairs, Strategic Acquisition Center General Services Administration, New York, NY

NSN(s)—Product Name(s): 6645–01–467–8481—Clock, Wall, Black Custom Logo, 28″ Diameter
Mandatory Source(s) of Supply: Chicago Lighthouse Industries, Chicago, IL
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7520–01–094–4309—Tray, Desk, Plastic, Side Loading, Stackable, Legal, Black
Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7930–01–513–9967—Cleaner, General, Disinfectant,

Aerosol, 18 oz.
Mandatory Source(s) of Supply: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: General Services Administration, Fort Worth, TX

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2017–00675 Filed 1–12–17; 8:45 am]

BILLING CODE 6353–01–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 and a service from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* February 12, 2017.

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 9/23/2016 (81 FR 65629–65630) and 12/9/2016 (81 FR 89086), 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

NSN(s)—Product Name(s):
6515–00–NIB–0571—Glove, Exam, Nitrile, Non-Latex, Textured, Midknight, Black, Small
6515–00–NIB–0572—Glove, Exam, Nitrile, Non-Latex, Textured, Midknight, Black, Medium
6515–00–NIB–0573—Glove, Exam, Nitrile, Non-Latex, Textured, Midknight, Black, Large
6515–00–NIB–0574—Glove, Exam, Nitrile, Non-Latex, Textured, Midknight, Black, X-Large
6515–00–NIB–8229—Glove, Vinyl, Powder-Free, Evolution One, Natural Color, X-Small
6515–00–NIB–8230—Glove, Vinyl, Powder-Free, Evolution One, Natural Color, Small
6515–00–NIB–8231—Glove, Vinyl, Powder-Free, Evolution One, Natural Color, Medium
6515–00–NIB–8232—Glove, Vinyl, Powder-Free, Evolution One, Natural Color, Large
6515–00–NIB–8233—Glove, Vinyl, Powder-Free, Evolution One, Natural Color, X-Large
6515–00–NIB–8235—Glove, Exam, Nitrile, Non-Latex, Textured, Midknight, Black, X-Small
Mandatory for: 100% of the requirement of the Federal Bureau of Investigation (FBI)
Mandatory Source(s) of Supply: Central Association for the Blind & Visually Impaired, Utica, NY
Contracting Activity: Dept of Justice, Federal Bureau of Investigation
Distribution: C-List

Service

Service Type: Mailroom Operation Service
Mandatory for:
Missile Defense Agency, MDA Mailroom Schriever AFB, CO
Mandatory Source(s) of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL
Contracting Activity: Missile Defense Agency, Huntsville, AL

Deletions

On 12/9/2016 (81 FR 89086) and 12/16/2016 (81 FR 91140–91141), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and service 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 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 deleted from the Procurement List.

End of Certification

Accordingly, the following products and service are deleted from the Procurement List:

Products

NSN(s)—Product Name(s): 7510–00–272–9804—Envelope, Transparent, 6–1/2″ x 10–1/2″, Clear Plastic, Job Ticket Holder
Mandatory Source(s) of Supply: UNKNOWN
Contracting Activity: General Services Administration, New York, NY
NSN(s)—Product Name(s): 6910–04–000–4482—Chalkboard
6910–04–000–4485—Chalkboard
Mandatory Source(s) of Supply: Tuscola County Community Mental Health Authority, Caro, MI
Contracting Activity: USPS, Topeka Purchasing Center
NSN(s)—Product Name(s): 2540–00–591–1108—Seat, Vehicular
Mandatory Source(s) of Supply: Tuscola County Community Mental Health Authority, Caro, MI
Contracting Activity: Defense Logistics Agency Land and Maritime
NSN(s)—Product Name(s):
2510–00–179–7093—Side Rack, Vehicle
2510–00–590–9734—Side Rack, Vehicle Body
Mandatory Source(s) of Supply: Tuscola County Community Mental Health Authority, Caro, MI
Contracting Activity: W4GG HQ US Army TACOM

Service

Service Type: Document Destruction Service
Mandatory for: Internal Revenue Service Office at the following location: 2725 N. Westwood Blvd., Poplar Bluff, MO
Mandatory Source(s) of Supply: Cape Girardeau Community Sheltered Workshop, Inc., Cape Girardeau, MO
Contracting Activity: Department of the Treasury

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2017–00688 Filed 1–12–17; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, January 18, 2017; 10:00 a.m.–11:30 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Closed to the Public.

Matter To Be Considered: Compliance Matters: The Commission staff will brief the Commission on the status of various compliance matters.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: January 10, 2017.

Todd A Stevenson,

Secretary.

[FR Doc. 2017–00799 Filed 1–11–17; 11:15 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Fulbright-Hays Doctoral Dissertation Research Abroad Fellowship Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

Overview Information:

Fulbright-Hays Doctoral Dissertation Research Abroad (DDRA) Fellowship Program Notice inviting applications for new awards for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.022A.

DATES: *Applications Available:* January 13, 2017.

Deadline for Transmittal of Applications: March 14, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The Fulbright-Hays DDRA Fellowship Program provides opportunities to doctoral candidates to engage in full-time dissertation research abroad in modern foreign languages and area studies. The program is designed to contribute to the development and improvement of the study of modern foreign languages and area studies in the United States.

Priorities: This notice contains one absolute priority, two competitive preference priorities, and one invitational priority. In accordance with 34 CFR 75.105(b)(2)(ii), the absolute and competitive preference priorities are from the regulations for this program (34 CFR 662.21(d)).

Absolute Priority: For FY 2017, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Specific Geographic Regions of the World.

A research project that focuses on one or more of the following geographic areas: Africa, East Asia, Southeast Asia and the Pacific Islands, South Asia, the Near East, Central and Eastern Europe and Eurasia, and the Western Hemisphere (excluding the United States and its territories). Please note that applications that propose projects focused on the following countries are not eligible: Andorra, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, United Kingdom, or Vatican City.

Competitive Preference Priorities: Within this absolute priority, we give competitive preference to applications that address one or both of the following priorities.

Under 34 CFR 75.105(c)(2)(i), for FY 2017, we award an additional three points to an application that meets Competitive Preference Priority 1 and two points for an application that meets Competitive Preference Priority 2 (up to 5 additional points possible).

These priorities are:

Competitive Preference Priority 1: Focus on Priority Languages (3 points).

A research project that makes use of any of the 78 priority languages selected from the U.S. Department of Education's list of Less Commonly Taught Languages, as follows:

Akan (Twi-Fante), Albanian, Amharic, Arabic (all dialects), Armenian, Azeri (Azerbaijani), Balochi, Bamanakan (Bamana, Bambara, Mandikan, Mandingo, Maninka, Dyula), Belarusian, Bengali (Bangla), Berber (all languages), Bosnian, Bulgarian, Burmese, Cebuano (Visayan), Chechen, Chinese (Cantonese), Chinese (Gan), Chinese (Mandarin), Chinese (Min), Chinese (Wu), Croatian, Dari, Dinka, Georgian, Gujarati, Hausa, Hebrew (Modern), Hindi, Igbo, Indonesian, Japanese, Javanese, Kannada, Kashmiri, Kazakh, Khmer (Cambodian), Kirghiz, Korean, Kurdish (Kurmanji), Kurdish (Sorani), Lao, Malay (Bahasa Melayu or Malaysian), Malayalam, Marathi, Mongolian, Nepali, Oromo, Panjabi, Pashto, Persian (Farsi), Polish, Portuguese (all varieties), Quechua, Romanian, Russian, Serbian, Sinhala (Sinhalese), Somali, Swahili, Tagalog, Tajik, Tamil, Telugu, Thai, Tibetan, Tigrigna, Turkish, Turkmen, Ukrainian, Urdu, Uyghur/Uigur, Uzbek, Vietnamese, Wolof, Xhosa, Yoruba, and Zulu.

Competitive Preference Priority 2: Thematic Focus on Academic Fields (2 points).

A research project conducted in the field of economics, engineering, international development, mathematics, political science, public health, science, comparative or international education, or technology.

Invitational Priority: For FY 2017, this priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority a competitive or absolute preference over other applications.

This priority is:

Applications from Minority-Serving Institutions. For purposes of this invitational priority, Minority-Serving Institution means an institution that is eligible to receive assistance under part A of title III, under part B of title III, or under title V of the Higher Education Act of 1965, as amended.

Program Authority: 22 U.S.C. 2452(b)(6).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The

regulations for this program in 34 CFR part 662.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Discretionary grants redistributed as fellowships to individual beneficiaries.

Estimated Available Funds: $3,477,151.

Estimated Range of Awards: $15,000 to $60,000.

Estimated Average Size of Awards: $33,461.

Estimated Number of Awards: 98.

Note: The Department is not bound by any estimates in this notice.

Project Period: The institutional project period is 18 months, beginning October 1, 2017. Students may request funding for a period of no less than six months and no more than 12 months.

III. Eligibility Information

1. *Eligible Applicants:* IHEs. As part of the application process, students submit individual applications to the IHE. The IHE then officially submits all eligible individual student applications with its grant application to the Department.

Note: As part of its FY 2017 budget request, the Administration proposed to continue to allow funds to be used to support the applications of individuals who plan both to utilize their language skills in world areas vital to United States national security and to apply their language skills and knowledge of these countries in the fields of government, international development, and the professions. Therefore, students planning to apply their language skills in such fields and those planning teaching careers are eligible to apply to IHEs for funds from this program.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* Both IHEs and student applicants can obtain an application package via the Internet or from the Education Publications Center (ED PUBS). To obtain a copy via the Internet, use the following address: *www.G5.gov*. To obtain a copy from ED Pubs, write, fax, or call the following: ED Pubs, U.S. Department of Education, P.O. Box 22207, Alexandria, VA 22304. Telephone, toll free: 1–877–433–7827. FAX: (703) 605–6794. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *www.EDPubs.gov* or at its email address: *edpubs@inet.ed.gov*.

If you request an application package from ED Pubs, be sure to identify this program as follows: CFDA number 84.022A.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms the applicant must submit, are in the application package for this program. Page Limit: The application narrative is where the student applicant addresses the selection criteria that reviewers use to evaluate the application. The student applicant must limit the application narrative to no more than 10 pages and the bibliography to no more than two pages, using the following standards:

- A ''page'' is 8.5″ × 11″, on one side only, with 1″ margins at the top, bottom, both sides, and portrait orientation.

Note: For purposes of determining compliance with the page limits, each page on which there are words will be counted as one full page.

- Double space (no more than three lines per vertical inch) all text in the application narrative. However, student applicants may single space all text in charts, tables, figures, graphs, titles, headings, footnotes, endnotes, quotations, bibliography, and captions.
- Use a font that is either 12 point or larger, or no smaller than 10 pitch (characters per inch). Student applicants may use a 10-point font in charts, tables, figures, graphs, footnotes, and endnotes. However, these items are considered part of the narrative and counted within the 10-page limit.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limits only apply to the application narrative and bibliography. The page limits do not apply to the Application for Federal Assistance face sheet (SF 424), the supplemental information form required by the Department of Education, or the assurances and certification. However, student applicants must include their complete responses to the selection criteria in the application narrative.

We will reject a student applicant's application if the application exceeds the page limits.

3. *Submission Dates and Times:*

Applications Available: January 13, 2017.

Deadline for Transmittal of Applications: March 14, 2017.

Applications for grants under this program must be submitted electronically using G5, the Department's grant management system, accessible through the Department's G5 site. For information (including dates and times) about how to submit an IHE's application electronically, or in paper format by mail or hand delivery if an IHE qualifies for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:*

To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can submit an application through G5.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

7. *Other Submission Requirements:* Applications for grants under this program must be submitted electronically unless an IHE qualifies for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the Fulbright-Hays DDRA Fellowship Program, CFDA number 84.022A, must be submitted electronically using the G5 system, accessible through the Department's G5 site at: *www.G5.gov.* While completing the electronic application, both the IHE and the student applicant will be entering data online that will be saved into a database. Neither the IHE nor the student applicant may email an electronic copy of a grant application to us.

We will reject an application if an IHE submits it in paper format unless, as described elsewhere in this section, the IHE qualifies for one of the exceptions to the electronic submission requirement *and* submits, no later than two weeks before the application deadline date, a written statement to the Department that the IHE qualifies for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

Please note the following:

- The process for submitting applications electronically under the Fulbright-Hays DDRA Fellowship Program has several parts. The following is a brief summary of the process; however, all applicants should review and follow the detailed description of the application process that is contained in the application package. In summary, the major steps are:

(1) IHEs must email the following information to *ddra@ed.gov:* Name of university and full name and email address of potential project director. We recommend that applicant IHEs submit this information as soon as possible to ensure that they obtain access to G5 well before the application deadline date. We suggest that IHEs send this information no later than two weeks prior to the closing date in order to facilitate timely submission of their applications;

(2) Students must complete their individual applications and submit them to their IHE's project director using G5;

(3) Persons providing references for individual students must complete and submit reference forms for the students and submit them to the IHE's project director using G5; and

(4) The IHE's project director must officially submit the IHE's application, which must include all eligible individual student applications, reference forms, and other required forms, using G5.

- The IHE must complete the electronic submission of the grant application by 4:30:00 p.m., Washington, DC time, on the application deadline date. G5 will not accept an application for this competition after 4:30:00 p.m., Washington, DC time, on the application deadline date. Therefore, we strongly recommend that both the IHE and the student applicant not wait until the application deadline date to begin the application process.
- The hours of operation of the G5 Web site are 6:00 a.m. Monday until 9:00 p.m., Wednesday; and 6:00 a.m. Thursday until 3:00 p.m., Sunday, Washington, DC time. Please note that, because of maintenance, the system is unavailable between 3:00 p.m. on Sundays and 6:00 a.m. on Mondays, and between 9:00 p.m. on Wednesdays and 6:00 a.m. on Thursdays, Washington, DC time. Any modifications to these hours are posted on the G5 Web site.
- Student applicants will not receive additional point value because the student submits his or her application in electronic format, nor will we penalize the IHE or student applicant if the applicant qualifies for an exception to the electronic submission requirement, as described elsewhere in this section, and submits an application in paper format.
- IHEs must submit all documents electronically, including all information typically provided on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Both IHEs and student applicants must upload any narrative sections and all other attachments to their application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.
- Student transcripts must be submitted electronically through the G5 system.
- Both the IHE's and the student applicant's electronic applications must comply with any page limit requirements described in this notice.
- Prior to submitting your electronic application, you may wish to print a copy of it for your records.
- After the individual student applicant electronically submits his or her application to the student's IHE, the student will receive an automatic

acknowledgment. After a person submits a reference electronically, he or she will receive an online confirmation. After the applicant IHE submits its application, including all eligible individual student applications, to the Department, the applicant IHE will receive an automatic acknowledgment that will include a unique PR/Award number for the IHE's application.

• Within three working days after submitting its electronic application—

(1) Print SF 424 from G5;

(2) The applicant IHE's Authorizing Representative must sign this form;

(3) Place the PR/Award number in the upper right-hand corner of the hard-copy signature page of the SF 424; and

(4) Fax the signed SF 424 to the Application Control Center at (202) 245–6272.

• We may request that you provide us original signatures on other forms at a later date.

Application Deadline Date Extension in Case of System Unavailability: If an IHE is prevented from electronically submitting its application on the application deadline date because the G5 system is unavailable, we will grant the IHE an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable the IHE to transmit its application electronically, by mail, or by hand delivery. We will grant this extension if—

(1) The IHE is a registered user of the G5 system and the IHE has initiated an electronic application for this competition; and

(2)(a) G5 is unavailable for 60 minutes or more between the hours of 8:30 a.m. and 3:30 p.m., Washington, DC time, on the application deadline date; or

(b) G5 is unavailable for any period of time between 3:30 p.m. and 4:30:00 p.m., Washington, DC time, on the application deadline date.

We must acknowledge and confirm these periods of unavailability before granting the IHE an extension. To request this extension or to confirm our acknowledgment of any system unavailability, an IHE may contact either (1) the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice or (2) the e-Grants help desk at 1–888–336–8930. If G5 is unavailable due to technical problems with the system and, therefore, the application deadline is extended, an email will be sent to all registered users who have initiated a G5 application. Extensions referred to in this section apply only to the unavailability of the G5 system.

Exception to Electronic Submission Requirement: An IHE qualifies for an exception to the electronic submission requirement, and may submit its application in paper format, if the IHE is unable to submit an application through G5 because—

• The IHE or a student applicant does not have access to the Internet; or

• The IHE or a student applicant does not have the capacity to upload large documents to G5; *and*

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), the IHE mails or faxes a written statement to the Department, explaining which of the two grounds for an exception prevents the IHE from using the Internet to submit its application. If an IHE mails a written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If an IHE faxes its written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax this statement to: Mariam Ouhamou, U.S. Department of Education, 400 Maryland Ave. SW., Room 3E207, Washington, DC 20202–4260. Telephone: (202) 453–6764 or by email: *ddra@ed.gov.*

The IHE's paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If an IHE qualifies for an exception to the electronic submission requirement, the IHE may mail (through the U.S. Postal Service or a commercial carrier) its application to the Department. The IHE must mail the original and two copies of the application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.022A), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

The IHE must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If the IHE mails its application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, the IHE should check with its local post office.

We will not consider applications postmarked after the application deadline date.

c. *Submission of Paper Applications by Hand Delivery.*

If an IHE qualifies for an exception to the electronic submission requirement, the IHE (or a courier service) may deliver its paper application to the Department by hand. The IHE must deliver the original and two copies of the application, by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.022A), 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260. The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If an IHE mails or hand delivers its application to the Department—

(1) The IHE must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which the IHE is submitting its application; and

(2) The Application Control Center will mail a notification of receipt of the IHE's grant application. If the IHE does not receive this grant notification within 15 business days from the application deadline date, the IHE should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *General:* For FY 2017, student applications are divided into seven categories based on the world area focus of their research projects, as described in the absolute priority listed in this notice. Language and area studies experts in discrete world area-based panels will review the student applications. Each panel reviews, scores, and ranks its applications separately from the applications assigned to the other world area panels. However, all fellowship applications will be ranked together from the highest to lowest score for funding purposes.

2. *Selection Criteria:* The selection criteria for this competition are from the

regulations for this program in 34 CFR 662.21 and are listed in the application package.

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

Under 34 CFR 662.22(b), no applicant may receive grants from the Fulbright U.S. Student Program (FUSP) and the Fulbright-Hays DDRA Fellowship Program concurrently. Once a candidate has accepted an award from FUSP and FUSP has expended funds on the student, the student is then ineligible for a grant under the Fulbright-Hays DDRA Fellowship Program. A student applying for a grant under the Fulbright-Hays DDRA Fellowship Program must indicate on the application if the student has currently applied for a FUSP grant. If, at any point, the candidate accepts a FUSP award prior to being notified of the candidate's status with the Fulbright-Hays DDRA Fellowship Program, the candidate should immediately notify the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If, after consultation with FUSP, we determine that FUSP has expended funds on the student (*e.g.,* the candidate has attended the pre-departure orientation or was issued grant funds), the candidate will be deemed ineligible for an award under the Fulbright-Hays DDRA Fellowship Program at that time.

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If a student application is successful, we notify the IHE's U.S. Representative and U.S. Senators and send the IHE a Grant Award Notification (GAN); or we may send the IHE an email containing a link to access an electronic version of the GAN. We may notify the IHE informally, also.

If a student application is not evaluated or not selected for funding, we notify the IHE.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates the approved application as part of the binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. Grantees are required to use the electronic data instrument *International Resource Information System* (IRIS) to complete the final report. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the objective for the Fulbright-Hays DDRA Fellowship Program is to provide grants to colleges and universities to fund individual doctoral students to conduct research in other countries in modern foreign languages and area studies for periods of 6 to 12 months.

The Department will use the following measures to evaluate its success in meeting this objective:

DDRA GPRA Measure 1: The percentage of DDRA fellows who increased their foreign language scores in speaking, reading, and/or writing by at least one proficiency level.

DDRA GPRA Measure 2: The percentage of DDRA fellows who complete their degree in their program of study within four years of receipt of the fellowship.

DDRA GPRA Measure 3: The percentage of DDRA fellows who found employment that utilized their language and area studies skills within eight years of receiving their award.

DDRA GPRA Measure 4: Efficiency Measure—The cost per DDRA fellow who found employment that utilized their language and area studies skills within eight years.

The information provided by grantees in their performance report submitted via IRIS will be the source of data for this measure. Reporting screens for institutions and fellows may be viewed at: *http://iris.ed.gov/iris/pdfs/DDRA_director.pdf; http://iris.ed.gov/iris/pdfs/DDRA_fellow.pdf.*

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Mariam Ouhamou, International and Foreign Language Education, U.S. Department of Education, 400 Maryland Ave. SW., Room 3E207, Washington, DC 20202–4260. Telephone: (202) 453–6764 or by email: *ddra@ed.gov.*

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

If you request an application from ED Pubs, be sure to identify this program as follows: CFDA number 84.022A.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 10, 2017.

Mohamed Abdel-Kader,

Deputy Assistant Secretary for International and Foreign Languages.

[FR Doc. 2017–00747 Filed 1–12–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Application for New Awards; Expanding Opportunity Through Quality Charter Schools Program (CSP)—Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Overview Information:

CSP—Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools

Notice inviting applications for new awards for fiscal year (FY) 2017.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.282M.

DATES:

Applications Available: January 13, 2017.

Date of Pre-Application Webinar: Tuesday, January 24, 2017, 1:00 p.m., Washington, DC time.

Deadline for Transmittal of Applications: February 27, 2017.

Deadline for Intergovernmental Review: April 28, 2017.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The major purposes of the CSP are to expand opportunities for all students, particularly traditionally underserved students, to attend charter schools and meet challenging State academic standards; provide financial assistance for the planning, program design, and initial implementation of public charter schools; increase the number of high-quality charter schools available to students across the United States; evaluate the impact of charter schools on student achievement, families, and communities; share best practices between charter schools and other public schools; encourage States to provide facilities support to charter schools; and support efforts to strengthen the charter school authorizing process. Through CSP Grants to Charter Management Organizations for the Replication and Expansion of High-Quality Charter Schools (CFDA number 84.282M) (also referred to as Charter Management Organization, or CMO, grants), the Department provides funds to *charter management organizations (CMOs)*[1] on a competitive basis to enable them to *replicate* or *expand* one or more *high-quality charter schools.* Grant funds may be used to expand the enrollment of one or more existing *high-quality charter schools,* or to *replicate* one or more new charter schools that are based on an existing, *high-quality charter school* model.

Background

The CMO grant program is intended to support *high-quality charter schools* that are operated by high-performing *CMOs* seeking to broaden and increase their impact on student achievement. Since FY 2010, the Department has awarded new CMO grants each year (except in FY 2013),[2] which has resulted in a portfolio of high-quality *CMOs* using Federal funds to *replicate* and *expand* their successful charter school models to serve greater numbers of students, particularly *educationally disadvantaged students.*

In December 2015, the CMO grant program was reauthorized under the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act of 2015 (ESSA) (20 U.S.C. 7221–7221j). This notice contains newly authorized priorities, definitions, application requirements, and selection criteria from the ESEA (as amended by the ESSA), as well as other priorities, definitions, application requirements, and selection criteria, to ensure that the Department's CMO grant portfolio continues to consist of *high-quality charter schools* operated by high-performing *CMOs* that are improving academic outcomes for all students, particularly *educationally disadvantaged students.* In particular, we continue to use the same absolute priority from previous competitions for serving a large percentage of low-income students. In addition, we include selection criteria that emphasize the applicant's success in operating more than one *high-quality charter school* and serving *educationally disadvantaged students,* and we continue to include a competitive preference priority for applicants that have not previously received funding under this program.

For FY 2017, we are establishing three competitive preference priorities. The first competitive preference priority is from the newly amended program statute, with a few minor changes to clarify the Department's goals.

Competitive Preference Priority 1—Promoting Diversity gives priority to applicants that plan to use CSP funds to operate or manage charter schools intentionally designed to be racially and socioeconomically diverse. An applicant addressing this priority is invited to discuss how the proposed design of its project will encourage approaches by charter schools that help bring together students of different backgrounds, including students from different racial and socioeconomic backgrounds, to attain the benefits that

[1] Italicized terms are defined in the Definitions section of this notice.

[2] From FY 2010 through FY 2016, the Department's authority to use CSP funds to award grants to CMOs and other eligible entities for the replication and expansion of high-quality charter schools was provided through annual appropriations acts.

flow from a diverse student body. The applicant should ensure that those approaches are permissible under current law, including applicable civil rights laws.[3]

The second competitive preference priority, School Improvement, focuses on applicants that have shown past success in turning around academically poor-performing schools and plan to use CMO grant funds to turn around academically poor-performing schools during the grant project period. Accordingly, this priority is intended both to reward and provide new incentives to high-performing *CMOs* for engaging in the difficult task of turning around our Nation's struggling public schools.

The third competitive preference priority is for *novice applicants.* In order to ensure that the CMO grant program is supporting a wide range of organizations, this priority provides additional points to applicants that have neither received a CSP Replication and Expansion of High-Quality Charter Schools[4] grant—either individually or as part of a group—at any point in the past nor received a discretionary grant from the Federal government in the previous five years.

This competition also includes an invitational priority that encourages applicants to conduct rigorous evaluations of practices within their charter schools that will, if well implemented, produce evidence that meets *What Works Clearinghouse (WWC) Evidence Standards.* The Department is committed both to increasing the number of schools that implement practices that are based on evidence and to building evidence of the effectiveness of a range of educational practices in order to identify educational practices that other schools or school systems can adopt to improve outcomes for their students (*e.g.,* educator induction practices or positive behavioral interventions and supports). In addition, building and utilizing evidence of the effectiveness of various educational approaches is a key feature of the reauthorized program under the ESEA, as amended by the ESSA.

All charter schools receiving CSP funds, as outlined in section 4310(2)(G) of the ESEA (as amended by the ESSA), must comply with various non-discrimination laws, including the Age Discrimination Act of 1975, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, section 444 of the General Education Provisions Act (GEPA), and part B of the Individuals with Disabilities Education Act (IDEA).

Priorities: This notice includes one absolute priority, three competitive preference priorities, and one invitational priority. We are establishing these priorities for the FY 2017 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA, 20 U.S.C. 1232(d)(1).

Absolute Priority: This priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: *Absolute Priority—Low-Income Demographic.*

To meet this priority, an applicant must demonstrate that at least 60 percent of the students across all of the charter schools the applicant currently operates or manages are *individuals from low-income families.*

Competitive Preference Priorities: These priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we will award an additional three points to an application that meets Competitive Preference Priority 1, an additional five points to an application that meets Competitive Preference Priority 2, and an additional two points to an application that meets Competitive Preference Priority 3. The maximum total competitive preference priority points an application can receive for this competition is 10.

These priorities are:

Competitive Preference Priority 1—Promoting Diversity. (0 or 3 points).

This priority is for projects that will provide for the replication or expansion of *high-quality charter schools* that have an intentional focus on recruiting and retaining racially and socioeconomically diverse student bodies (see Section 4305(b)(5)(A) of the ESEA, as amended by the ESSA).

Note: For information on permissible ways to meet this priority, please refer to the joint guidance issued by the Department's Office for Civil Rights and the U.S. Department of Justice entitled, ''Guidance on the Voluntary Use of Race to Achieve Diversity and Avoid Racial Isolation in Elementary and Secondary Schools'' (*www2.ed.gov/about/offices/list/ocr/docs/guidance-ese-201111.pdf*).

Competitive Preference Priority 2—School Improvement through Turnaround Efforts. (0 or 5 points).

This priority is for applicants that both:

(a) Demonstrate past success in improving the academic performance of one or more academically poor-performing public schools by taking over the operation of the school or restarting the school as a charter school; and

(b) Propose to use CMO funds to restart as a charter school one or more academically poor-performing public schools during the project period, to do so by replicating a successful charter school model for which the applicant has provided evidence of success, and to do so by targeting a similar student population in the replicated charter school as was served by the academically poor-performing public school. In accordance with section 4310(2)(B) of the ESEA, as amended by the ESSA, students who are enrolled in the academically poor-performing public school at the time of restart are exempt from the charter school's lottery.

For purposes of this priority, academically poor-performing public schools may include, but are not limited to, *persistently lowest-achieving schools,* as defined in this notice and the final requirements for the School Improvement Grants (SIG) program under Title I of the ESEA (*https://www.federalregister.gov/articles/2015/02/09/2015-02570/final-requirements-school-improvement-grants-title-i-of-the-elementary-and-secondary-education-act*); and priority schools in States that exercised flexibility[5] under the ESEA, as amended by the No Child Left Behind Act of 2001 (NCLB) (see the Department's June 7, 2012 guidance entitled, ''ESEA Flexibility,'' at *www.ed.gov/esea/flexibility,* and the Office of Elementary and Secondary Education's December 18, 2015 Dear Colleague Letter at *https://www2.ed.gov/policy/elsec/leg/essa/transition-dcl.pdf*).

Note: For applicants proposing to use CMO grant funds to *replicate* a *high-quality charter school* by restarting as a charter school one or more academically poor-performing public schools, the *CMO's* proposed charter school must be newly created and operating under

[3] For information about how applicants can lawfully promote student body diversity, see the Department's December 2, 2011 ''Guidance on the Voluntary Use of Race to Achieve Diversity and Avoid Racial Isolation in Elementary and Secondary Schools,'' available at *http://www2.ed.gov/ocr/docs/guidance-ese-201111.pdf.*

[4] The name of the competition in this notice has changed from previous years; from FY 2010 through FY 2016, the Department had the authority to make CMO grants under the Grants for Replication and Expansion of High-Quality Charter Schools competition.

[5] As of August 1, 2016, States may no longer exercise flexibility, except in the limited circumstances where they implemented interventions previously in priority schools under the SIG program. For additional information related to ESEA flexibility and interventions in priority schools, see section B of the Department's June 29, 2016 guidance entitled, ''Transitioning to the Every Student Succeeds Act—Frequently Asked Questions,'' at *http://www2.ed.gov/policy/elsec/leg/essa/essafaqstransition62916.pdf.*

a separate charter and governance than the academically poor-performing public school.

Competitive Preference Priority 3—Novice Applicant. (0 or 2 points).

This priority is for applications submitted by *novice applicants.*

Invitational Priority: This priority is an invitational priority. Under 34 CFR 75.105(c)(1), we do not give an application that meets this invitational priority any preference over other applications.

This priority is: Invitational Priority—Rigorous Evaluation of School Practices.

The Secretary is particularly interested in funding applications that demonstrate that the applicant is currently conducting, or will conduct, a rigorous independent evaluation of specific practices within the applicant's charter schools (*e.g.,* positive behavioral interventions and supports or professional development practices, such as teacher coaching) through a *quasi-experimental design study* or *randomized controlled trial* that will, if well implemented, meet *WWC Evidence Standards,* and that other schools or school systems can adopt to improve outcomes for their students.

Definitions

The following definitions, where cited, are from 34 CFR 75.225 and 77.1 and the ESEA, as amended by the ESSA. We are establishing the remaining definitions for the FY 2017 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Ambitious means promoting continued, meaningful improvement for program participants or for other individuals or entities affected by the grant, or representing a significant advancement in the field of education research, practices, or methodologies. When used to describe a *performance target,* whether a *performance target* is *ambitious* depends upon the context of the relevant *performance measure* and the *baseline* for that measure. (34 CFR 77.1)

Baseline means the starting point from which performance is measured and targets are set. (34 CFR 77.1)

Charter management organization means a nonprofit organization that operates or manages a network of charter schools linked by centralized support, operations, and oversight. (Section 4310(3) of the ESEA, as amended by the ESSA)

Educationally disadvantaged students means students in the categories described in section 1115(c)(2) of the ESEA, as amended by the ESSA, which include children who are economically disadvantaged, students with disabilities, migrant students, English learners, neglected or delinquent students, and homeless students.

Expand, when used with respect to a *high-quality charter school,* means to significantly increase enrollment or add one or more grades to the *high-quality charter school.* (Section 4310(7) of the ESEA, as amended by the ESSA)

High-quality charter school means a charter school that—

(a) Shows evidence of strong academic results, which may include strong student academic growth, as determined by a State;

(b) Has no significant issues in the areas of student safety, financial and operational management, or statutory or regulatory compliance;

(c) Has demonstrated success in significantly increasing student academic achievement, including graduation rates where applicable, for all students served by the charter school; and

(d) Has demonstrated success in increasing student academic achievement, including graduation rates where applicable, for each of the subgroups of students, as defined in section 1111(c)(2), except that such demonstration is not required in a case in which the number of students in a group is insufficient to yield statistically reliable information or the results would reveal personally identifiable information about an individual student. (Section 4310(8) of the ESEA, as amended by the ESSA)

Individual from a low-income family means an individual who is determined by a State educational agency (SEA) or local educational agency (LEA) to be a child from a low-income family on the basis of (a) data used by the Secretary to determine allocations under section 1124 of the ESEA, (b) data on children eligible for free or reduced-price lunches under the Richard B. Russell National School Lunch Act, (c) data on children in families receiving assistance under part A of title IV of the Social Security Act, (d) data on children eligible to receive medical assistance under the Medicaid program under Title XIX of the Social Security Act, or (e) an alternate method that combines or extrapolates from the data in items (a) through (d) of this definition.

Logic model (also referred to as theory of action) means a well-specified conceptual framework that identifies key components of the proposed process, product, strategy, or practice (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the relationships among the key components and outcomes, theoretically and operationally. (34 CFR 77.1)

Novice applicant means—

(a) Any applicant for a grant from the Department that—

(1) Has never received a grant or subgrant under the program from which it seeks funding;

(2) Has never been a member of a group application, submitted in accordance with 34 CFR 75.127–75.129, that received a grant under the program from which it seeks funding; and

(3) Has not had an active discretionary grant from the Federal government in the five years before the deadline date for applications for new awards under the program.

(b) For purposes of paragraph (a)(3), a grant is active until the end of the grant's project or funding period, including any extensions of those periods that extend the grantee's authority to obligate funds. (34 CFR 75.225)

Performance measure means any quantitative indicator, statistic, or metric used to gauge program or project performance. (34 CFR 77.1)

Performance target means a level of performance that an applicant would seek to meet during the course of a project or as a result of a project. (34 CFR 77.1)

Persistently lowest-achieving school means, as determined by the State—

(a)(1) Any title I school in improvement, corrective action, or restructuring that—

(A) Is among the lowest-achieving five percent of title I schools in improvement, corrective action, or restructuring or the lowest-achieving five title I schools in improvement, corrective action, or restructuring in the State, whichever number of schools is greater; or

(B) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years; and

(2) Any secondary school that is eligible for, but does not receive, title I funds that—

(A) Is among the lowest-achieving five percent of secondary schools or the lowest-achieving five secondary schools in the State that are eligible for, but do not receive, title I funds, whichever number of schools is greater; or

(B) Is a high school that has had a graduation rate as defined in 34 CFR 200.19(b) that is less than 60 percent over a number of years.

(b) To identify the lowest-achieving schools, a State must take into account both—

(1) The academic achievement of the ''all students'' group in a school in

terms of proficiency on the State's assessments under section 1111(b)(3) of the ESEA in reading/language arts and mathematics combined; and

(2) The school's lack of progress on those assessments over a number of years for the ''all students'' group. (80 FR 7223)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet *WWC Evidence Standards* with reservations (but not *WWC Evidence Standards* without reservations). (34 CFR 77.1)

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcome for the treatment group and for the control group. These studies, depending on design and implementation, can meet *WWC Evidence Standards* without reservations. (34 CFR 77.1)

Replicate, when used with respect to a *high-quality charter school,* means to open a new charter school, or a new campus of a *high-quality charter school,* based on the educational model of an existing *high-quality charter school,* under an existing charter or an additional charter, if permitted or required by State law. (Section 4310(9) of the ESEA, as amended by the ESSA)

What Works Clearinghouse (WWC) Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following link:*//ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.* (34 CFR 77.1)

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities, selection criteria, definitions, and requirements. Section 437(d)(1) of GEPA, however, allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for this program under section 4305(b) of the ESEA, as amended by the ESSA, and, therefore, this competition qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on the priorities, requirements, definitions, and selection criteria in this notice in accordance with section 437(d)(1) of GEPA. These priorities, requirements, definitions, and selection criteria will apply to grants awarded under this competition in FY 2017 and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: Section 4305(b) of the ESEA, as amended by the ESSA.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 76, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: For FY 2017, the Administration has requested $350,000,000 under the CSP and authority to use up to $100,000,000 of CSP funds for CMO awards. We intend to use an estimated $57,000,000 for new awards under this competition and may use FY 2017 funds to support multiple years of a grant project for one or more grantees. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications now to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2018 from the list of unfunded applications from this competition.

Estimated Range of Awards: $600,000–$3,500,000 per year.

Estimated Average Size of Awards: $2,000,000 per year.

Maximum Award: See *Reasonable and Necessary Costs* in section III.4.(a) for information regarding the maximum amount of funds that may be awarded per new school seat and per new school.

Estimated Number of Awards: 10–20 awards.

Note: The Department is not bound by any estimates in this notice. The estimated range and average size of awards are based on a single 12-month budget period.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants: Charter management organizations.* Eligible applicants may apply individually or as part of a group or consortium.

2. *Audits:* (a) All grantees must provide to the Department their most recent independent audits of the *CMO's* financial statements prepared in accordance with generally accepted accounting principles, and all grantees must continue to provide independent, annual audits of their financial statements prepared in accordance with generally accepted accounting principles each year of the grant.

(b) All grantees must ensure that charter schools operated or managed by the applicant conduct independent, annual audits of their financial statements prepared in accordance with generally accepted accounting principles, and ensure that any such audits are publicly reported.

3. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

4. *Other:* (a) *Reasonable and Necessary Costs:* The Secretary may elect to impose maximum limits on the amount of grant funds that may be awarded per charter school *replicated,* per charter school *expanded,* or per new school seat created.

For this competition, the maximum limit of grant funds that may be awarded per new school seat in a new charter school is $3,400, including a maximum limit per *replicated* charter school of $900,000. The maximum limit per new school seat in a charter school that is *expanding* its enrollment is $1,700, including a maximum limit per *expanded* school of $900,000.

Note: Applicants must ensure that all costs included in the proposed budget are reasonable and necessary in light of the goals and objectives of the proposed project. Any costs determined by the Secretary to be unreasonable or unnecessary will be removed from the final approved budget.

(b) *Other CSP Grants:* A charter school that previously has received CSP funds for replication or expansion, or for planning or initial implementation of a charter school under CFDA number 84.282A or 84.282B (as administered under the ESEA, as amended by the NCLB), may not use funds under this grant for the same purpose. However, such charter school may be eligible to receive funds under this competition to *expand* the charter school beyond the existing grade levels or student count.

Likewise, a charter school that receives funds under this competition is ineligible to receive funds for the same purpose under section 4303(b)(1) of the ESEA, as amended by the ESSA, including opening and preparing for the operation of a new charter school, opening and preparing for the operation of a *replicated high-quality charter school,* or *expanding* a *high-quality charter school* (*i.e.,* CFDA number 84.282A or 84.282B).

(c) *Costs for Evaluation:* In accordance with 34 CFR 75.590, CMO grant funds may be used to cover post-award costs associated with an evaluation described in response to the invitational priority or Selection Criterion (c) of this notice, provided that such costs are reasonable and necessary to meet the objectives of the approved project.

IV. Application and Submission Information

1. *Address to Request Application Package:*

Eddie Moat, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W259, Washington, DC 20202–5970. Telephone: (202) 401–2266 or by email: *charterschools@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2.a. *Content and Form of Application Submission:* Requirements concerning the content and form of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the priorities, selection criteria, and application requirements that reviewers use to evaluate your application. We recommend that you limit the application narrative to no more than 60 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial. An application submitted in any other font (including Times Roman or Arial Narrow) will not be accepted.

The page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative.

b. *Submission of Proprietary Information:* Given the types of projects that may be proposed in applications for the CMO grant competition, your application may include business information that you consider proprietary. In 34 CFR 5.11 we define ''business information'' and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended).

Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you feel is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under ''Other Attachments Form,'' please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Submission Dates and Times:*

Applications Available: [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Date of Pre-Application Webinar: The Department will hold a pre-application meeting via Webinar for prospective applicants on January 24, 1:00 p.m., Washington, DC, time. Individuals interested in attending this meeting are encouraged to pre-register by emailing their name, organization, and contact information with the subject heading ''PRE-APPLICATION MEETING'' to *CharterSchools@ed.gov.* There is no registration fee for attending this meeting.

For further information about the pre-application meeting, contact Eddie Moat, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W259, Washington, DC 20202–5970. Telephone: (202) 401–2266 or by email: *charterschools@ed.gov.*

Deadline for Transmittal of Applications: February 27, 2017.

Applications for grants under this competition must be submitted electronically using the *Grants.gov* Apply site (*Grants.gov*). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: [INSERT DATE 105 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* Grantees under this program must use the grant funds to *replicate* or *expand* the charter school model or models for which the applicant has presented evidence of success. Grant funds must be used to carry out allowable activities, as described in section 4303(h) of the ESEA, as amended by the ESSA, which include—

(a) Preparing teachers, school leaders, and specialized instructional support personnel, including through paying costs associated with—

(i) Providing professional development; and

(ii) Hiring and compensating, during the applicant's planning period specified in the application for funds, one or more of the following:

(A) Teachers,

(B) School leaders, and

(C) Specialized instructional support personnel.

(b) Acquiring supplies, training, equipment (including technology), and educational materials (including developing and acquiring instructional materials).

(c) Carrying out necessary renovations to ensure that a new school building complies with applicable statutes and regulations, and minor facilities repairs (excluding construction).

(d) Providing one-time, startup costs associated with providing transportation to students to and from the charter school.

(e) Carrying out community engagement activities, which may include paying the cost of student and staff recruitment.

(f) Providing for other appropriate, non-sustained costs related to the *replication* or *expansion* of *high-quality charter schools* when such costs cannot be met from other sources.

A grantee may use up to 20 percent of grant funds for initial operational costs associated with the expansion or improvement of the grantee's oversight or management of its charter schools, provided that (i) the specific charter schools being *replicated* or *expanded* under the grant are the intended beneficiaries of such expansion or improvement; (ii) such expansion or improvement is intended to improve the grantee's ability to manage or oversee the charter schools *replicated* or *expanded* under the grant; and (iii) the costs cannot be met from other sources.

We reference additional regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* To do business with the Department of Education, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

Note: Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, *Grants.gov.*

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a *SAM.gov* Tip Sheet, which you can find at: *www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, if you are submitting your application via *Grants.gov*, you must (1) be designated by your organization as an Authorized Organization Representative (AOR); and (2) register yourself with *Grants.gov* as an AOR. Details on these steps are outlined at the following *Grants.gov* Web page: *www.grants.gov/web/grants/register.html.*

7. *Other Submission Requirements.* Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

a. *Electronic Submission of Applications.*

Applications for grants under the CSP Grants to Charter Management Organizations for Replication and Expansion of High-Quality Charter Schools, CFDA number 84.282M, must be submitted electronically using the Governmentwide *Grants.gov* Apply site at *www.Grants.gov.* Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement *and* submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement.*

You may access the electronic grant application for CSP Grants to Charter Management Organizations for Replication and Expansion of High-Quality Charter Schools at *www.Grants.gov* You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (*e.g.,* search for 84.282, not 84.282M).

Please note the following:

- When you enter the *Grants.gov* site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- Applications received by *Grants.gov* are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the *Grants.gov* system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the *Grants.gov* system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from *Grants.gov*, we will notify you if we are rejecting your application because it was date and time stamped by the *Grants.gov* system after 4:30:00 p.m., Washington, DC time, on the application deadline date.
- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through *Grants.gov.*

• You should review and follow the Education Submission Procedures for submitting an application through *Grants.gov* that are included in the application package for this competition to ensure that you submit your application in a timely manner to the *Grants.gov* system. You can also find the Education Submission Procedures pertaining to *Grants.gov* under News and Events on the Department's G5 system home page at *www.G5.gov*. In addition, for specific guidance and procedures for submitting an application through *Grants.gov,* please refer to the *Grants.gov* Web site at: *www.grants.gov/web/grants/applicants/apply-for-grants.html*.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

• You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

• You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (*e.g.,* Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the application narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from *Grants.gov* an automatic notification of receipt that contains a *Grants.gov* tracking number. This notification indicates receipt by *Grants.gov* only, not receipt by the Department. *Grants.gov* will also notify you automatically by email if your application met all the *Grants.gov* validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by *Grants.gov,* the Department will retrieve your application from *Grants.gov* and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by *Grants.gov,* it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through *Grants.gov,* please contact the *Grants.gov* Support Desk, toll free, at 1–800–518–4726. You must obtain a *Grants.gov* Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the *Grants.gov* system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with *Grants.gov*, along with the *Grants.gov* Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the *Grants.gov* system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the *Grants.gov* system. We will not grant you an extension if you failed to fully register to submit your application to *Grants.gov* before the application deadline date and time or if the technical problem you experienced is unrelated to the *Grants.gov* system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the *Grants.gov* system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the *Grants.gov* system; *and*

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Eddie Moat, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W259, Washington, DC 20202–5970. FAX: (202) 401–2266.

Your paper application must be submitted in accordance with the mail or hand delivery instructions described in this notice.

b. Submission of Paper Applications by Mail.

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You must mail the original and two copies of your application, on or before the application deadline date, to the

Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.282M, LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline.

c. Submission of Paper Applications by Hand Delivery.

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: CFDA Number 84.282M, 550 12th Street SW., Room 7039, Potomac Center Plaza, Washington, DC 20202–4260.

The Application Control Center accepts hand deliveries daily between 8:00 a.m. and 4:30:00 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

1. *Application Requirements:* Applications for CSP CMO grant funds must address the following application requirements. An applicant must respond to requirement (a) in a stand-alone section of the application or in an appendix. For all other application requirements, an applicant may choose to respond in the context of its responses to the selection criteria in section V.2 of this notice.

(a) Demonstrate that the applicant currently operates or manages more than one charter school. For purposes of this competition, multiple charter schools are considered to be separate schools if each school—

(i) meets the definition of ''charter school'' under section 4310(2) of the ESEA, as amended by the ESSA, and

(ii) is treated as a separate school by its authorized public chartering agency and the State, including for purposes of accountability and reporting under title I of the ESEA, as amended.

(b) For each charter school currently operated or managed by the applicant, provide—

1. Student assessment results for all students and for each subgroup of students described in section 1111(c)(2) of the ESEA, as amended by the NCLB; [6]

2. Attendance and student retention rates for the most recently completed school year and, if applicable, the most recent available four-year adjusted cohort graduation rates and extended year adjusted cohort graduation rates;

3. Suspension and expulsion rates for the past three years for each subgroup of students described in section 1111(c)(2) of the ESEA, as amended by the NCLB; and

4. Information on any significant compliance and management issues encountered within the last three school years by any school operated or managed by the eligible entity, including in the areas of student safety and finance.

(c) Provide information, including information regarding how any compliance issues were resolved, on any charter schools operated or managed by the applicant that have been closed; have had their charter(s) revoked due to problems with statutory or regulatory compliance, including compliance with sections 4310(2)(G) and (J) of the ESEA, as amended by the ESSA; have had their affiliation with the applicant revoked or terminated, including through voluntary disaffiliation; or have experienced significant problems with statutory or regulatory compliance, including compliance with sections 4310(2)(G) and (J) of the ESEA, as amended by the ESSA, that could lead to revocation of the school's charter(s).

(d) Provide a complete *logic model* for the grant project. The *logic model* must include the applicant's objectives for implementing a *high-quality charter school* program with funding under this competition, including the number of *high-quality charter schools* the applicant proposes to *replicate* or *expand.*

(e) Describe the educational program that the applicant will implement in each *replicated* or *expanded* charter school, including—

(1) Information on how the program will enable all students to meet the State's challenging academic and performance standards;

(2) The grade levels or ages of students who will be served; and

(3) The instructional practices that will be used, including whether the applicant currently operates or is proposing to *replicate* or *expand* a single-sex charter school or coeducational charter school that provides a single-sex class or extracurricular activity (collectively referred to as a ''single-sex educational program'').

Note: Prior to receiving an award, an applicant currently operating or proposing to *replicate* or *expand* a charter school that provides a single-sex educational program must demonstrate that the existing and proposed single-sex educational programs are in compliance with applicable nondiscrimination laws, including the Equal Protection Clause of the U.S. Constitution (as interpreted in *United States* v. *Virginia,* 518 U.S. 515 (1996), and other cases) and Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, *et seq.*) and implementing regulations, including 34 CFR 106.34. Such an applicant likely will be required to provide fact-specific information about the single-sex educational program(s) within specified timeframes. In addition, special conditions related to compliance with applicable nondiscrimination laws are likely to be placed on any grant awarded to an applicant that operates or proposes to *replicate* or *expand* a charter school that provides a single-sex educational program. Please see the application package for additional information related to the requirements for single-sex educational programs.

(f) Describe how the applicant currently operates or manages the charter schools for which it has presented evidence of success, and how the proposed *replicated* or *expanded*

[6] Section 5(e)(1)(B) of the ESSA states that ''subsections (c) and (d) of section 1111 of the [ESEA] (20 U.S.C. 6311), as amended by [the ESSA], shall take effect beginning with school year 2017–2018.'' For purposes of this competition, ''section 1111(c)(2)'' refers to section 1111(c)(2) of the ESEA, as amended by the NCLB.

charter schools will be operated or managed. Include a description of central office functions, relationship with charter holder(s) if other than the applicant, governance, daily operations, financial management, human resources management, and instructional management. If applying as a group or consortium, describe the roles and responsibilities of each member of the group or consortium and how each member will contribute to this project.

(g) Describe how the operation of each *replicated* or *expanded* charter school will be sustained after the grant has ended, which shall include a multi-year financial and operating model for the applicant.

(h) Describe how the applicant will solicit, consider, and include in governance input from parents and other members of the community on the implementation and operation of each *replicated* or *expanded* charter school.

(i) Describe how the applicant will ensure that each *replicated* or *expanded* charter school will recruit and enroll students, including students with disabilities, English learners, and other *educationally disadvantaged students,* and describe the lottery and enrollment procedures that will be used for each *replicated* or *expanded* charter school if more students apply for admission than can be accommodated. For applicants that propose to use a weighted lottery, describe how the weighted lottery complies with section 4303(c)(3)(A) of the ESEA, as amended by the ESSA.

(j) Describe how the applicant will ensure that all eligible students with disabilities receive a free appropriate public education in accordance with Part B of the IDEA.

(k) Describe how the proposed project will assist *educationally disadvantaged students* in mastering State academic content standards and State student academic achievement standards.

(l) Describe the applicant's planned activities and expenditures of Federal grant funds.

(m) Include a request and justification for any waivers of Federal statutory or regulatory requirements that the applicant believes are necessary for the successful operation of its *replicated* or *expanded* charter schools.

2. *Selection Criteria.* The maximum possible score for addressing all of the criteria in this section is 100 points. The maximum possible score for addressing each criterion is indicated in parentheses following the criterion.

In evaluating an application, the Secretary considers the following criteria:

(a) *Quality of the eligible applicant.* (45 points)

1. The degree to which the applicant has demonstrated success in increasing academic achievement, including graduation rates where applicable, for all students and for each of the subgroups of students described in section 1111(c)(2) of the ESEA, as amended by the NCLB, attending the charter schools the applicant operates or manages (15 points).

2. The extent to which the academic achievement results (including annual student performance on statewide assessments and annual student attendance and retention rates, and where applicable and available, student academic growth, high school graduation rates, college attendance rates, and college persistence rates) for *educationally disadvantaged students* served by the charter schools operated or managed by the applicant have exceeded the average academic achievement results for such students in the State (15 points).

3. The extent to which charter schools operated or managed by the applicant have not been closed; have not had a charter revoked due to noncompliance with statutory or regulatory requirements; have not had their affiliation with the applicant revoked or terminated, including through voluntary disaffiliation; have not had any significant issues in the area of financial or operational management; have not experienced significant problems with statutory or regulatory compliance that could lead to revocation of the school's charter; and have not had any significant issues with respect to student safety (15 points).

(b) *Contribution in assisting educationally disadvantaged students.* (25 points)

The significance of the contribution the proposed project will make in expanding educational opportunities for *educationally disadvantaged students* and enabling those students to meet challenging State academic standards. In determining the significance of the contribution the proposed project will make, the Secretary considers:

1. The extent to which charter schools currently operated or managed by the applicant serve *educationally disadvantaged students,* including students with disabilities and English learners, at rates comparable to surrounding public schools (10 points); and

2. The quality of the plan to ensure that the charter schools the applicant proposes to *replicate* or *expand* will recruit and enroll *educationally disadvantaged students* (15 points).

(c) *Quality of the evaluation plan for the proposed project.* (10 points)

In determining the quality of the evaluation plan for the proposed project, the Secretary considers the alignment of the evaluation plan to the *logic model* for the proposed grant project and the extent to which the methods of evaluation include the use of objective *performance measures* that are clearly related to the intended outcomes of the proposed grant project articulated in the applicant's response to application requirement (c) and will produce quantitative and qualitative data by the end of the performance period.

(d) *Quality of the management plan and personnel.* (20 points)

In determining the quality of the management plan and personnel to *replicate* or *expand high-quality charter schools* under the proposed project, the Secretary considers—

(1) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (5 points);

(2) The qualifications, including relevant training and experience, of the project director, chief executive officer or organization leader, and key project personnel, especially in managing projects of the size and scope of the proposed project (10 points); and

(3) The ability of the applicant to sustain the operation of the *replicated* or *expanded* charter schools after the grant has ended, as demonstrated by the multi-year financial and operating model included in the applicant's response to application requirement (g) (5 points).

3. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

4. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that, over the course of the project period, may exceed the simplified acquisition threshold (currently $150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through SAM. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures:* (a) The primary goal of the CSP is to support the creation and development of a large number of *high-quality charter schools* that are free from State or local rules that inhibit flexible operation, are held accountable for enabling students to reach challenging State performance standards, and are open to all students. The Secretary has two performance indicators to measure progress towards this goal: (1) The number of charter schools in operation around the Nation, and (2) the percentage of fourth- and eighth-grade charter school students who are achieving at or above the proficient level on State assessments in mathematics and reading/language arts. Additionally, the Secretary has established the following measure to examine the efficiency of the CSP: Federal cost per student in implementing a successful school (defined as a school in operation for three or more consecutive years).

(b) *Project-Specific Performance Measures.* Applicants must propose project-specific *performance measures* and *performance targets* consistent with the objectives of the proposed project. Applications must provide the following information as directed under 34 CFR 75.110(b) and (c):

(1) *Performance measures.* How each proposed *performance measure* would accurately measure the performance of the project and how the proposed *performance measure* would be consistent with the *performance measures* established for the program funding the competition.

(2) *Baseline data.* (i) Why each proposed *baseline* is valid; or (ii) if the applicant has determined that there are no established *baseline* data for a particular *performance measure,* an explanation of why there is no established *baseline* and of how and when, during the project period, the applicant would establish a valid *baseline* for the *performance measure.*

(3) *Performance targets.* Why each proposed *performance target* is *ambitious* yet achievable compared to the *baseline* for the *performance measure* and when, during the project period, the applicant would meet the *performance target(s).*

(4) *Data collection and reporting.* (i) The data collection and reporting methods the applicant would use and why those methods are likely to yield reliable, valid, and meaningful performance data; and (ii) the applicant's capacity to collect and report reliable, valid, and meaningful performance data, as evidenced by high-quality data collection, analysis, and reporting in other projects or research.

All grantees must submit an annual performance report with information that is responsive to these *performance measures.*

5. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things, whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the *performance targets* in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

6. *Project Director's Meeting:* Applicants approved for funding under this competition must attend a two-day meeting for project directors at a location to be determined in the continental United States during each year of the project. Applicants may include the cost of attending this meeting in their proposed budgets.

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Eddie Moat, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W259, Washington, DC 20202–5970. Telephone: (202) 401–2266 or by email: *charterschools@ed.gov.*

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

VIII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 10, 2017.

Margo Anderson,

Acting Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2017–00748 Filed 1–12–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0092]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; EDFacts Data Collection School Years 2016–17, 2017–18, and 2018–19

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before February 13, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0092. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* 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, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

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: EDFacts Data Collection School Years 2016–17, 2017–18, and 2018–19.

OMB Control Number: 1850–0925.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 61.

Total Estimated Number of Annual Burden Hours: 126,800.

Abstract: EDFacts is a U.S. Department of Education (ED) initiative to collect, analyze, report on and promote the use of high-quality, pre-kindergarten through grade 12 (pre-K–12) performance data for use in education planning, policymaking, and management and budget decision making to improve outcomes for students. EDFacts enables the National Center for Education Statistics (NCES) to report on students, schools, staff, services, and education outcomes at the state, district, and school levels, by centralizing data provided by state education agencies, local education agencies, and schools. This centralized approach provides ED users with the ability to efficiently analyze and report on submitted data and has reduced the reporting burden for state and local data producers through the use of streamlined data collection, analysis, and reporting tools. EDFacts collects information on behalf of ED grant and program offices for approximately 180 data groups for all 50 states, Washington DC, Puerto Rico, and seven outlying areas and freely associated states (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, and the U.S. Virgin Islands), the Department of Defense Education Activity (DoDEA), and the Bureau of Indian Education (BIE). NCES seeks authorization from OMB to revise its EDFacts data collection and is requesting a new

clearance for the 2016–17, 2017–18, and 2018–19 school years in order to support the Elementary and Secondary Act (ESEA), as amended by the Every Student Succeeds Act (ESSA) in December, 2015. In response to the 60-day public comment period announced in the **Federal Register** on August 24, 2016, ED received comments from 21 distinct commenters and 5 anonymous submissions. A summary of the comments and ED's responses are provided in Attachment F. This notice announces that the revised collection package is now available for a 30-day public comment period. This submission includes a few proposed changes to the EDFacts data collection. The proposed changes are detailed for review in Attachments C and B.

Dated: January 10, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–00666 Filed 1–12–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Request for Public Comment on Draft Consent-Based Siting Process for Consolidated Storage and Disposal Facilities for Spent Nuclear Fuel and High-Level Radioactive Wastes

AGENCY: Spent Fuel & Waste Disposition, Office of Nuclear Energy, Department of Energy.

ACTION: Notice of public comment period.

SUMMARY: The U.S. Department of Energy (DOE) is designing a consent-based siting process to establish an integrated waste management system to transport, store, and dispose of commercial spent nuclear fuel and high-level radioactive waste. In a consent-based siting approach, DOE will work with communities, tribal governments and states across the country that express interest in hosting federal consolidated interim storage facilities and disposal facilities for spent nuclear fuel and high-level radioactive waste as part of an integrated waste management system. The Department is seeking input on the *Draft Consent-Based Siting Process for Consolidated Storage and Disposal Facilities for Spent Nuclear Fuel and High-Level Radioactive Wastes.*

DATES: The 90-day public comment period begins January 12, 2017 and ends April 14, 2017.

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

Email: Responses may be provided by email to *consentbasedsiting@hq.doe.gov.* Please submit electronic comments in Microsoft Word, or PDF file format, and avoid the use of special characters or any form of encryption.

Mail: Responses may be provided by mail to the following address: U.S. Department of Energy, Office of Nuclear Energy, Draft Consent-Based Siting Process, 1000 Independence Ave. SW., Washington, DC 20585.

Fax: Responses may be faxed to 202–586–0544. Please include ''Draft Consent-Based Siting Process'' on the fax cover page.

Online: Responses will be accepted online at *www.regulations.gov.*

Data collected via the mechanisms listed above will not be protected from the public view in any way. Individual commentors' names and addresses (including email addresses) received as part of this Request for Public Comment are part of the public record. DOE plans to reproduce comment documents in their entirety, as appropriate, and to post all comment documents received in their entirety at *energy.gov/consentbasedsiting* following the close of the public comment period. Any person wishing to have his/her name, address, email address, or other identifying information withheld from the public record of comment documents must state this request prominently at the beginning of any comment document, or else no redactions will be made.

FOR FURTHER INFORMATION CONTACT: Requests for further information should be sent to Mr. Andrew Griffith via *consentbasedsiting@hq.doe.gov* or at U.S. Department of Energy, Office of Spent Fuel and Waste Disposition (NE–8), Office of Nuclear Energy, 1000 Independence Ave. SW., Washington, DC 20585. Telephone: (202) 586–3715.

SUPPLEMENTARY INFORMATION: *General Information:* Where can I obtain a copy of the *Draft Consent-Based Siting Process for Consolidated Storage and Disposal Facilities for Spent Nuclear Fuel and High-Level Radioactive Wastes*?

All documents in the docket are listed in the *www.regulations.gov* index. You may also download a copy of the document at *energy.gov/consentbasedsiting.*

Issued in Washington, DC, on January 9, 2017.

Melissa Bates,

Acting Team Lead for Office of Integrated Waste Management, Spent Fuel & Waste Disposition, Office of Nuclear Energy, Department of Energy.

[FR Doc. 2017–00670 Filed 1–12–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Innovative Pathways Funding Opportunity Announcement

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of funding opportunity announcement.

SUMMARY: The U.S. Department of Energy's (DOE) Office of Energy Efficiency and Renewable Energy's (EERE) Technology-to-Market (T2M) team is issuing a Funding Opportunity Announcement (DE–FOA–0001703) entitled Innovative Pathways. This FOA is seeking to surface new testable and scalable ways to alleviate common structural challenges facing promising new energy technologies on the pathway to market.

DATES: Letters of Intent are requested on or before January 18, 2017 and Full Applications are requested on or before February 15, 2017.

ADDRESSES: Interested persons are encouraged to submit questions, which must be submitted electronically to *T2M@ee.doe.gov.* The complete FOA, including the list of specific questions and submission instructions for the Letters of Intent and Full Applications, can be found at *https://eere-exchange.energy.gov/.*

FOR FURTHER INFORMATION CONTACT: Questions may be directed to Johanna Wolfson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–61, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: 202–586–1040. Email: *T2M@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: EERE is seeking proposals under two topic areas: (1) Technical Community and Industry Collaboration, and (2) Lowering Barriers to Resource Access. The two highlighted areas of interest for this FOA are Models for industry-startup partnerships under Topic 1, and New investment models under Topic 2. EERE's intent is to pilot and evaluate new mechanisms, and

position those that are successful for adoption by the private sector. These mechanisms are intended to augment existing Tech-to-Market efforts currently supported. This Funding Opportunity is not intended to fund individual technology solutions directly. Rather, it will fund approaches that address common barriers across the larger energy ecosystem and help create more efficient pathways to market for clean energy technologies.

Subject to the availability of funds, up to $4,200,000 in Federal assistance will be provided over two years through this funding opportunity. A 20% recipient cost-share is required. EERE anticipates selecting up to seven pilot projects in the first year. After the first year, EERE will conduct a continuation review of the pilot projects. Up to three of the projects will be granted a continuation for a second year.

Lead applicants may include, but are not limited to, educational institutions, incubators/accelerators, research labs, non-profit entities, industry associations, corporations, and investment/financial/insurance firms.

Issued in Washington, DC, on January 9, 2017.

Johanna Wolfson,

Program Director/Selection Official, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2017–00664 Filed 1–12–17; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2016–0094–1138; FRL–9958–27–OEI]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Collection for Importation of On-Highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''Importation of On-highway Vehicles and Motorcycles and Nonroad Engines, Vehicles, and Equipment'' EPA ICR Number 2583.01, OMB Control Number 2060–NEW to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This new ICR is the consolidation of two individual ICRS that are currently approved by OMB. EPA currently has an approved collection that covers the information requirements for importation of on-highway vehicles which expires on February 28, 2017 (OMB Control Number 2060–0095, ICR Number 0010.14). EPA also has an approved collection for information requirements for importation of nonroad engines and recreational vehicles (OMB Control Number 2060–0320, ICR Number 1723.07), which expires February 28, 2017.

Public comments were requested via the **Federal Register** on September 16, 2016 (81 FR 63758) during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 13, 2017.

ADDRESSES: Submit your comments referencing Docket ID No. EPA–HQ–OAR–2016–0094, to (1) EPA online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Holly Pugliese, Compliance Division, Office of Transportation and Air Quality, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan, 48105; telephone number: 734–214–4288; fax number: 734–214–4869; email address: *pugliese.holly@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR will consolidate two separate ICRs that currently individually cover EPA Declaration Forms 3520–1, 3520–21, and 3520–8. EPA Declaration Form 3520–1 is used by importers of on-highway vehicles and motorcycles and EPA Declaration Form 3520–21 is used by importers of nonroad vehicles, engines and equipment to help facilitate importation of products at U.S. Borders. Each form identifies the regulated category of engine or vehicle and the regulatory provisions under which the importation is taking place. In addition, this ICR covers the burden of EPA Form 3520–8 which is used to request final importation clearance for Independent Commercial Importers (ICIs) of on-highway vehicles who are required to bring the on-highway vehicles into compliance and provide test results. This form is currently covered by OMB 2060–0095. EPA is consolidating these two ICRS due to the effort being undertaken by the U.S. Customs and Border Protection to require electronic filing for all importers. Over the last several years, CBP has been developing the Automated Commercial Environment (ACE) for electronic filing. By the end of 2016, ACE will become the primary system the trade community and other importers will use to report imports and exports. Through ACE as the single window, manual processes will be streamlined and automated, and paper submissions (*e.g.,* fillable PDFs) will essentially be eliminated. However, EPA will continue to maintain the forms on our Web site in fillable PDF format.

EPA does not collect the forms, but rather makes them available to importers and CBP to facilitate entry of goods at the port. EPA may ask for them upon request to assist CPB and/or EPA enforcement personnel for any given import for which there are questions or issues. The forms are primarily used by CBP at the time of importation to assist CBP in making determination if entry should be allowed. CBP regulations require that the forms be submitted as applicable at the time of entry; see 19 CFR 12.73 and 12.74.

Form Numbers: 3520–1, 3520–21, 3520–8.

Frequency of Response: Once per entry. (One form per shipment may be used.)

Respondents/Affected Entities: Individual importers, or companies who import and/or manufacture on-highway

vehicles and nonroad engines, vehicles, and equipment.

Respondent's Obligation to Respond: Required for any importer to legally import nonroad vehicles or engines into the U.S.

Estimated Number of Respondents: 14,810.

Total Estimated Burden: 13,985 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total Estimated Cost: $513,633 (per year), includes $48,064 annualized capital or operation & maintenance costs.

Changes in Estimates: EPA is establishing new burden estimates as we combine the burden estimates for the two separate ICRs that currently cover the forms.

Courtney Kerwin,

Director, Regulatory Supprt Division.

[FR Doc. 2017–00698 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0547; FRL–9957–66–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Performance Evaluation Studies on Wastewater Laboratories (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''Performance Evaluation Studies on Wastewater Laboratories (Renewal)'' (EPA ICR No. 0234.12, OMB Control No. 2080–0021) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through March 31, 2017. Public comments were previously requested via the **Federal Register** (81 FR 44017) on July 6, 2016 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before February 13, 2017.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0547, to (1) EPA online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Gregory Savitske, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2601; fax number: (202) 564–0050; email address: *Savitske.Gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Discharge Monitoring Report-Quality Assurance (DMR–QA) study program participation is mandatory for major and selected minor National Pollutant Discharge Elimination System (NPDES) permit holders in accordance with Clean Water Act Section 308. The DMR–QA study program is designed to evaluate the analytic ability of the laboratories that perform chemical, microbiological and whole effluent toxicity (WET) analyses required in the NPDES permits for reporting results in Discharge Monitoring Reports (DMR). Under DMR–QA, the permit holder is responsible for having their in-house and/or contract laboratories perform proficiency tests and submit results for grading by proficiency test (PT) providers. Graded results are transmitted by either the permittee or PT provider to the appropriate federal or state NPDES regulatory authority. Permit holders are responsible for submitting corrective action reports to the appropriate regulatory authority when results are unsatisfactory.

Form Numbers: EPA Form 6400–01.

Respondents/Affected Entities: Major and selected minor permit holders under the Clean Water Act's National Pollutant Discharge Elimination System (NPDES).

Respondent's Obligation To Respond: Mandatory under Clean Water Act Section 308(a).

Estimated Number of Respondents: 5,700 (total).

Frequency of Response: Annually, On occasion.

Total Estimated Burden: 37,620 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total Estimated Cost: $5,113,983 (per year), includes $3,194,052 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 1,259 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase in burden hours can be attributed to an increase in discretionary selection of minor permit holders for participation by state coordinators. Labor costs were revised upward due to market changes and inflation. Non-labor costs for obtaining proficiency test samples also increased.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2017–00697 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9958–04–ORD]

Environmental Laboratory Advisory Board (ELAB) Meeting Dates and Agenda

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of teleconferences and face-to-face meetings.

The Environmental Protection Agency's Environmental Laboratory Advisory Board (ELAB), as previously announced, holds teleconference meetings the third Wednesday of each month at 1:00 p.m. ET and two face-to-face meetings each calendar year. For 2017, teleconference only meetings will be February 15, March 15, April 19, May 17, June 21, July 19, September 20, October 18, November 15, and December 20, to discuss the ideas and

views presented at the previous ELAB meetings, as well as new business. Items to be discussed by ELAB during the monthly meetings include: (1) Issues in continuing the expansion of national environmental accreditation; (2) ELAB support to the Agency on issues relating to measurement and monitoring for all programs; and (3) follow-up on some of ELAB's past recommendations and issues. In addition to the teleconferences, ELAB will hold two face-to-face meetings with teleconference line also available on January 23, 2017 at the Hyatt Regency Houston Galleria in Houston, TX at 1:00 p.m. (CT) and on August 7, 2017 at the Hyatt Regency in Washington, DC at 1:00 p.m. (ET). Written comments on laboratory accreditation issues and/or environmental monitoring or measurement issues are encouraged and should be sent to Ms. Lara P. Phelps, Designated Federal Official, U.S. EPA (E243–05), 109 T.W. Alexander Drive, Research Triangle Park, NC 27709 or emailed to *phelps.lara@epa.gov.* Members of the public are invited to listen to the teleconference calls, and time permitting, will be allowed to comment on issues discussed during this and previous ELAB meetings. Those persons interested in participating should call Lara P. Phelps at (919) 541–5544 to obtain teleconference information. For information on access or services for individuals with disabilities, please contact Lara P. Phelps at the number above. Requests for accommodation of a disability should be made at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Thomas A. Burke,

EPA Science Advisor.

[FR Doc. 2017–00745 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9031–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EISs)

Filed 01/02/2017 Through 01/06/2017

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: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170000, Draft, NOAA, CA, Calam Monterey Peninsula Water Supply Project, Comment Period Ends: 02/27/2017, Contact: Karen Grimmer 831–647–4253.

EIS No. 20170001, Draft, USFS, MT, South Gravelly Allotment Management Plans, Comment Period Ends: 02/27/2017, Contact: Jake Stewart 406–682–4253.

EIS No. 20170002, Draft, DOE, CA, Remediation of Area IV and the Northern Buffer Zone of the Santa Susana Field Laboratory, Comment Period Ends: 03/14/2017, Contact: Stephie Jennings 1–805–842–3864.

EIS No. 20170003, Draft Supplement, FHWA, DE, US 113 North South Study Millsboro South Area, Comment Period Ends: 02/27/2017, Contact: Nick Blendy 302–734–2966.

EIS No. 20170004, Draft, USFWS, NPS, WA, North Cascades Ecosystem Draft Grizzly Bear Restoration Plan, Comment Period Ends: 03/14/2017, Contact: Karen Taylor-Goodrich 360–854–7205.

The U.S. Department of Interior's National Park Service and the U.S. Fish and Wildlife Service are joint lead agencies for the above project.

EIS No. 20170005, Draft, BR, NM, Pojoaque Basin Regional Water System, Comment Period Ends: 02/27/2017, Contact: Lawrence Moore 505–462–3702.

EIS No. 20170006, Final, USFS, BLM, UT, Transwest Express Powerline (TWE), Review Period Ends: 02/27/2017, Contact: Charles Call 435–691–0768.

EIS No. 20170007, Final, NPS, UT, Glen Canyon National Recreation Area Off-Road Vehicle Management Plan, Review Period Ends: 02/13/2017, Contact: Lindsay Gillham 303–969–2085.

EIS No. 20170008, Final, BLM, USFS, UT, Energy Gateway South Powerline (EGS), Review Period Ends: 02/27/2017, Contact: Kenton Call 435–691–0768.

EIS No. 20170009, Draft Supplement, NOAA, AK, Management of the Subsistence Harvest of Northern Fur Seals on St. Paul Island, Alaska, Comment Period Ends: 02/27/2017, Contact: Michael Williams 907–271–5117.

EIS No. 20170010, Final, USFS, ID, Lookout Pass Ski Area Expansion EIS, Review Period Ends: 02/27/2017, Contact: Shoshana Cooper 208–765–7211.

Amended Notices

EIS No. 20160298, Draft, USFS, MT, Ten Lakes Travel Management Project, Comment Period Ends: 02/14/2017, Contact: Bryan Donner 406–296–2536.

Revision to FR Notice Published 12/16/2016; Extending Comment Period from 1/30/2017 to 2/14/2017.

EIS No. 20160321, Draft Supplement, FTA, CA, BART Silicon Valley Phase II Extension Project, Comment Period Ends: 02/21/2017, Contact: Mary Nguyen 213–202–3960.

Revision to FR Notice Published 01/06/2017; Correction to Comment Period Ends 02/21/2017.

EIS No. 20160328, Draft Supplement, USACE, LA, Mississippi River, Baton Rouge to the Gulf of Mexico Mississippi River-Gulf Outlet, Louisiana, New Industrial Canal Lock and Connecting Channels Project, Comment Period Ends: 02/21/2017, Contact: Mark Lahare 504–862–1344.

Revision to FR Notice Published 01/06/2017; Correction to Comment Period Ends 02/21/2017.

Dated: January 10, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2017–00716 Filed 1–12–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 30, 2017.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *James R. Barta, Fremont, Nebraska, individually; and together with Jack*

Barta, Fremont, Nebraska, and Walter Hoff, Atlanta, Georgia, as members of the Barta/Hoff Group acting in concert; to acquire voting shares of Woodstock Land and Cattle Company, and thereby control Fullerton National Bank, both of Fullerton, Nebraska.

Board of Governors of the Federal Reserve System, January 10, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–00711 Filed 1–12–17; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0121: Docket No. 2017–0001; Sequence 1]

General Services Administration Acquisition Regulation; Information Collection; Industrial Funding Fee and Sales Reporting

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division is submitting a request to the Office of Management and Budget (OMB) to review and approve an extension of a previously approved information collection associated with General Services Administration Acquisition Regulation clause 552.238–74, Industrial Funding Fee and Sales Reporting. GSA uses this information to collect the Industrial Funding Fee and administer the Federal Supply Schedule (FSS) program.

DATES: *Submit comments on or before:* March 14, 2017.

ADDRESSES: Submit comments identified by Information Collection 3090–0121, Industrial Funding Fee and Sales Reporting, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0121, Industrial Funding Fee and Sales Reporting.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0121, Industrial Funding Fee and Sales Reporting'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–0121, Industrial Funding Fee and Sales Reporting.

Instructions: Please submit comments only and cite Information Collection 3090–0121, Industrial Funding Fee and Sales Reporting, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Matthew McFarland, Senior Policy Advisor, GSA Acquisition Policy Division, at 202–690–9232 or *matthew.mcfarland@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA's Federal Supply Schedule (FSS) program, commonly known as the GSA Schedules program or Multiple Award Schedule (MAS) program provides federal agencies with a simplified process for acquiring commercial supplies and services. The FSS program is the Government's preeminent contracting vehicle, accounting for approximately 10 percent of all federal contract dollars with $33 billion of purchases made through the program in fiscal year 2016.

Activities placing orders against a GSA Schedule contract must pay an Industrial Funding Fee (IFF) that reimburses GSA's Federal Acquisition Service (FAS) for the costs of operating the FSS program. FAS recoups its operating costs from ordering activities (*i.e.,* customers) as set forth in 40 U.S.C. 321: Acquisition Services Fund. Net operating revenues generated by the IFF are also applied to fund initiatives benefitting other authorized FAS programs, in accordance with 40 U.S.C. 321. The IFF, currently set at 0.75 percent, is included in the order price, so when a vendor is paid for an FSS order, it is also collecting the IFF. Collection is similar to a state sales tax, where a customer pays the tax due to a merchant, and then the merchant remits the taxes collected to the state government.

GSA requires vendors to report their FSS sales each quarter so it can determine the amount of IFF the vendors have collected from customers, and therefore must remit to GSA. However, GSA also uses this information for other purposes, including budgeting, determining whether vendors have met the minimum sales requirement,[1] evaluating the program's performance, and monitoring small business participation.

Vendor reporting and remittance requirements are set forth in General Services Administration Acquisition Regulation (GSAR) clause 552.238–74, Industrial Funding Fee and Sales Reporting, or Alternate I of that clause. While both clause versions govern how the IFF is calculated and remitted, the reporting requirements differ between the basic version and Alternate I:

Clause 552.238–75: Basic Version: This version requires vendors to report their FSS contract sales to GSA once a quarter. GSA then calculates the IFF due based on the total amount of sales reported, and the vendor must remit that amount within 30 days after the end of the quarter. The basic version of the clause applies to approximately 72 percent of GSA Schedule contracts.

Clause 552.238–75: Alternate I: While the basic version requires vendors to report their total FSS sales each quarter, Alternate I requires vendors to report the transactional data generated from orders each month. GSA then calculates the IFF due based on the transactional data reported, and the vendor must remit that amount within 30 days after the end of the quarter. Alternate I of the clause applies to FSS contracts participating in the Transactional Data Reporting pilot. The pilot commenced on June 23, 2016 and will run for at least a year before substantial changes are considered. Approximately 28 percent of GSA Schedule contracts are eligible to participate in the pilot.

Since the reporting requirements vary by the two versions of clause 552.238–74, separate Paperwork Reduction Act information collections have been established for each version. The information collection associated with OMB control number 3090–0306, which expires on 8/31/2019, applies to Alternate I. This information collection (OMB control number 3090–0121) applies to the basic version of the clause.

Information Collection Changes and Updates

- The population of vendors subject to this information collection is smaller than the previous version, as FSS contracts eligible to participate in the Transactional Data Reporting pilot

[1] The FSS Contract Sales Criteria clause requires vendors to have at least $25,000 in sales over the first two years of a contract and then $25,000/year in sales for each year thereafter. Vendors that have not satisfied the minimum sales requirement are subject to cancellation in accordance with GSAR clause 552.238–73 *Cancellation.*

(approximately 28 percent of all GSA Schedule contracts) are now included under OMB control number 3090–0306.

• Previous justifications for this information collection limited the burden to the amount of time needed for vendors to input sales data in the 72A Reporting System and remit IFF payments. However, GSA now recognizes recordkeeping, quality assurance, reporting, and remittance should be included in the burden estimates. Since recordkeeping and quality assurance are the largest burden drivers for both vendors and the Government, the burden estimates for both the public and Government have increased.

B. Annual Reporting Burden

Population Overview: The basic version of clause 552.238–74 is included in 14,306 contracts held by 12,254 vendors. This includes 1,128 new contracts awarded to 819 vendors.[2]

Cost Estimates: The estimated cost burden for respondents was calculated by multiplying the burden hours by an estimated cost of $68/hour ($50/hour with a 36% overhead rate).[3]

Categorization of Vendors by Quarterly Sales Revenue: Sales reporting imposes a progressive burden — one that increases with a vendor's sales volume. Quarterly reporting times will increase with a vendor's applicable sales volume, as vendors with lower to no reportable sales will spend little time on quarterly reporting, while those with more reportable sales with face a higher reporting burden.

GSA separated vendors into categories based on average quarterly sales volume[4] in order to account for the differences in reporting burden. These categories are:

• Category 1: No sales activity (average quarterly sales of $0)

• *Category 2:* Average quarterly sales between $0 and $60,000

• *Category 3:* Average quarterly sales between $60,000 and $600,000

• *Category 4:* Average quarterly sales between $600,000 and $3 million

• *Category 5:* Average quarterly sales over $3 million

The distribution of vendors by sales category is as follows:

FSS AND VENDORS BY SALES CATEGORY

	FSS vendors (count)	FSS vendors (percentage)
Category 1	4,217	34
Category 2	4,020	33
Category 3	2,768	23
Category 4	970	8
Category 5	279	2
Total	12,254	100.00

Automated vs. Manual Reporting Systems: Vendors subject to these clauses must create systems or processes to produce and report accurate data. Generally, vendors will use automated or manual systems to identify the quarter's reportable sales. An automated system is one that relies on information technology, such as an accounting system or data management software, to identify and compile reportable data. These systems can tremendously streamline the reporting process but require upfront configuration to perform the tasks, such as coding the sales types to be retrieved. Conversely, a manual system is one that incorporates little to no automation and instead relies on personnel to manually identify and compile the reportable data. An example of a manual system would be an accountant reviewing invoices to identify the reportable data and then transferring the findings to a spreadsheet. In contrast to automation, a manual system requires relatively little setup time but the reporting effort will generally increase with the vendor's sales volume.

The likelihood of a vendor adopting an automated system increases with their applicable sales volume. Vendors with little to no reportable data are unlikely to expend the effort needed to establish an automated reporting system since it will be relatively easy to identify and report a limited amount of data. In fiscal year 2015, 34 percent of FSS vendors subject to this collection reported $0 sales, while another 33 percent reported average quarterly sales between $1 and $60,000 per quarter. However, as a vendor's applicable average quarterly sales increase, they will be increasingly likely to establish an automated system to reduce the quarterly reporting burden. Consequently, vendors with higher reportable sales will likely bear a higher setup burden to create an automated system, or absorb a high quarterly reporting burden if they choose to rely on manual reporting methods.

The following chart depicts the likelihood of the population of vendors adopting manual and automated reporting systems:

VENDORS BY REPORTING SYSTEM TYPE

(Manual vs. Automated)

	Manual system (vendor percentage)	Automated system (vendor percentage)	Manual system (vendor count)	Automated system (vendor count)
Category 1	100	0	4,217	0
Category 2	100	0	4,020	0

[2] These are approximations based on FY2015 data. The number of vendors equals the number of unique Data Universal Numbering System (DUNS) numbers, which are assigned to business entities.

[3] The 36% overhead rate was used in reference Office of Management and Budget (OMB) Circular No. A–76. Circular A–76 requires agencies to use standard cost factors to estimate certain costs of government performance. These cost factors ensure that specific government costs are calculated in a standard and consistent manner to reasonably reflect the cost of performing commercial activities with government personnel. The standard cost factor for fringe benefits is 36.25%; GSA opted to round to the nearest whole number for the basis of its burden estimates.

[4] Average quarterly sales volume was computed by taking a vendor's total annual sales volume and dividing it by 4. All sales data is from FY2015.

VENDORS BY REPORTING SYSTEM TYPE—Continued

(Manual vs. Automated)

	Manual system (vendor percentage)	Automated system (vendor percentage)	Manual system (vendor count)	Automated system (vendor count)
Category 3	90	10	2,491	277
Category 4	50	50	485	485
Category 5	10	90	28	251
Total Vendor Count by System Type			11,241	1,013
Vendor Percentage by System Type			92	8

Initial Setup: Vendors with active FSS contracts already have procedures in place to meet these longstanding reporting requirements. However, new FSS vendors will absorb a one-time setup burden to establish reporting systems. The estimated setup time varies between automated and manual reporting systems. Vendors implementing a manual system must acclimate themselves with the new reporting requirements and train their staff as accordingly, while those with automated systems must perform these tasks in addition to configuring information technology resources. GSA is attributing the setup burden by vendor, not by contracts, because a vendor holding multiple contracts subject to this rule will likely use a single reporting system.

GSA estimates the average one-time setup burden is 8 hours for vendors with a manual system and 40 hours for those with an automated system. GSA also attributes the same system type probabilities (manual system 92%, automated system 8%) to the population of new vendors. These estimates apply to the 819 vendors awarded FSS contracts in fiscal year 2015.

Quarterly Reporting: Vendors are required to report sales within 30 calendar days after the end of each quarter. The average reporting times vary by system type (manual or automated) and by sales categories. GSA estimates vendors using a manual system will have average quarterly reporting times ranging from 15 minutes (0.25 hours) per quarter for vendors with $0 sales, to an average of 8 hours per quarter for vendors with quarterly sales over $3 million. On the other hand, GSA projects vendors with automated systems will have reporting times of 2 hours per quarter, irrespective of quarterly sales volume, as a result of efficiencies achieved through automated processes. The following table shows GSA's projected quarterly reporting times per sales category and system type.

QUARTERLY REPORTING HOURS BY SYSTEM TYPE AND CATEGORY

	Manual systems	Automated systems
Category 1	0.25	2.00
Category 2	1.00	2.00
Category 3	2.00	2.00
Category 4	4.00	2.00
Category 5	8.00	2.00

Annualized Public Burden Estimates

The burden estimates consist of quarterly reporting times for all 12,254 participating vendors and a one-time setup burden for the 819 new vendors:

Quarterly Reporting

Annual Burden (Hours): 56,983.
Annual Burden (Cost): $3,874,817.

Initial Setup

Annual Burden (Hours): 8,718.
Annual Burden (Cost): $592,846.

Total Information Collection Burden

Number of Respondents: 12,254.
Response per Respondent: 4.
Total Annual Responses: 49, 016.
Hours Per Response: 1.3404.
Total Burden (Hours): 65,701.
Annual Burden (Cost): $4,467,663.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0235, Price Reductions Clause, in all correspondence.

Jeffrey A. Koses,

Director, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2017–00687 Filed 1–12–17; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–17–16BGH]

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

Canine Leptospirosis Surveillance in Puerto Rico—Existing Collection in use without an OMB Control Number—National Center for Emerging and Zoonotic Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Bacterial Special Pathogens Branch (BSPB) requests a two-year approval of data collection tools used for active surveillance of canine leptospirosis in Puerto Rico. Active surveillance will allow for the collection of prospective data on acute cases to determine the incidence and distribution of leptospirosis in dogs, assess risk factors for infection, characterize circulating *Leptospira* serovars and species, assess applicability of vaccines currently in use based on serovar determination, and assess rodent, livestock, and wildlife reservoirs of leptospirosis based on infecting serovars found in dogs. Findings from this study will aid in the development of evidence-based, targeted interventions for the prevention of canine leptospirosis, be used to focus human leptospirosis surveillance efforts, and guide future investigations on leptospirosis in humans and animals in Puerto Rico.

The information collection for which approval is sought is in accordance with BSPB's mission to prevent illness, disability, or death caused by bacterial zoonotic diseases through surveillance, epidemic investigations, epidemiologic and laboratory research, training and public education. Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). Successful execution of BSPB's public health mission requires data collection activities in collaboration with the state health department in Puerto Rico and with local veterinary clinics and animal shelters participating in the study.

Researchers will collect information on dogs that meet the study case definition for a suspect case of canine leptospirosis seen at participating veterinary clinics and shelters (sites) throughout Puerto Rico. Examples of information collected about the dog include the dog's signalment, risk factors, clinical signs and symptoms, laboratory results, treatment, and clinical outcome. In addition, basic information about participating clinics and shelters such as site capacity, available resources, vaccination practices, and origin of dogs will also be collected to enhance data analysis and aid in study management.

BSPB will not directly collect the information. Veterinary staff including veterinarians, assistants, and administrative staff will record the information onsite using paper forms by interviewing dog owners, and reviewing medical and administrative records, as necessary. BSPB and Puerto Rico Department of Health study coordinators will maintain the collected information in an electronic database.

BSPB estimates involvement of 26 veterinarians and their staff, and a maximum of 624 responses from owners of enrolled dogs. The enrollment questionnaire is completed once in the beginning of the study while the log sheet and case questionnaires will be completed for each enrolled suspect case. The number of suspect leptospirosis cases can vary from 0 to 2 cases per month per location based on anecdotal reports from local veterinarians. Taking the highest possible response per month, the number of responses per form for the log sheet and case questionnaire is calculated by multiplying 2 cases/month with 12 months giving a total of 24 responses per form for each veterinarian. The total number of veterinarians is not expected to exceed 26 (the maximum number of participating sites).

A minimum of 385 responses from dog owners is needed based on sample size calculation. However, extra clinics were enrolled to ensure that the sample size is met in the event that some clinics withdraw from the study or if fewer numbers of suspect leptospirosis cases are enrolled at the clinics. Given this, a maximum of 624 responses (26 clinics × 24 responses/clinic) are calculated for the burden to the general public (dog owners). Although it is unlikely the maximum number of responses will be reached, the total number of dog owners will not exceed 624.

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data.

The total annualized burden for this information collection is estimated to be 168 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Veterinarian	Enrollment Questionnaire	26	1	5/60
	Log Sheet	26	24	1/60
	Case Questionnaire	26	24	10/60
General Public (Dog owner)	Case Questionnaire	624	1	5/60

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. 2017–00590 Filed 1–12–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Pathways for Advancing Careers and Education (PACE): Third Follow-Up Data Collection.

OMB No.: 0970–0397.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Pathways for Advancing Careers (PACE) evaluation. PACE is an evaluation of nine promising career pathways strategies to promote education, employment, and self-sufficiency. The major goal of PACE is to increase the empirical knowledge about the effectiveness of programs for low-income individuals and families to achieve educational credentials, attain employment, and advance to positions that enable self-sufficiency.

PACE is one project within the broader portfolio of research that the ACF Office of Planning, Research, and Evaluation (OPRE) is utilizing to assess the success of career pathways programs and models. In addition to PACE, this strategy includes a multi-pronged research and evaluation approach for the Health Profession Opportunity Grants (HPOG) Program to better understand and assess the activities conducted and their results. In order to maximize learning across this portfolio, survey development for the HPOG and PACE baseline and follow up surveys has been coordinated, and the majority of the data elements collected in these surveys are similar. (See OMB Control #0970–0394 for HPOG data collection.)

Three data collection efforts have been approved for PACE: One for baseline data collection (approved November 2011); a second for data collection activities to document program implementation, data collection activities for an initial follow-up survey of participants administered approximately 15 months after random assignment, and data collection through in-depth interviews for a small sample of study participants (approved August 2013); and a third for a second follow-up survey of participants administered 36 months after random assignment (approved December 2014).

This **Federal Register** Notice provides the opportunity to comment on a proposed new information collection activity for PACE—a third follow-up survey for PACE participants approximately 72 months after program enrollment. The purpose of the survey is to follow-up with study participants to document their education and training experiences; employment experiences including their advancement in their career; economic well-being; student debt and repayment status; and parenting practices and child outcomes for participants with children.

Previously approved collection activities under 0970–0397 will continue under this new request, specifically the 36-Month Follow-Up Survey and Follow-Up Survey Contact Information Update Letters.

Respondents: Individuals enrolled in the PACE study at programs selected for long-term follow-up.

ANNUAL BURDEN ESTIMATES

[This information request is for a three-year period]

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
72-Month Follow-Up Survey	3,600	1,200	1	0.75	1,125.

Estimated Total Annual Burden Hours: 1,125.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–00583 Filed 1–12–17; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) and the National Treasury Employees Union (NTEU) have renewed the ACF Labor Management Committee Charter.

FOR FURTHER INFORMATION CONTACT: Benjamin Goldhaber, Deputy Assistant Secretary for Administration, 330 C Street SW., Washington, DC 20201, (202) 795–7790.

The ACF Labor Management Committee Charter is being published as follows:

Cooperation Agreement and Charter for the Labor Management Committee (LMC) the Administration for Children and Families (ACF) and National Treasury Employees Union (NTEU)

The Administration for Children and Families (ACF) and the National Treasury Employees Union (NTEU) jointly establish the ACF/NTEU Labor Management Committee (Committee or LMC). The parties recognize that a strong relationship between labor and management as true and equal partners is essential in order for ACF to continue to deliver high quality human services to the American people as well as continue to recognize and value its employees and their union representation. This cooperative relationship envisions the open sharing of information at the earliest pre-decisional stage thereby engendering mutual trust and respect.

Purpose and Objectives

The Committee's goal is to establish an ACF/NTEU labor-management culture that fosters the full development and utilization of employees' skills, knowledge, expertise and capabilities through cooperative dialogue and endeavors with ACF employees and their union representative.

In pursuit of this goal, the Committee sets forth the following objectives:

- Focus on ACF mission achievement by serving the public interest first;
- Promote a quality workplace through improved working conditions and enhanced working relationships;
- Provide a communication and information sharing channel for all bargaining-unit employees through their union representatives;
- Enhance and establish policy and program improvement initiatives through pre-decisional involvement of NTEU without regard to whether those matters are negotiable subjects of bargaining under 5 U.S.C. § 7106;
- Make a good-faith effort to resolve issues concerning proposed changes in conditions of employment as it relates to numbers, types, and grades of employees and positions assigned to any organizational subdivision, work product, or tour of duty; and the technology, methods, and means of performing work;
- Identify and target mutual interests and shared problems and craft solutions;
- Respect each other as equal partners in order to address issues from a problem-solving, interest based, and cooperative perspective;
- Promote cooperative labor-management working relationships across the Agency; and
- Provide a forum from which to build mutual trust, respect, and understanding between the partners.

Scope

The ACF LMC will implement the purposes and objectives on which it is founded by:

- Identifying issues impacting ACF's mission, labor-management relations, and others of mutual interest to committee members and providing proposed recommendations to ACF and NTEU leadership;
- Discussing issues and developing proposed recommendations on items referred to the Committee by ACF or NTEU leadership;
- Exchanging facts and information about agency-wide issues affecting management, labor and mission achievement, and serving as a forum for discussion of such issues; and
- Promoting and facilitating labor-management cooperation throughout ACF, including cooperative relationships at all appropriate levels.

The Parties recognize that although the work of the Committee may reduce the need for formal bargaining, the discussion of issues by the Committee does not relieve the Agency of its bargaining obligations under the Federal Labor-Management Relations Statute (the Statute), absent explicit agreement by the Union.

Principles

1. ACF allows employees through their union representatives to have pre-decisional involvement in workplace matters to the fullest extent practicable without regard to whether those matters are negotiable subjects of bargaining pursuant to 5 U.S.C. § 7106. Pre-decisional involvement takes place before the bargaining process.

2. The basic principles that underlie pre-decisional involvement are as follows:

a. The pre-decisional process begins early: as soon as management identifies an issue or problem that it intends to address but before the scope of the problem has been defined or potential solutions are evaluated.

b. Information is shared freely during the entire process.

c. There is an understanding of confidentiality.

d. The parties use interest-based problem solving.

e. The parties must have a high degree of commitment to the process and to achieving their shared goals.

3. The Committee is responsible for reaching a common understanding on the structure of their pre-decisional involvement process.

4. Pre-decisional involvement does not waive management's statutory right to make decisions under 5 U.S.C. § 7106, nor does it waive the NTEU's right to engage in bargaining prior to implementation consistent with 5 U.S.C. § 7106. Either party retains the right to reject any recommendations and/or proposed agreements arrived at during discussions. It is understood that no agreement will become final and binding until the parties have signed a written agreement to memorialize the terms. Pre-decisional involvement may result in an agreement on an issue, which should be memorialized in a Memorandum of Understanding (MOU) that eliminates the need for further bargaining on the matter. Agency head review is required for any MOU that the parties propose.

5. ACF recognizes that bargaining unit employees represented by NTEU are an essential source of ideas and information about the realities of achieving the ACF's mission. Their input generated through the Committee will assist management in making better informed decisions before making changes in working conditions that affect them. It is the intent of the parties that collaboration will result in less formal bargaining and/or fewer issues that must be referred to the collective bargaining process.

Structure

Composition

1. *Membership:* The Committee will consist of eight members, four NTEU representatives and four management representatives. All members of the Committee must be current and active employees of ACF. In addition, an Executive Secretary will be appointed by the Co-Chairs to perform administrative duties as directed by the Committee. The ACF Deputy Assistant Secretary for Administration and the NTEU National President, or their designees, will be considered ex officio members of the Committee. NTEU representatives will be appointed by the NTEU National President and management representatives will be appointed by the ACF Deputy Assistant Secretary for Administration or his/her designee. The parties will provide the names of appointed committee members and alternates as soon as possible, but no later than 30 days from the date of execution of this Charter. In the event that a committee member is no longer able to serve, a replacement member will be appointed as soon as possible, but no later than 30 days after the original committee member resigns. NTEU and ACF may each appoint one alternate. Alternates can participate fully in discussions but not in decisions. NTEU's representatives will be allocated appropriate official time to prepare for and participate in in the Committee, to include travel time to and from each meeting.

2. *Co-Chairs:* NTEU and ACF will each appoint a Committee Co-Chair for a term to be established individually by each entity.

3. *Guests:* NTEU and ACF may each invite two non-member guests per committee meeting. Guests may provide information and their individual views to the Committee and may fully participate in committee discussions, but will not be involved in the decision making process of the Committee and shall not be involved in making final recommendations to ACF management. Guests may vary per meeting, and may include, but are not limited to, individuals from NTEU's national office, retired/former federal government employees, and the Department's National Labor Relations Office.

Decision Making: All Committee members have equal status during Committee deliberations. The Committee has authority to recommend action to ACF management and NTEU. However, the Committee can only make decisions regarding recommendations when a quorum is present. A quorum exists when at least three representatives from labor and three representatives from ACF are present. When there is no quorum, meetings may still be held to discuss issues, however no decisions may be made. All decisions must be made by consensus. If consensus is

not reached, each party may use its statutory and other rights as specified in the ''Preservation of Rights'' section below. This decision making process will be evaluated by the Committee after one full year of its operation.

Meeting Schedule and Logistics: The Committee will meet on a quarterly basis or more frequently by consensus of its members. The Committee will normally meet at ACF Central Office in Washington, DC, but may also meet at another location by consensus. If a Committee member is unable to physically attend a meeting, he/she may participate by phone or video teleconferencing. The date and time for any meetings will be established by mutual agreement. Committee meetings may be held in conjunction with other meetings where it is deemed cost effective and there is consensus.

Working Groups: The Committee has the authority to form workgroups that may include individuals who are not members of the Committee. Any such workgroups will be given their charge and/or responsibilities from the LMC in writing. Non-Committee member bargaining unit participants on such groups will be appointed by NTEU and will be provided appropriate official time to participate in workgroup activities.

Support: The Committee will use the services of a facilitator trained in interest-based bargaining techniques as needed. The appointed Executive Secretary will provide administrative support to the Committee. Such support shall include creation and dissemination of meeting agenda and minutes, announcements of meetings, and other matters as determined by the Committee. The Agency will make available the use of video and telephone conferencing for the participation of all committee members at meetings. The Agency will provide meeting rooms for LMC meetings.

Participation: The Agency encourages the use of video and telephone conferencing for the participation of those members who are domiciled outside the 50 mile radius of Washington, DC, and will provide the necessary equipment to facilitate the process. Union representatives will be granted official time for preparation and participation in the meetings, pursuant to Article 10 of the Collective Bargaining Agreement. The Agency will pay for all reasonable local travel expenses, namely transportation and parking. For those participants domiciled outside the 50 mile radius, the Agency agrees to reimburse the Union representatives 50 percent of reasonable travel expenses, including transportation, lodging, and per diem.

In the interest of facilitating the working relations among the members, the Agency agrees to assume the full costs associated with travel, including transportation, lodging and per diem for participants for the first scheduled meeting of the Committee. For all subsequent meetings, the Agency will reimburse the Union representatives for 50 percent as stated above.

Agenda Development and Dissemination: The LMC's potential agenda items will be submitted to the Co-Chairs who will mutually establish a formal agenda for the next LMC meeting. The formal agenda will be distributed to all LMC members at least three work days prior to the next LMC meeting. For issues requiring a decision by the LMC, all proposals or related materials will be distributed to the LMC members as soon as possible but no later than seven work days prior to the meeting at which the decision will need to be made.

Communication: Final, approved minutes of the Committee will be disseminated and made available to all ACF employees via methods determined by the Committee.

Evaluation

The Committee will evaluate its progress on an annual basis. It will determine whether to renew its procedures and/or to make changes in any aspect of the LMC.

Preservation of Rights

Cooperation is not intended to supplant the decision-making authority, or to usurp the responsibility of agency management, but to further involve ACF employees in developing ACF decisions through the active and systematic participation of NTEU and those it represents who perform ACF's work. This LMC is based on the belief that NTEU participation in ACF decision-making will promote decisions of such a nature that the need for formal bargaining will be reduced and, where bargaining becomes necessary, will inform and facilitate the negotiations.

Accordingly, subject to statute, executive orders, and the collective bargaining agreement, ACF reserves the right to determine whether to implement recommendations arising from the cooperation endeavor, and NTEU reserves the right to bargain concerning the substance, impact and implementation of final ACF decisions prior to implementation. The ACF recognizes its statutory, regulatory, and/or contractual obligations to provide notification to NTEU and to bargain.

Effective Date, Duration, and Modifications

This LMC shall be instituted upon the date the parties have signed the Charter. The partners may amend or supplement this Agreement at any time upon consensus. This Agreement may be terminated by either of the parties to this Agreement. Termination by either party shall be provided in writing and shall be considered effective exactly 30 calendar days after receipt by the recipient party. Notification of termination shall be sent out in a written notice to all ACF staff within 10 days of the termination and shall be published in the **Federal Register** within 30 days of the termination.

On behalf of NTEU and ACF, the undersigned execute this Agreement on this 30th day of December, 2016, by Anthony Reardon, NTEU National President; Mark H. Greenberg, Acting Assistant Secretary for Children and Families; and Benjamin Goldhaber, Deputy Assistant Secretary for Administration, Administration for Children and Families.

Dated: January 6, 2017.

Mark H. Greenberg,

Assistant Secretary for Children and Families.

[FR Doc. 2017–00655 Filed 1–12–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1524]

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.'' This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), when a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages certain human drug products.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1524 for ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities.'' FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

Repackaged drugs are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. For example, repackaged drugs are generally subject to the premarket approval, misbranding, adulteration, and drug supply chain security provisions of the FD&C Act, including section 505 (concerning new drug applications), section 502(f)(1) (concerning labeling with adequate directions for use), section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)), and section 582 (drug supply chain security requirements) (21 U.S.C. 355, 352(f)(1), 351(a)(2)(B), and 360eee–1).

Further, drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b). Therefore, drugs repackaged by state-licensed pharmacies, Federal facilities, or outsourcing facilities are not eligible for the exemptions provided under those sections.

This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), 582, and, where specified in the guidance, section 501(a)(2)(B) of the FD&C Act, when a state-licensed pharmacy, Federal facility, or outsourcing facility repackages certain drug products.

In the **Federal Register** of February 19, 2015 (80 FR 8884), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on May 20, 2015. FDA received approximately 625 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. For example, FDA removed from the guidance the condition concerning ''anticipatory repackaging'' (repackaging before the receipt of a patient-specific prescription) of no more than a 14-day supply. FDA made this change partly in response to comments indicating that pharmacies sometimes need to repackage more than a 14-day supply of repackaged drug products in advance of a prescription. FDA also revised the conditions concerning beyond-use-dates (BUDs) for repackaged drugs to reflect BUDs for compounded drugs in, as applicable, United States Pharmacopeia (USP) Chapter <795>, the USP's proposed revision to Chapter <797>, and FDA's guidance concerning current good manufacturing practice requirements for outsourcing facilities.

FDA received comments on the draft guidance from hospital organizations regarding the potential implications of the proposed policies in the draft guidance concerning patient-specific prescriptions for drugs repackaged for in-patient settings. The final guidance notes that FDA is considering the applicability of the policies described in this guidance to in-patient settings, including long-term care facilities and hospitals, and intends to address these issues in separate guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on repackaging human drug products by pharmacies, Federal facilities, and outsourcing facilities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of February 19, 2015, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance (80 FR 8884 at 8885).

After publishing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal Agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, we will be submitting a proposed collection of information to OMB for review and clearance. FDA is issuing this guidance as final with portions of it subject to OMB approval of the collection of information and shaded gray. Those provisions that are shaded gray and subject to OMB approval will be final if the collection of information is approved. If the collection is approved, FDA will publish a notice in the **Federal Register** concerning OMB approval and providing an OMB control number for these provisions.

The guidance also references registration and adverse event reporting for outsourcing facilities. The collections of information for outsourcing facility registration have been approved by OMB under OMB control number 0910–0777. The collections of information for adverse event reporting by outsourcing facilities have been approved by OMB under OMB control number 0910–0800.

III. Electronic Access

Persons with access to the Internet can obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00723 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1543]

Nonproprietary Naming of Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Nonproprietary Naming of Biological Products.'' The guidance describes our current thinking on the need for biological products previously and newly licensed under the Public Health Service Act (PHS Act) to bear nonproprietary names that include FDA-designated suffixes. Accordingly, we intend to designate nonproprietary names for originator biological products, related biological products, or biosimilar products which will include a core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. This guidance finalizes the draft guidance issued on August 28, 2015.

FDA is also 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: Submit either electronic or written comments on Agency guidances at any time. Submit written comments on the collection of information by February 13, 2017.

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—New and title ''Nonproprietary Naming of Biological Products.'' Also include the FDA docket number found in brackets in the heading of this document.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1543 for ''Nonproprietary Naming of Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042; or Stephen Ripley, 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. *Regarding the information collection:* FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonproprietary Naming of Biological Products.'' The guidance describes our current thinking on the need for biological products licensed under section 351(a) and (k) of the PHS Act (42 U.S.C. 262(a) and (k)) to bear a nonproprietary name that includes an FDA-designated suffix. Under this naming convention, the nonproprietary name designated for each originator biological product, related biological product, and biosimilar product will be a proper name that is a combination of the core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. The suffix format described in this guidance is applicable to originator biological products, related biological products, and biosimilar products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act. FDA is continuing to consider the appropriate suffix format for interchangeable biological products.

This naming convention will facilitate pharmacovigilance for originator biological products, related biological products, and biosimilar products containing related drug substances when other means to track a specific dispensed product are not readily accessible or available. Distinguishable nonproprietary names will also facilitate accurate identification of these biological products by health care practitioners and patients. Further, distinguishing suffixes should help minimize inadvertent substitution of any such products that have not been determined to be interchangeable. Application of the naming convention to biological products licensed under the PHS Act should (1) encourage routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices and (2) avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway, as described in detail in the guidance.

The guidance provides information to industry, the health care community, other regulatory agencies, and the public on FDA's rationale for this naming convention. The guidance is also intended to assist applicants and application holders in proposing the suffix to be incorporated into an originator biological product, related biological product, or biosimilar product's nonproprietary name.

In the **Federal Register** of August 28, 2015 (80 FR 52296), FDA announced the availability of the draft guidance of the same title. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In the notice announcing the draft guidance, FDA asked about the benefits and challenges of designating (1) a suffix that is devoid of meaning versus meaningful (*e.g.,* derived from the name of the license holder) and (2) a suffix that is unique to each biological product versus shared by each biological product manufactured by that license holder. FDA determined that the suffix format that best achieves the goals described in the guidance is a suffix that is devoid of meaning and not shared by each biological product manufactured by that license holder.

FDA intends to apply a naming convention to interchangeable products that will feature a core name and a suffix included in the proper name; however, FDA is continuing to consider the appropriate format of the suffix for these products.

This guidance also will apply to those biological products that are approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) on or before March 23, 2020, when such products are deemed to be licensed under section 351 of the PHS Act on March 23, 2020 (section 7002(e)(2) through (e)(4) of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act)). FDA intends to provide additional guidance regarding administrative issues associated with the transition (including the process for implementing the naming convention described in this guidance).

For the purposes of the guidance, unless otherwise specified, references to biological products include biological products licensed under the PHS Act, such as therapeutic protein products, vaccines, allergenic products, and blood derivatives, and do not include certain biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), such as in vitro reagents (*e.g.,* antibody to hepatitis B surface antigen, blood grouping reagents, hepatitis C virus encoded antigen) and blood donor screening tests (*e.g.,* HIV and hepatitis C). Also, for the purposes of the

guidance, unless otherwise specified, references to biological products do not include products for which a proper name is provided in the regulations (*e.g.,* 21 CFR part 640) or to certain categories of biological products for which there are well-established, robust identification and tracking systems to ensure safe dispensing practices and optimal pharmacovigilance (*e.g.,* ISBT 128 for cord blood products and blood components).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonproprietary naming of biological products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

II. Paperwork Reduction Act of 1995, Nonproprietary Naming of Biological Products, OMB Control Number 0910—New

The guidance describes FDA's current thinking on the need for biological products licensed under the PHS Act to bear a nonproprietary name that includes an FDA-designated suffix. There is a need to clearly identify biological products to facilitate pharmacovigilance and safe use. Accordingly, for originator biological products, related biological products, or biosimilar products licensed under the PHS Act, FDA intends to designate a nonproprietary name that includes a core name and a distinguishing suffix. This naming convention is applicable to biological products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act.

The final guidance proposes a new collection of information by requesting that applicants and application holders propose a suffix composed of four lowercase letters for use as the suffix included in the proper name. The proper name is designated by FDA in the license for biological products licensed under the PHS Act. The suffix will be incorporated in the nonproprietary name of the product. The guidance recommends that applicants and application holders submit up to 10 proposed suffixes, in the order of the applicant's preference. FDA also recommends including supporting analyses demonstrating that the proposed suffixes meet the factors described in the final guidance for FDA's consideration.

As indicated in table 1, we estimate that we will receive a total of approximately 40 requests annually for the proposed proper name for biological products submitted under section 351(a) of the PHS Act and six requests annually for the proposed proper name for biological products submitted under section 351(k) of the PHS Act. The average burden per response (hours) is based on the Agency's experience with similar information collection requirements for applicants to create and submit suffix proposals to FDA.

As noted, in the **Federal Register** of August 28, 2015, FDA published a 60-day notice requesting public comment on the proposed collection of information. Most comments supported FDA's proposal to designate a suffix. Many comments suggested that a meaningful, distinguishable suffix may help to improve pharmacovigilance, enhance safety, and facilitate identification between biological products. Some comments supported use of a random suffix to avoid creating an unfair advantage for specific manufacturers. Several comments stated that the current practices of FDA and non-FDA entities for identifying products is sufficient for the purpose of pharmacovigilance, and designation of a suffix is not needed. One comment stated that FDA's estimate of 6 hours to submit proposed suffixes is based only on the time needed to prepare the submission itself after the multiple suffixes have been selected. The comment further stated that because FDA suggests that each respondent submit three suggested suffixes for Agency consideration, the time needed to do an analysis of each suffix would exceed 720 hours per suffix (based on their own company experience) or 2,160 hours total for the three suffixes. The commenter subsequently submitted additional information to clarify how the estimates were calculated.

Response: FDA's estimate of the annual reporting burden results from information that would be submitted to FDA by applicants in order to facilitate FDA's designation of a suffix as part of the proper name of a biological product. We estimated that sponsors would spend 2 hours completing the submission for each of the three suffixes, resulting in 6 hours as the average burden. This estimate for submission of the requested information is based on the average number of responses per respondent and the average burden per response over a 3-year period. FDA understands that there is a certain amount of research and other costs that an applicant might encounter in analyzing any proposed name for a biological product. FDA also recognizes that the burden may be higher for some applicants and lower for other applicants based on a variety of factors specific to the applicant.

The comment suggests that it will take 720 hours to complete an analysis and submission for each suffix. We have considered the information provided in support of this estimate and believe the estimate is likely too high. Our original estimate of 6 hours was based on the Agency's familiarity with the time it would take to make similar submissions to FDA. However, as identified by the comment, FDA's original estimate failed to adequately account for the time spent on creating proposed suffixes. We have reconsidered our original estimate as a result of the comment, and we have revised our estimate to account for the burden to create and submit up to 10 proposed suffixes to FDA for designation. As indicated in table 1, we estimate an average burden of approximately 420 hours to account for creating and submitting multiple proposed suffixes.

FDA estimates the information collection burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(a) of the PHS Act	20	2	40	420	16,800

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(k) of the PHS Act	3	2	6	420	2,520
Total					19,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information related to the submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products) has been approved under OMB control number 0910–0719. The guidance also refers to a previously approved collection of information found in FDA regulations that is expected to change as a result of the guidance and the retrospective application of the naming convention. The collections of information in 21 CFR part 601 related to the submission of a biologics license application (BLA) and changes to an approved application have been approved under OMB control number 0910–0338. As a result of the guidance, the estimated number of additional responses for the annual burden for changes to an approved application under § 601.12 would be increased by approximately 25 responses.

FDA is issuing this final guidance subject to OMB approval of the collections of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00694 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–3389]

Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request For Scientific Data, Information, and Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the document requesting scientific data, information, and comments entitled ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates'' that appeared in the **Federal Register** of November 23, 2016 (81 FR 84595). In the document, we requested scientific data, information, and comments to help us determine whether a particular isolated or synthetic non-digestible carbohydrate should be added to our definition of ''dietary fiber'' for purposes of being declared as dietary fiber on a Nutrition Facts or Supplement Facts label. We also announced in the document the availability for comment of a scientific literature review document that we conducted that summarizes clinical studies associated with 26 specific isolated or synthetic non-digestible carbohydrates. We are taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by February 13, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–3389 for ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at

http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2579.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 2016 (81 FR 84595), we published a document requesting scientific data, information, and comments that would help us evaluate the beneficial physiological effects to human health of isolated or synthetic non-digestible carbohydrate that are added to food. We requested such scientific data, information, and comments to help us determine whether a particular isolated or synthetic non-digestible carbohydrate should be added to our definition of ''dietary fiber'' that is found in the Nutrition and Supplement Facts label final rule, which appeared in the **Federal Register** of May 27, 2016 (81 FR 33741). Only those isolated or synthetic non-digestible carbohydrates that meet the definition can be declared as a dietary fiber on a Nutrition and Supplement Facts label. The notice also announced the availability of a document entitled ''Science Review of Isolated and Synthetic Non-Digestible Carbohydrates,'' which summarizes a scientific literature review that we conducted of clinical studies associated with the 26 specific isolated or synthetic non-digestible carbohydrates. We provided a 45-day comment period that ended on January 9, 2017.

We have received requests to extend the period during which interested parties may submit scientific data, information, and comments regarding isolated or synthetic non-digestible carbohydrates generally and regarding our scientific literature review summary document specifically. The requests conveyed concern that the original 45-day comment period would not allow sufficient time to develop meaningful or thoughtful scientific data, information, or comments.

We have considered the requests but were unable to issue a notice extending the comment period before January 9, 2017. Consequently, we are reopening the comment period for an additional 30 days. Interested parties have until February 13, 2017, to submit scientific data, information, or comments to the docket. We believe that this action allows adequate time for interested persons to submit additional scientific data, information and comments.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00725 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0086]

Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council; Establishment of a Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on policy issues that may be considered by the FDA Combination Product Policy Council (Council). These comments will help the Agency identify and address combination product policy issues that need clarification through guidance, notice and comment procedures, or other means.

DATES: Submit either electronic or written comments by April 13, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–0086 for ''Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Nina L. Hunter, Office of Medical Products and Tobacco (OMPT), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2312, Silver Spring, MD 20993–0002, 301–796–6171, FAX: 301–847–8514, *CombinationProductCouncil@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In April 2016, FDA established the Council to ensure better coordination of combination product policy development and implementation across the Agency and consistent, predictable communication of combination product policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by the Deputy Commissioner of OMPT, the Council provides a senior-level forum through which combination product policy issues can be raised, considered, developed, and implemented. Council members include the following senior leaders: The Center Directors and one representative from the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health; the Office Director from the Office of Combination Products (OCP); and the Associate Commissioner for Special Medical Programs. Additional staff from the Centers and other FDA offices provide expertise as needed for specific combination product policy topics under consideration. While there are various other mechanisms available to raise issues for Agency consideration, by establishing this docket, FDA seeks to provide a forum for the public to recommend specific topics that should have direct, collective engagement and consideration by the Council. The Agency believes that this process will also further enhance transparency in FDA's approach to policy development and implementation.

II. Range of Policy Issues To Be Considered

FDA envisions a variety of combination product policy topics that may be appropriate for consideration by the Council, which typically would meet one or more of the following criteria:

- A novel combination product policy issue requiring senior management input;
- An identical issue on which FDA seems to have taken inconsistent combination product policy positions;
- An existing combination product policy position that should be reconsidered in light of scientific or regulatory advances; or
- A combination product policy that may be triggered by a specific combination product, but that will be applicable to other combination products.

III. Establishment of a Docket and Request for Comments

The docket is being made available for public suggestions, recommendations, and comments relating to the combination product policy criteria identified in this document that may warrant consideration by the Council. Submissions should describe the following: (1) The combination product policy issue recommended for discussion (*e.g.,* clarifying previous advice or precedents on a specified combination product policy topic, reconciling apparently differing perspectives within FDA or between FDA and regulated industry on a specified combination product policy topic); (2) the rationale for doing so, including why it requires direct engagement by the Council; (3) recommendations on how the combination product policy issue could be addressed; and (4) existing policy documents (*e.g.,* final guidance) relevant to the combination product policy issue.

Note that combination product policy issues concerning any draft guidance or proposed rule should be submitted to the docket for that draft guidance or rulemaking; product-specific disputes should first be addressed through the appropriate appeals mechanism of the Center or other Agency component involved; and general recommendations for topics to address through guidance or rulemaking should be made to the Center, OCP, or other relevant Agency component through the mechanisms provided by that component.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the

comment. In general, combination product policy decisions reached by the Council are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00646 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0040]

How To Prepare a Pre-Request for Designation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''How to Prepare a Pre-Request for Designation (Pre-RFD).'' The purpose of this guidance is to explain the Pre-RFD process at the FDA Office of Combination Products (OCP), describe and help a sponsor understand the type of information that the sponsor should include in a Pre-RFD, and assist sponsors in obtaining a preliminary assessment from FDA through the Pre-RFD process. The Pre-RFD process is available to provide informal, non-binding feedback regarding the regulatory identity or classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 13, 2017. Submit either written or electronic comments on this collection of information by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0040 for ''How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry.''

Submit written requests for single copies of the draft guidance document entitled ''How to Prepare a Pre-Request for Designation (Pre-RFD)'' to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8619. See the **SUPPLEMENTARY**

INFORMATION section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Leigh Hayes, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, or via email at *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their product. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biologic, or a combination product, and which FDA medical product Center (CDER, CBER, or CDRH) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see ''How to Write a Request for Designation'' at *http://www.fda.gov/Regulatory Information/Guidances/ ucm126053.htm*). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to FDA. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the ''Pre-Request for Designation (Pre-RFD) Program.''

This draft guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on how to prepare a Pre-RFD. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry; How To Prepare a Pre-Request for Designation (Pre-RFD)

This draft guidance describes how to prepare a Pre-RFD. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between OCP, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Pre-RFD submissions	136	1	136	12	1,632
Pre-RFD meetings	136	1	136	1	136
Total					1,768

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are product sponsors and industry representatives subject to FDA's laws and regulations. FDA estimates that it will receive approximately 136 Pre-RFDs annually. The Agency reached this estimate through its experience with the formal Request for Designation (RFD) program, by reviewing the number of informal, pre-RFD inquiries from sponsors that the Agency received over the past 3 years. Based on FDA's experience with

these informal, Pre-RFD inquiries, FDA expects the proposed Pre-RFD program to be utilized as a viable program in the future and expects that the number of Pre-RFDs will increase initially to approximately 180 submissions.

FDA estimates from past experience with informal Pre-RFD inquiries that the complete process involved with preparing the Pre-RFD submission takes approximately 12 hours and an additional 1 hour for meetings.

This average is based upon estimates by FDA administrative and technical staff who are familiar with the information collection relating to informal, Pre-RFD inquiries, who have consulted and advised sponsors and industry representatives on the information collection, and who have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 1,768 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of respondents	Total burden hours annualized	Hourly wage rate	Total cost annualized
136	13	$33.26	$58,803.68

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Assuming an hourly wage plus benefit rate of $33.26,[1] the result is a cost of $432.38 per respondent. The estimated submission cost of $432.38 multiplied by 136 submissions per year equals $58,803.68, which is the estimated aggregated industry reporting cost annualized.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 3 are approved under OMB control number 0910–0523.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm534661.htm.*

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00629 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

[1] Wage is based on the 2015 Bureau of Labor Statistic's survey, National Industry Specific Occupational Employment and Wage Estimate, for standard occupational code 13–1041, compliance officer in pharmaceutical and medicine manufacturing (*http://www.bls.gov/oes/current/oes131041.htm*).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4460]

Multiple Endpoints in Clinical Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Multiple Endpoints in Clinical Trials.'' This draft guidance provides sponsors and review staff with the Agency's thinking about the problems posed by multiple endpoints in the analysis and interpretation of study results and how these problems can be managed in clinical trials for human drugs, including drugs subject to licensing as biological products. Most clinical trials performed in drug development contain multiple endpoints to assess the effects of the drug and to document the ability of the drug to favorably affect one or more disease characteristics. The purpose of this guidance is to describe various strategies for grouping and ordering endpoints for analysis and applying some well-recognized statistical methods for managing multiplicity within a study to control the chance of making erroneous conclusions about a drug's effects.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–4460 for ''Multiple Endpoints in Clinical Trials; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Scott Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Multiple Endpoints in Clinical Trials.'' This guidance describes various strategies for grouping and ordering endpoints for analysis and applying some well-recognized statistical methods for managing multiplicity within a study. FDA's International Conference on Harmonization (ICH) guidance for industry ''E9 Statistical Principles for Clinical Trials'' is a broad-ranging guidance that includes discussion of multiple endpoints. This draft guidance provides greater detail on the topic of multiple endpoints. The issuance of this draft guidance represents partial fulfillment of an FDA commitment under the Food and Drug Administration Amendments Act of 2007. (Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85)). Under section XI (Expediting Drug Development) of the Prescription Drug User Fee Act (PDUFA) Performance Goals, FDA agreed to develop and publish for comment draft guidance on ''Multiple Endpoints in Clinical Trials,'' and to complete the final guidance within one year of the close of the public comment period of the PDUFA Performance Goals (see *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

Failure to account for multiplicity when there are several clinical endpoints evaluated in a study can lead to false positive conclusions regarding the effects of the drug. The regulatory concern regarding multiplicity arises principally in the evaluation of clinical trials intended to demonstrate effectiveness and support drug approval; however, this issue is important throughout the drug development process.

The focus of this draft guidance is control of the Type 1 error rate for the planned primary and secondary endpoints of a clinical trial so that the major findings are well supported. Multiplicity adjustments provide a means for controlling Type 1 error when there are multiple analyses of the drug's effects. The issues of multiplicity and methods to address them are illustrated in the draft guidance with examples of different study endpoints. Both the issues and methods that apply to multiple endpoints also apply to other sources of multiplicity, including multiple doses, time points, or study population subgroups.

Once a trial is successful (demonstrates effectiveness or ''wins'' on the primary endpoint(s)), there are many other attributes of a drug's effects that may be described. Analyses that describe these other attributes of a drug can be informative and are often included in physician labeling. Such descriptive analyses are not the subject of this draft guidance and are not addressed in detail.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on multiple endpoints in clinical trials. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00695 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1496]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of rapid response surveys to obtain data on safety information to support quick turnaround decisionmaking about potential safety problems or risk management solutions from health care professionals, hospitals, and other user facilities (*e.g.,* nursing homes, etc.); consumers; manufacturers of biologics, drugs, and medical devices; distributors; and importers, when FDA must quickly determine whether or not a problem with a biologic, drug, or medical device impacts the public health.

DATES: Submit either electronic or written comments on the collection of information by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–1496 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys (Generic Clearance).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA Rapid Response Surveys (Generic Collection), OMB Control Number 0910–0500—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. Under section 519 of the FD&C Act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-

related deaths, serious injuries, and malfunctions to FDA; to require user facilities to report device-related deaths directly to FDA and to manufacturers; and to report serious injuries to the manufacturer. Section 522 of the FD&C Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the FD&C Act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the FD&C Act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for Agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently, FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system.

FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to quickly obtain vital information about medical product risks and interventions to reduce risks so the Agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

FDA projects 6 emergency risk related surveys per year with a sample of between 50 and 10,000 respondents per survey. FDA also projects a response time of 0.5 hour per response. These estimates are based on the maximum sample size per questionnaire that FDA may be able to obtain by working with health care professional organizations. The annual number of surveys was determined by the maximum number of surveys per year FDA has ever conducted under this collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Survey	10,000	6	60,000	0.5	30,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00632 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1777]

Factors To Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions; Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions.'' The purpose of this guidance is to provide greater clarity for FDA staff and Investigational Device Exemptions (IDE) application sponsors and sponsor-investigators regarding the principal factors that the Agency considers when assessing the benefits and risks of IDE applications for human clinical study. The guidance also characterizes benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your

comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–1777 for ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Karen Ulisney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1545, Silver Spring, MD 20993–0002, 301–796–5513; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A primary goal of this guidance is to clarify the factors that FDA considers when assessing risks and anticipated benefits for IDE studies, and how uncertainty may be offset by a variety of risk mitigation measures that can ensure appropriate patient and participant protections in investigational research settings. At earlier stages of device development, FDA considers appropriate mitigation measures for anticipated possible risks and unanticipated risks, whereas in later stages, risk mitigation focuses increasingly on the most probable risks. Another important goal of this guidance is to characterize benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others (to the extent there are indirect benefits to subjects or reflect the importance of knowledge to be gained).

As with the benefit-risk framework for evaluating marketing applications, FDA assessment of benefits and risks for an IDE application takes into account the contextual setting in which the study is being proposed, including, but not limited to, the characterization of the disease or condition being treated or diagnosed, the availability of alternative treatments or diagnostics, and the risks associated with them. When available, information characterizing subject tolerance for risk and perspective on benefit may provide useful context during this assessment.

In the **Federal Register** on June 18, 2015 (80 FR 34909), FDA announced the availability of the draft guidance and interested parties were requested to comment by September 16, 2015. FDA has considered all of the public comments received prior to finalizing this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance Regulatoryinformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1783 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 50.23 (Exception from general requirements for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR 56.115 (Institutional Review Board records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 50, subpart B (Informed Consent of Human Subjects) and part 56 (Institutional Review Boards) have been approved under OMB control number 0910–0755.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00604 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1525]

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application; Revised Draft Guidance For Industry; Availability

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' This revised draft guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, a Federal facility, or an outsourcing facility that mixes, dilutes, or repackages certain biological products outside the scope of an approved biologics license application (BLA). It also describes the conditions under which FDA does not intend to take action when a State-licensed pharmacy, a Federal facility, an outsourcing facility, or a physician prepares prescription sets of allergenic extracts for subcutaneous immunotherapy. This revised draft guidance for industry replaces the draft guidance for industry of the same title issued in February 2015.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1525 for ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20903, 301–796–3110; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' Certain licensed biological products may sometimes be mixed, diluted, or repackaged in a way not described in the approved labeling for the product to meet the needs of a specific patient. For example, for some biological products there is no licensed pediatric strength and/or dosage form. In addition, there may be certain circumstances when a person would remove a licensed biological product from its original container and place it into a different container(s) (repackage it), in a manner that is not within the scope of the approved labeling for the product. As described in the draft guidance, mixed, diluted, or repackaged biological products are not eligible for the statutory exemptions available to certain compounded drugs under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 353b). In addition, a biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is considered an unlicensed biological product under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262).

This draft guidance describes the conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and section 502(f)(1) (21 U.S.C. 352(f)(1)), section 582 (21 U.S.C. 360eee–1), and where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) of the FD&C Act, when a state-licensed pharmacy, a Federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance, when finalized, will represent FDA's current thinking on mixing, diluting, and repackaging of biological products not within the scope of the product's approved BLA as described in the approved labeling for the product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the annual reporting and recordkeeping 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 the collection of information.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance includes the following collection of information under the PRA.

One condition described in the draft guidance is that if the labeling for the licensed biological product includes storage and/or handling instructions (*e.g.,* protect from light, do not freeze, keep at specified storage temperature), the labeling for the biological product that is mixed, diluted, or repackaged specifies the same storage conditions.

Another condition described in the draft guidance is that, if the biological product is mixed, diluted, or repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the mixed, diluted, or repackaged product includes the following information:

- The statement ''This biological product was mixed/diluted by [name of outsourcing facility],'' or ''This product was repackaged by [name of outsourcing facility],'' whichever statement is appropriate;
- The address and phone number of the outsourcing facility that mixed, diluted, or repackaged the biological product;
- The proper name of the original biological product that was mixed, diluted, or repackaged;
- The lot or batch number of the mixed, diluted, or repackaged biological product;
- The dosage form and strength;
- A statement of either the quantity or the volume of the mixed, diluted, or repackaged biological product, whichever is appropriate;
- The date the biological product was mixed, diluted, or repackaged;
- The beyond-use-date (BUD) of the mixed, diluted, or repackaged biological product;
- Storage and handling instructions for the mixed, diluted, or repackaged biological product;
- The National Drug Code (NDC) number of the mixed, diluted, or repackaged biological product, if available; [1]
- The statement ''Not for resale,'' and, if the biological product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement ''Office Use Only''; and
- If included on the label of the FDA-licensed product from which the biological product is being mixed, diluted, or repackaged, a list of the active and inactive ingredients; and if the biological product is mixed or diluted, a list of any ingredients that appear in the mixed or diluted product in addition to those ingredients that are on the label of the original FDA-licensed biological product.

In addition, the draft guidance includes as a condition for biological products mixed, diluted, or repackaged by an outsourcing facility that, if the immediate product label is too small to bear the active and inactive ingredients, such information should be included on the label of the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed).

The draft guidance also describes the condition for biological products mixed, diluted, or repackaged by an outsourcing facility that the label on the container from which the individual units are removed for administration

[1] The NDC number of the original licensed biological product should not be placed on the mixed, diluted, or repackaged biological product.

include directions for use, including, as appropriate, dosage and administration, and the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088.

Finally, the draft guidance described a condition for biological products repackaged by an outsourcing facility for which the BUD is established based on a stability program conducted in accordance with Appendix A of the draft guidance, that the outsourcing facility maintains records of the testing performed in accordance with Appendix A.

We estimate that annually a total of approximately 15 outsourcing facilities that mix, dilute, or repackage biological products (''Number of Respondents'' in table 1, row 1) will each design, test, and produce approximately five different labels (''Frequency per Disclosure'' in table 1, row 1), for a total of 75 labels that include the information set forth in section III.B of the draft guidance (including directions for use) as well as inclusion of storage and/or handling instructions (''Total Disclosures'' in table 1, row 1). We also estimate that designing, testing, and producing each label will take approximately 0.5 hours (''Hours per Disclosure'' in table 1, row 1). The provision to add *http://www.fda.gov/medwatch* and 1–800–FDA–1088 is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Section III.C of the draft guidance discusses the preparation of prescription sets (*i.e.,* licensed allergenic extracts that are mixed and diluted to provide subcutaneous immunotherapy to an individual patient) by a physician, State-licensed pharmacy, a Federal facility, or outsourcing facility. One of the conditions described in the draft guidance is if the prescription set is mixed or diluted by an outsourcing facility, the label on the immediate container of the prescription set (primary packaging) includes:

- The patient's name as identified on the prescription or order;
- The statement ''This prescription set was prepared by [name of outsourcing facility]'';
- The address and phone number of the outsourcing facility that prepared the prescription set;
- The identity of each allergenic extract in the prescription set and the quantity of each;
- The dilution of each dilution vial;
- The lot or batch number of the prescription set;
- The date the prescription set was prepared;
- The BUD as the expiry date for the prescription set;
- Storage and handling instructions for the prescription set; and
- The statement ''Not for resale.''

Another condition under the draft guidance is that if the prescription set is prepared by an outsourcing facility, the label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: *http://www.fda.gov/medwatch* and 1–800–FDA–1088. Each prescription set prepared by an outsourcing facility is also accompanied by instructions for use.

We estimate that annually a total of approximately five outsourcing facilities that prepare prescription sets (''Number of Respondents'' in table 2, row 1) will each include the information set forth in section III.C of the draft guidance (including directions for use) on the labels, packages, and/or containers of approximately 300 prescription sets (''Frequency per Disclosure'' in table 2, row 1) for a total of 1500 disclosures (''Total Disclosures'' in table 2, row 1). We also estimate that the initial process of designing, testing, and producing, and attaching each label, package, and/or container to each prescription set will take approximately 0.5 hours (''Hours per Disclosure'' in table 2, row 1). The provision to add ''*http://www.fda.gov/medwatch*'' and ''1–800–FDA–1088'' is not included in this burden estimate because it is not considered a collection of information under the PRA because the information is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

We estimate that annually a total of approximately 5 outsourcing facilities that repackage biological products and establish a BUD in accordance with Appendix A (''No. of Recordkeepers'' in table 3) will maintain approximately 150 records of the testing, as described in Appendix A (''total annual records'' in table 3). We estimate that maintaining the records will take approximately 5 minutes per record.

The total estimated third-party disclosure burden resulting from the draft guidance is as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Biological product mixing, diluting, and repackaging	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product.	15	5	75	0.5 (30 minutes)	37.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Preparation of prescription sets	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers.	5	300	1,500	0.5 (30 minutes)	750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records that the outsourcing facility maintains of the testing performed in accordance with Appendix A of the guidance.	5	30	150	0.083 (5 minutes)	12.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The draft guidance also references registration, adverse event reporting, product reporting, and current good manufacturing practice (CGMP) requirements for outsourcing facilities. The collections of information for outsourcing facility registration have been approved by the Office of Management and Budget (OMB) under OMB control number 0910–0777 (79 FR 69859). The collections of information for adverse event reporting by outsourcing facilities have been approved by OMB under OMB control number 0910–0800 (80 FR 60917). In the **Federal Register** of December 4, 2013 (78 FR 72897), FDA estimated the burden resulting from outsourcing facility electronic drug product reporting. In the **Federal Register** of July 2, 2014 (79 FR 37743), FDA estimated the burden resulting from outsourcing facility compliance with CGMP requirements.

IV. Electronic Access

Persons with access to the Internet can obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.*

Dated: January 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00722 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4645]

180-Day Exclusivity: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''180-Day Exclusivity: Questions and Answers.'' This draft guidance is intended to address questions that have been raised about the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that relate to generic drug exclusivity, which commonly is known as ''180-day exclusivity'' for generic drug products. As a general matter, FDA has implemented these statutory provisions within the context of application-specific decisions. Some FDA decisions have been made publicly available (*e.g.,* in FDA citizen petition responses and documents released in litigation). FDA believes that a guidance for industry that provides answers to commonly asked questions about 180-day exclusivity would enhance transparency and facilitate the development, approval, and timely marketing of generic drug products. FDA intends to update this guidance to include additional questions and answers as appropriate.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 14, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–4645 for ''180-Day Exclusivity: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Harry Schwirck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1672, Silver Spring, MD 20993–0002, 301–796–4271; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''180-Day Exclusivity: Questions and Answers.'' This draft guidance is intended to address questions that have been raised about the provisions of the FD&C Act, which relate to 180-day exclusivity for generic drug products. These provisions provide an incentive and reward to generic drug applicants that expose themselves to the risk of patent litigation that may arise during the abbreviated new drug application (ANDA) process (see section 505(j) of the FD&C Act (21 U.S.C. 355(j)). It does so by providing for a 180-day period of marketing exclusivity vis-a-vis certain other ANDA applicants to the first applicant(s) who are eligible for the exclusivity under applicable statutory provisions (see section 505(j)(2) and (j)(5) of the FD&C Act).

FDA has received a number of questions about 180-day exclusivity and has identified commonly asked questions for inclusion in the guidance. FDA expects the information provided in the guidance to enhance transparency and facilitate the development, approval, and timely marketing of generic drug products. FDA intends to update the guidance to include additional questions and answers as appropriate.

The draft guidance contains questions and answers organized according to subject matter. The subject areas are: Applicable statutory scheme, first applicants, 180-day exclusivity and patents, 180-day exclusivity trigger and scope, 180-day exclusivity relinquishment and waiver, forfeiture of 180-day exclusivity, and procedural questions regarding 180-day exclusivity determinations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''180-Day Exclusivity: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00631 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1025]

Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry and other stakeholders entitled ''Emergency Use Authorization of Medical Products and Related Authorities.'' The purpose of this guidance is to explain FDA's current thinking on the authorization of the emergency use of certain medical products under certain sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents, including emerging infectious disease threats.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1025 for ''Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–8510. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4320, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and other stakeholders entitled ''Emergency Use Authorization of Medical Products and Related Authorities.'' This guidance explains FDA's general recommendations and procedures applicable to the authorization of the emergency use of certain medical products under sections 564, 564A, and 564B of the FD&C Act [1] (21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b) as amended or added by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) [2] (Pub. L. 113–5). The provisions in PAHPRA include key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving CBRN agents, including emerging infectious disease threats such as pandemic influenza. PAHPRA clarifies and enhances FDA's authority to support emergency preparedness and response and foster the development and availability of medical products for use in these emergencies. These medical products, also referred to as ''medical countermeasures'' (MCMs) include drugs (*e.g.,* antivirals and antidotes), biological products (*e.g.,* vaccines, blood products, and biological therapeutics), and devices (*e.g.,* in vitro diagnostics and personal protective equipment).

This guidance finalizes the draft guidance ''Emergency Use Authorization of Medical Products and Related Authorities'' (April 2016) and replaces the following two guidance documents, ''Emergency Use Authorization of Medical Products'' (July 2007) and ''Emergency Use Authorization Questions and Answers'' (April 2009). The public comments received on the draft guidance have been considered and the guidance has been revised to clarify issues raised as appropriate. This guidance is intended to inform industry and government sponsors and other stakeholders involved in emergency response activities, including government agencies and public health and emergency response stakeholders, and FDA staff of FDA's general recommendations and procedures for:

• Issuance of Emergency Use Authorizations (EUAs) under section 564 of the FD&C Act;

• Implementation of the emergency use authorities set forth in section 564A of the FD&C Act; and

• Reliance on the governmental pre-positioning authority set forth in section 564B of the FD&C Act.

Section 564 of the FD&C Act, as amended by PAHPRA, permits the

[1] Section 564 was first added to the FD&C Act by the Project BioShield Act of 2004 (Pub. L. 108–276).

[2] Section 3088 of the 21st Century Cures Act, signed into law by the President on December 13, 2016, (Pub. L. 114–255) amends sections 564, 564A, and 564B of the FD&C Act to add new authorities to: (1) Authorize emergency use of unapproved animal drugs; (2) make applicable other emergency use authorities (*e.g.,* to issue emergency dispensing orders, waive compliance with current good manufacturing practices), make available Centers for Disease Control and Prevention emergency use instructions, and extend expiration dates to approved animal drugs; and (3) allow unapproved animal drugs to be held for emergency use. While much of what is described in this guidance will apply to these new authorities, this guidance does not by its terms reference them; FDA asks anyone interested in utilizing these authorities to contact FDA directly to discuss how to proceed. FDA plans to review these new authorities and address any new procedural issues raised as we develop more experience with these new authorities.

Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Department of Health and Human Services (HHS) Secretary has made a declaration of an emergency or threat justifying emergency use. That declaration by the HHS Secretary must in turn be based on a determination of an emergency or potential emergency or material threat associated with the CBRN agent by, respectively, the Secretary of Homeland Security, the Secretary of Defense, or the HHS Secretary. The Commissioner may issue an EUA to allow an MCM to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a CBRN agent, or by a product used to diagnose, treat, or prevent such diseases or conditions, when available data meet specified criteria to support such uses and there are no adequate, approved, and available alternatives.

Section 564A, as added by PAHPRA, establishes streamlined mechanisms to facilitate preparedness and response activities involving certain FDA-approved MCMs without FDA issuing EUAs, which can be a resource-intensive process. These authorities, which apply only to eligible FDA-approved medical products intended for use during a CBRN emergency, include provisions that:

- Empower FDA to extend the expiration date of an eligible FDA-approved MCM stockpiled for use in a CBRN emergency, and establish appropriate conditions relating to such extensions, such as appropriate storage, sampling, and labeling;
- Permit FDA to waive otherwise applicable current good manufacturing practice requirements (*e.g.,* storage or handling) to accommodate emergency response needs;
- Allow emergency dispensing of MCMs during an actual CBRN emergency event without requiring an individual prescription, or all of the information otherwise required, for each recipient of the MCM; and
- Permit the Centers for Disease Control and Prevention to create and issue ''emergency use instructions'' concerning the FDA-approved conditions of use for eligible products.

These authorities, and the definition of eligible products to which they apply, are discussed in this guidance.

To enable stakeholders to prepare for potential rapid deployment of MCMs during an actual CBRN emergency, section 564B (also added by PAHPRA) permits Federal, State, and local governments to pre-position (*e.g.,* stockpile, forward-deploy) MCMs in anticipation of FDA approval or clearance, authorization of an investigational use, or the issuance of an EUA. This authority is also discussed in this document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on emergency use authorization of medical products and related authorities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/regulatoryinformation/Guidances/default.htm, http://www.regulations.gov,* or *http://www.fda.gov/medicalcountermeasures.*

IV. Paperwork Reduction Act of 1995

This guidance 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). This guidance refers to previously approved collections of information. These collections of information have been approved under OMB control numbers 0910–0308, 0910–0230, 0910–0471, 0910–0014, 0910–0078 and 0910–0595. The collection of information in this guidance was approved under OMB control number 0910–0595.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00721 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The theme of the February meeting will be clinical trials for Alzheimer's disease and related dementias and recruitment challenges. Additional presentations in the afternoon will include updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017.

DATES: The meeting will be held on Friday, February 3, 2017 from 9:00am to 5:00pm EDT.

ADDRESSES: The meeting will be held in the Great Hall in the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, ASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. All comments should be submitted to *napa@hhs.gov* for the record and to share with the Advisory Council by January 27, 2017. Those submitting comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, *rohini.khillan@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''February Meeting Attendance'' in the Subject line by Friday, January 20, 2017 so that their names may be put on a list of expected attendees and forwarded to the security officers the Humphrey Building. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The theme of the February meeting will be clinical trials for Alzheimer's disease

and related dementias and recruitment challenges. Additional presentations in the afternoon will include updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017.

Procedure and Agenda: This meeting is open to the public. Please allow 45 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live*.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: January 5, 2017.

Kathryn E. Martin,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2017–00606 Filed 1–12–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, 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. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Date: February 15, 2017.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: Program reports and presentations; business of the Board.

Closed: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove 9609 Medical Center Drive, Room TE406 Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute—Shady Grove National Institutes of Health, 9609 Medical Center Drive, Room 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ncab/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(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: January 9, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00579 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Predictors and Determinants of Age-Related Resiliencies to Physical Stressors, RFA–AG–014 (UH2).

Date: February 23, 2017.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carmen Moten, Ph.D., MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Late Onset of Alzheimer's Disease (LOAD), PAR–16–205 (U24).

Date: March 7, 2017.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carmen Moten, Ph.D., MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 10, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00733 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of action under the *NIH Guidelines.*

SUMMARY: The National Institutes of Health (NIH) considered a proposal to conduct research involving the deliberate transfer of a chloramphenicol resistance trait to *Rickettsia typhi, conorii, rickettsii,* and *felis.* The acquisition of this antibiotic resistance trait could possibly compromise the use of a class of antibiotics for the treatment of Rickettsia infections in humans. Under the *NIH Guidelines* (*http://www.osp.od.nih.gov/sites/default/files/*

NIH_Guidelines.html), these experiments can proceed only after they are reviewed by the NIH Recombinant DNA Advisory Committee (RAC) and specifically approved by the NIH Director as Major Actions. This proposal was discussed at the December 4, 2015, RAC meeting. The proposal was published in the **Federal Register** on December 29, 2015, (80 FR 81346) with a request for public comment; one comment was received. This notice announces the final NIH action regarding this proposal.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional background information about this action, please contact the NIH by email at *SciencePolicy@od.nih.gov,* or by telephone at 301–496–9838 and reference this notice.

SUPPLEMENTARY INFORMATION: This final action does not allow an investigator at the University of Chicago to transfer chloramphenicol resistance to three different Rickettsia species: *Rickettsia typhi, rickettsii,* and *felis.* The investigator also proposed to transfer chloramphenicol resistance to a fourth Rickettsia species, *R. conorii.* Transfer of chloramphenicol resistance to *R. conorii* was previously approved by the NIH Director as a Major Action (see 73 FR 32719) and therefore did not need to be reviewed and approved under Section III–A–1–a of the *NIH Guidelines.* Thus, the University of Chicago investigator was allowed to proceed with the transfer of chloramphenicol resistance to *R. conorii* under Section III–B–2 of the *NIH Guidelines.*

The proposal to transfer chloramphenicol resistance to *R. typhi, rickettsii,* and *felis* was discussed with a working group of the RAC via a teleconference call on October 22, 2015. The recommendations of this group were presented to and discussed with the RAC at its December 4, 2015, meeting. At the March 8, 2016, meeting, the RAC continued the discussion which included consideration of the one comment received to the December 29, 2015, notice and unanimously recommended (by a vote of 11 in favor, none opposed, and no abstentions) that the transfer of chloramphenicol resistance to *R. typhi, rickettsii,* and *felis* should not be allowed to proceed. On August 23, 2016, the NIH Director disapproved the proposal to transfer chloramphenicol resistance to *R. typhi, rickettsii,* and *felis.*

Dated: January 6, 2017.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2017–00766 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Monoclonal Antibodies That Neutralize Norovirus

Description of Technology: Vaccines and therapies to prevent and treat Norovirus infections do not exist, despite the worldwide prevalence of Norovirus infections. Outbreaks of human gastroenteritis attributable to Norovirus commonly occur in group setting, such as hospitals, nursing homes, schools, dormitories, cruise ships and military barracks. This technology relates to chimpanzee-human chimeric monoclonal antibodies, which specifically bind to Norovirus and have therapeutic potential. The antibodies that were tested in a primate model of infection have shown protection against Norovirus. These Norovirus antibodies may have application as immunoprophylaxis to protect individuals from infections or as a possible treatment for infected individuals, or can be used to develop a diagnostic for detection of norovirus infections.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Therapeutics
- Diagnostics

Competitive Advantages:

- There are currently no vaccines or therapeutics available against Norovirus infections

Development Stage:

- In vivo data available (animal)

Inventors: Zhaochun Chen, Robert H. Purcell, Lisbeth Kim Green, Stanislav Sosnovtsev, Karin Bok (all from NIAID).

Publications: Chen Z, et al., Development of Norwalk virus-specific monoclonal antibodies with therapeutic potential for the treatment of Norwalk virus gastroenteritis, J Virol. 2013 Sep; 87(17):9547–57. [PMID 23785216].

Intellectual Property: HHS Reference No. E–226–2011/0—U.S. Provisional Application No. 61/763,879, filed February 12, 2013; PCT Application No. PCT/US2014/015809, filed February 11, 2014; European Application No. 14706239.2, filed August 5, 2015 (pending); U.S. Application No. 14/767,274, filed August 11, 2015 (allowed); and U.S. Application No. 15/359,438, filed November 22, 2016 (pending).

Licensing Contact: Dr. Jenish Patel, 240–669–2894; *Jenish.Patel@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize for development of a therapeutic or a diagnostic for Norovirus infections. For collaboration opportunities, please contact Dr. Jenish Patel, 240–669–2894; *Jenish.Patel@nih.gov.*

Dated: January 9, 2017.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2017–00735 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity Research.

Date: January 26, 2017.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R13 Conference Grant Applications.

Date: February 23, 2017.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–16–126: High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2)—Renal Repair and Regeneration.

Date: March 1, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894 *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–16–011: Central Primary Reference Laboratory for HbA1C and C-Peptide Measurements (UC4).

Date: March 2, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, NAtional Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 9, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00581 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review Group; Training and Workforce Development Subcommittee—C, To Review R25 Research Training Grant Applications.

Date: March 9–10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Wardman Park, 2660 Woodley Road NW., Washington, DC 20008.

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 1 Democracy Plaza, 6701 Democracy Blvd., Room 1068, Bethesda, MD 20892, 301–435–0807, *slicelw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 9, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00582 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; AITRC Independent SEP.

Date: February 13, 2017.

Time: 2:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Zhuqing (Charlie) Li, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3G41B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5068, *zhuqing.li@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34, R01, U01).

Date: February 14, 2017.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834, Rockville, MD 20852, 301–496–2550, *amir.zeituni@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 10, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00734 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Systems Biology.

Date: February 16, 2017.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bita Nakhai, PH.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 9, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00580 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: February 8–9, 2017.

Time: 7:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Villa Florence Hotel, 225 Powell Street, San Francisco, CA 94102.

Contact Person: Weihua Luo, M.D., Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Auditory System Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

Contact Person: Jana Drgonova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, *jdrgonova@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Projects: Animal/Biological Resource Facilities.

Date: February 9–10, 2017.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, (301) 455–1761, *kellya2@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Aspects of Musculoskeletal and Dermal Biology.

Date: February 10, 2017.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Srikanth Ranganathan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7802, Bethesda, MD 20892, 301–435–1787, *srikanth.ranganathan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Targets for Cancer Interventions

Date: February 13–14, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 10, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00731 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; DAP (Diversity Action Plan).

Date: March 8, 2017.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 5635 Fishers Lane, 3rd Floor Conference Room, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ken D. Nakamura, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, 301–402–0838, *nakamurk@mail.nih.gov.*

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Clinical Genome Resource.

Date: March 9, 2017.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 5635 Fishers Lane, 3rd Floor Conference Room, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852, (301) 402–0838, *pozzattr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 9, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00732 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–16–292 Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21).

Date: January 26–27, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Gabriel B Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, 923 16th St. NW., Washington, DC 20006.

Contact Person: Sung Sug Yoon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, Bethesda, MD 20892, *sungsug.yoon@nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Molecular and Integrative Signal Transduction Study Section.

Date: February 9, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Charles Selden, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 5187 MSC 7840, Bethesda, MD 20892, 301–451–3388, *seldens@mail.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Virginian Suites, 1500 Arlington Boulevard, Arlington, VA 22209.

Contact Person: Baljit S Moonga, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, *moongabs@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Allergy, Asthma and Mucosal Inflammation.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review (CSR), National Institutes of Health (NIH), 6701 Rockledge Dr., Room 4203, Bethesda, MD 20817, (301) 435–3566, *alok.mulky@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Hypertension and Microcirculation Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, *zouai@mail.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington National Airport, 1480 Crystal Dr., Arlington, VA 22202.

Contact Person: Ola Mae Zack Howard, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr. Room 4192, MSC 7806, Bethesda, MD 20892, 301–451–4467, *howardz@mail.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Neurological, Aging and Musculoskeletal Epidemiology Study Section.

Date: February 9–10, 2017.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dana on Mission Bay, 1710 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–1721, *hfriedman@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: February 10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: San Diego Mission Valley Marriott, 8757 Rio San Diego Drive, San Diego, CA 92108.

Contact Person: Fouad A. El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Technologies for Healthy Independent Living.

Date: February 10, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301–402–9607, *Jan.Li@nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Aging Systems and Geriatrics Study Section.

Date: February 13–14, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nursing and Related Clinical Sciences II.

Date: February 13–14, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Martha L. Hare, RN, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov*.

Name of Committee: Vascular and Hematology Integrated Review Group; Hemostasis and Thrombosis Study Section.

Date: February 13, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bayside, 4875 North Harbor Drive, San Diego, CA 92106.

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Vascular and Hematology IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Brain Injury and Neurovascular Pathologies Study Section.

Date: February 13–14, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301–435–1254, *yakovleva@csr.nih.gov*.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Psychopathology and Disorders of Aging Study Section.

Date: February 13–14, 2017.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, (301) 500–5829, *sechu@csr.nih.gov*.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Arthritis, Connective Tissue and Skin Study Section.

Date: February 14–15, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexey Belkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr, Rm 4102, Bethesda, MD 20817, 301–435–1786, *alexey.belkin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 9, 2017.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00578 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Medical Imaging Study Section.

Date: February 6–7, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

Contact Person: Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Biomedical Imaging Technology B Study Section.

Date: February 8–9, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Eileen W. Bradley, DSC, IRG Chief, Surgical Sciences Biomedical Imaging and Bioengineering, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: February 9–10, 2017.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Xin Yuan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, *yuanx4@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Academic Research Enhancement Award.

Date: February 10, 2017.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Inna Gorshkova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1784, *gorshkoi@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 9, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–00730 Filed 1–12–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–1073]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The Chemical Transportation Advisory Committee will meet on February 28, March 1, and March 2, 2017, in Houston, TX to discuss committee matters relating to the safe and secure marine transportation of hazardous materials. These meeting will be open to the public.

DATES: Chemical Transportation Advisory Committee subcommittees will meet on Tuesday, February 28, 2017, from 9 a.m. to 5 p.m.; and on Wednesday, March 1, 2017, from 9 a.m. to 5 p.m. The full Committee will meet Thursday, March 2, 2017, from 9 a.m. to 5 p.m. Please note that the meetings may close early if the Committee completes its business.

ADDRESSES: The meeting will be held at United States Coast Guard Sector Houston-Galveston, 13411 Hilliard St., Houston, TX 77034, *http://homeport.uscg.mil/houstongalveston.*

All visitors to Sector Houston-Galveston will have to pre-register to be admitted to the building. U.S. citizens must provide your name, telephone number, and email address by close of business on February 17, 2017, to the contact person listed in **FOR FURTHER INFORMATION CONTACT** below. Non U.S. citizens must provide your name, date of birth, place of birth, country of citizenship, passport country, passport number, country of residence, company, telephone number, and email address by January 27, 2017, to the contact person listed in **FOR FURTHER INFORMATION CONTACT** below.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** as soon as possible.

Instructions: To facilitate public participation, written comments on the issues to be considered by the Committee as listed in the ''Agenda'' section below must be submitted no later than Friday, February 10, 2017, if you want the Committee members to review your comment prior to the meeting. Written comments must be submitted using Federal eRulemaking Portal: *http://www.regulations.gov.* You must include the words ''Department of Homeland Security'' and the number (USCG–2016–1073). Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005 issue of the **Federal Register** (70 FR 15086). If you encounter technical difficulties with comment submission, contact the individual in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Docket Search: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* type ''USCG–2016–1073'' in the ''Search'' box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Julie Blanchfield, Alternate Designated Federal Official of the Chemical Transportation Advisory Committee, 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509, Telephone 202–372–1419, Fax 202–372–8380, or *Julie.e.blanchfield@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the Federal Advisory Committee Act, (Title 5, United States Code Appendix).

The Chemical Transportation Advisory Committee is an advisory Committee authorized under section 871 of the Homeland Security Act of 2002, 6 United States Code 451, and is chartered under the provisions of the Federal Advisory Committee Act. The Committee acts solely in an advisory capacity to the Secretary of the Department of Homeland Security through the Commandant of the Coast Guard and the Deputy Commandant for Operations on matters relating to safe and secure marine transportation of hazardous materials activities insofar as they relate to matters within the United States Coast Guard's jurisdiction. The Committee advises, consults with, and makes recommendations reflecting its independent judgment to the Secretary.

Agendas of Meetings

Subcommittee Meetings on February 28 and March 1, 2017

The subcommittee meetings will separately address the following tasks:

1. Task Statement 13–03: Safety Standards for the Design of Vessels Carrying Natural Gas or Using Natural Gas as Fuel.
2. Task Statement 15–01: Marine Vapor Control System Certifying Entities Guidelines update and Vapor Control System Policy Letter to supplement the implementation of the final rule.
3. Task Statement 16–01: Hazardous Cargo Transportation Security Subcommittee.

The task statements from the last Committee meeting are located at Homeport at the following address: *http://homeport.uscg.mil/ctac.* The agenda for each subcommittee meeting will include the following:

1. Review task statements, which are listed in paragraph (7) of the agenda for the March 2, 2017, Committee meeting.
2. Work on tasks assigned in task statements mentioned above.
3. Public comment period.
4. Discuss and prepare proposed recommendations for the Chemical Transportation Advisory Committee meeting on March 2, 2017, on tasks assigned in detailed task statements mentioned above.

Full Committee Meeting on March 2, 2017

The agenda for the Chemical Transportation Committee meeting on Thursday, March 2, 2017, is as follows:

1. Introductions and opening remarks.
2. Swear in newly appointed Committee members, and thank outgoing members.
3. Thank you letter presentation for the Ships Carrying Bulk Liquid, Liquefied Gas, or Compressed Gas Hazardous Materials (46 CFR 153) Subcommittee.
4. Review of September 29, 2016, meeting minutes and status of task items.
5. Coast Guard Leadership Remarks.
6. Chairman's and Designated Federal Officer's remarks.
7. Committee will review, discuss, and formulate recommendations on the following items:

a. Task Statement 13–03: Safety Standards for the Design of Vessels Carrying Natural Gas or Using Natural Gas as Fuel.

b. Task Statement 15–01: Marine Vapor Control System (Certifying

Entities Guidelines update and vapor control System supplementary guidance for the implementation of the final rule).

c. Task Statement 16–01: Hazardous Cargo Transportation Security Subcommittee.

8. USCG presentations on the following items of interest:

a. Update on International Maritime Organization activities as they relate to the marine transportation of hazardous materials.

b. Update on U.S. regulations and policy initiatives as they relate to the marine transportation of hazardous materials.

c. Update on the Chemical Data Guide.

9. Presentation on lessons learned from a lightning strike on a methanol operation.

10. New business and subcommittee recommendation discussion.

11. Set next meeting date and location.

12. Set subcommittee meeting schedule.

13. Public comment period.

Public comments or questions will be taken throughout the meeting as the Committee discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the period allotted, following the last call for comments. Contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above to register as a speaker.

Dated: January 9, 2017.

J.G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2017–00648 Filed 1–12–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2017–0003; OMB No. 1660–0005]

Agency Information Collection Activities: Proposed Collection; Comment Request; National Flood Insurance Program Claims Forms

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information related to the flood insurance claims process.

DATES: Comments must be submitted on or before March 14, 2017.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments.

(1) *Online:* Submit comments at *www.regulations.gov* under Docket ID FEMA–2017–0003. Follow the instructions for submitting comments.

(2) *Mail:* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Bernstein, Mitigation, National Flood Insurance Program, (202) 212–2113. You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP) is codified as 42 U.S.C. 4001, *et sec.* and is authorized by Public Law 90–448 (1968) and expanded by Public Law 93–234 (1973). The National Flood Insurance Act of 1968 requires that the Federal Emergency Management Agency (FEMA) provides flood insurance at full actuarial rates with limited exceptions for certain structures reflecting the complete flood risk to structures built or substantially improved on or after the effective date for the initial Flood Insurance Rate Map (FIRM) for the community, or after December 31, 1974, whichever is later, so that the risk associated with buildings in flood-prone areas are borne by those located in such areas and not by the taxpayers at large. In accordance with Public Law 93–234, the purchase of flood insurance is mandatory when Federal or federally related financial assistance is being provided for acquisition or construction of buildings located, or to be located, within FEMA-identified special flood hazard areas of communities that are participating in the NFIP. When flood damage occurs to insured property, information is collected to report, investigate, and negotiate in order to settle the claim.

The NFIP Appeals Process

Section 205 of The Bunning-Bereuter-Blumenauer Flood Insurance Reform Act (FIRA) of 2004, Public Law 108–264, requires FEMA to establish by regulation an additional process for the appeal of decisions of flood insurance claims issued through the NFIP. Consequently, FEMA published an interim final rule on May 26, 2006 (71 FR 30294) and a final rule on October 13, 2006 (71 FR 60435) codifying into regulation what was previously an existing informal process to handle appeals regarding decisions related to coverage, or claims under the NFIP.

Collection of Information

Title: National Flood Insurance Program Claims Forms.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0005.

FEMA Forms: FEMA Form 086–0–6; Worksheet-Contents-Personal Property; 086–0–7; Worksheet—Building; 086–0–8; Worksheet—Building (Continued); 086–0–9; Proof of Loss; 086–0–10; Increased Cost of Compliance Proof of Loss; 086–0–11; Notice of Loss; 086–0–12; Statement as to Full Cost of Repair or Replacement under the Replacement Cost Coverage, Subject to the Terms and Conditions of this Policy (proposed for removal); 086–0–13; National Flood Insurance Program Preliminary Report; 086–0–14; National Flood Insurance Program Final Report; 086–0–15; National Flood Insurance Program Narrative Report; 086–0–16; Cause of Loss and Subrogation Report; 086–0–17; Manufactured (Mobile) Home/Travel Trailer Worksheet; 086–0–18; Manufactured (Mobile) Home/Travel Trailer Worksheet (continued); 086–0–19; Increased Cost of Compliance (ICC) Adjusters Report; 086–0–20; Adjuster Preliminary Damage Assessment; 086–0–21; Adjuster Certification Application. NFIP Claims Appeals Process (Flood Claims Insurance Handbook).

Abstract: The NFIP appeal process establishes a formal mechanism to allow NFIP policyholders to appeal the

decisions of any insurance agent, adjuster, insurance company, or any FEMA employee or contractor, in cases of unsatisfactory decisions on claims, proof of loss, and loss estimates.

Affected Public: Individuals, households, farms, businesses, and other for profit.

Number of Respondents: 49,373.

Number of Responses: 49,373.

Estimated Total Annual Burden Hours: 31,737.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $1,432,419. There are no recordkeeping, capital, start-up or maintenance costs associated with this information collection. The cost to the Federal Government is $4,000,434.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Dated: January 9, 2017.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2017–00673 Filed 1–12–17; 8:45 am]

BILLING CODE 9110–52–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5173–N–09–C]

Affirmatively Furthering Fair Housing Assessment Tool for Public Housing Agencies: Announcement of Final Approved Document

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice.

SUMMARY: This notice announces that the Assessment Tool developed by HUD for use by Public Housing Agencies receiving assistance under the United States Housing Act of 1937 has completed the notice and comment process required by the Paperwork Reduction Act (PRA), been reviewed by the Office of Management and Budget and approved. While this Assessment Tool has been approved, this Notice does not trigger the obligation of PHAs to conduct and submit an AFH in accordance with 24 CFR 5.160, as HUD has not yet provided PHAs with the data they will need. As HUD makes data available for certain PHAs, HUD will publish, in the **Federal Register**, a Notice announcing the availability of data for certain PHAs, triggering their obligation to conduct and submit an AFH, and will post such Notice on the HUD Exchange. HUD also anticipates that, at that time, the online User Interface will be available for use by PHAs. Until such time that PHAs are required to conduct and submit an AFH, HUD notes that PHAs must continue to comply with existing fair housing and civil rights requirements. This Assessment Tool, referred to as the PHA Assessment Tool, was modeled on the Local Government Assessment Tool, first approved by OMB on December 31, 2015 but with modifications to address the different public housing and Housing Choice Voucher operations that PHAs have compared to local governments, and how fair housing planning may be undertaken by PHAs in a meaningful manner. As with the Local Government Assessment Tool, the PHA Assessment Tool allows for collaboration with other PHAs. To reduce burden for PHAs, HUD has increased the threshold for the insert from QPHAs that have 550 units or less to PHAs with 1,250 or fewer combined public housing and HCV units. HUD has also committed to developing an additional Assessment Tool specifically for use by Qualified PHAs (QPHAs) who conduct and submit an individual AFH or collaborate with other QPHAs to conduct and submit a joint AFH to be issued in 2017. Therefore, this PHA Assessment Tool will be for use by PHAs submitting AFHs individually or jointly, and for collaborations among PHAs with 1,250 or fewer units and with PHAs with more than 1,250 units. In addition, to reduce burden further, this Assessment Tool includes an insert with streamlined questions for PHAs with 1,250 or fewer units to use if jointly submitting with PHA with more than 1,250 units. In addition, this Assessment Tool includes revised instructions based on public comments received during the 30-day PRA review that provide more guidance to PHAs in conducting the AFH, including how the regional analysis is to be prepared based on the location of a PHA's geographic region and program type. Through the notice and comment process required by the PRA, HUD made changes to the PHA Assessment Tool from the 30-day notice published in the **Federal Register** on August 23, 2016.

FOR FURTHER INFORMATION CONTACT: Krista Mills, Deputy Assistant Secretary, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 7th Street SW., Room 5246, Washington, DC 20410; telephone number 866–234–2689 (toll-free) or 202–402–1432 (local). Individuals who are deaf or hard of hearing and individuals with speech impediments may access this number via TTY by calling the toll-free Federal Relay Service during working hours at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2015, at 80 FR 42357, HUD published in the **Federal Register** its Affirmatively Furthering Fair Housing (AFFH) final rule. The AFFH final rule provides HUD program participants with a new approach for planning and implementing locally-developed housing goals, actions and strategies involving increasing choice, mobility, preservation, community revitalization and other collaborative or outreach efforts that are designed to reduce disparities in access to opportunity and improve fair housing outcomes that will assist them in meeting their statutory obligation to affirmatively further fair housing as required by the Fair Housing Act. To assist HUD program participants in improving planning to achieve meaningful fair housing outcomes, the new approach involves an ''assessment tool'' for use in completing the regulatory requirement to conduct an assessment of fair housing (AFH) as set out in the AFFH rule. Because of the variations in the different HUD program participants subject to the AFFH rule, HUD has developed three separate assessment tools: One for public housing agencies (PHAs) receiving assistance under section 8 or 9 of the United States Housing Act of 1937 (42 U.S.C. 1437f or 1437g), which is the subject of this notice, the PHA Assessment Tool; one for local governments, the Local Government Assessment Tool; and one for State and Insular Areas, the State and Insular Areas Assessment Tool. PHAs submitting alone or with other PHAs

will use the PHA Tool, PHAs submitting with local governments will use the Local Government Tool, and PHAs submitting with State or Insular Areas will use the State Tool. All three assessment tools, because they are information collection documents, are required to undergo the PRA notice and comment process. HUD has also committed to developing a fourth Assessment Tool specifically for use by QPHAs who choose to conduct and submit an individual AFH or that collaborate with other QPHAs to conduct and submit a joint AFH.

II. PHA Assessment Tool

A. The PRA Process

On March 23, 2016, at 81 FR 15549, HUD published its 60-day notice, the first notice for public comment required by the PRA, to commence the process for approval of the PHA Assessment Tool. The 60-day public comment period ended on May 23, 2016, and HUD received 39 public comments.

On September 20, 2016, at 81 FR 64475, HUD published its 30-day notice under the PRA. In the 30-day notice, HUD addressed the significant issues raised by the commenters on the 60-day notice. HUD received 142 public comments in response to the 30-day notice. HUD appreciates the comments received in response to the 30-day notice, and, in developing this final version of the Assessment Tool, all comments were carefully considered. The significant issues commenters raised and HUD's responses to these issues are addressed in Section II.C. of this notice. All comments submitted on the September 20, 2016, notice can be found on *www.regulations.gov* at *https://www.regulations.gov/document?D=HUD-2016-0103-0001*. In addition, HUD has posted on its Web site at *http://www.huduser.gov/portal/affht_pt.html* and *https://www.hudexchange.info/programs/affh/*, a comparison of the PHA Assessment Tool that was published for 30-day public comment on September 20, 2016 and this final PHA Assessment Tool as announced by this notice.

B. Changes Made to the PHA Assessment Tool

The following highlights changes made to the Assessment Tool for Public Housing Agencies in response to public comment and further consideration of issues by HUD.

Contributing Factors. HUD has tailored the definitions of Contributing Factors, found in Appendix D of the Assessment Tool, to better apply in the context of a PHA's operations. HUD has made changes to contributing factors that include: Admissions and occupancy policies and procedures, including preferences in publicly supported housing; Impediments to mobility; Lack of access to opportunity due to high housing costs; Lack of local public and/or private fair housing outreach, enforcement, and/or resources; Lack of meaningful language access; Lack of public and/or private investment in specific neighborhoods, including services or amenities; Land use and zoning laws; Location of accessible housing; Source of income discrimination; and State or local laws, policies, or practices that discourage individuals with disabilities from living in apartments, family homes, and other integrated settings. HUD has consolidated and therefore removed certain contributing factors based on public comment, such as: Lack of local public fair housing enforcement; Lack of resources for fair housing agencies and organizations; Lack of state or local fair housing laws; Local Restrictions or Requirements for Landlords Renting to Voucher-holders; and Nuisance laws. HUD has combined and added certain contributing factors based on public comment, such as: Displacement of and/or lack of housing support for victims of domestic violence, dating violence, sexual assault, and stalking; Loss of affordable housing; and Private Discrimination and/or lack of fair housing laws.

Goal Setting. HUD has provided further clarifying instructions about how PHAs should identify contributing factors and that PHAs should create fair housing goals that are within their own capacity. For PHAs in a joint or regional collaboration, the User Interface will provide for PHAs to identify which fair housing goal is to be accomplished by which PHA (or PHAs) in the collaboration.

Insert for PHAs with 1,250 or fewer Units. In the 30-day PRA notice, HUD added an insert for use by QPHAs (eligible PHAs with a combined unit total of 550 or fewer) that collaborate with non-qualified PHAs. HUD has revised this threshold, and PHAs with a combined unit total of 1,250 or fewer combined public housing units or Housing Choice Vouchers (HCVs, *i.e.,* Section 8) units can use this insert when collaborating with a PHA with a combined unit total above 1,250. The insert is meant to cover the analysis required for the collaborating PHA's service area, and region, where applicable—*i.e.,* not analyzed by another PHA, such as in the case where PHAs have overlapping regional geographies. For PHAs with 1,250 or fewer units, the insert is designed to make the analysis less burdensome while retaining the fair housing analysis required by the AFFH Rule. The instructions to the Assessment Tool have also been revised to explain this and help program participants to understand which Tool to use.

PHA Regional Analysis. In this final version of the Assessment Tool designed for PHAs, HUD has provided instructions related to the regional analysis that various size PHAs and QPHAs (*e.g.,* rural PHAs, PHAs within metropolitan areas, PHAs within micropolitan areas, etc.) must conduct when completing an AFH. There are multiple parts to this explanation: (1) A description of the service area, also known as the jurisdiction, of various size PHAs in terms of their authorized geographic operations; (2) a description of the PHA's region for purposes of analysis under the AFFH rule; (3) a description of the HUD-provided data for the PHA's applicable region; (4) instructions related to use of data and identification of fair housing issues and related contributing factors for different size PHAs; and (5) instructions related to rural PHAs, State PHAs, and PHAs in Insular Areas.

PHA jurisdiction/service area [1]	HUD-provided data for PHA region
Metropolitan and Micropolitan (CBSA) PHAs: PHA jurisdiction/service area is located within a CBSA.	Maps and Tables for the CBSA.
Sub-County Rural (Non-CBSA) PHAs: PHA jurisdiction/service area is outside of a CBSA and smaller than a county.	Tables for the county. Maps are available for the county and if patterns of segregation, R/ECAPs, disparities in access to opportunity extend into a broader area, maps are also available to identify such patterns, trends, and issues.

PHA jurisdiction/service area [1]	HUD-provided data for PHA region
County-Wide or Larger Rural (Non-CBSA) PHAs [2]: PHA jurisdiction/service area is outside of a CBSA and boundaries are consistent with the county or larger.	Tables for all contiguous counties, including PHA county, in the same state. Maps are available for all counties and if patterns of segregation, R/ECAPs, disparities in access to opportunity extend into a broader area, maps are also available to identify such patterns, trends, and issues.
Statewide PHAs: The PHA's jurisdiction/service area is the State.	HUD will generally provide data consistent with that provided to the State. Maps may be used to analyze fair housing issues that extend beyond the state's borders, where applicable, but tables are provided with data within the state's borders.

As the above chart indicates, HUD will provide regional data for PHAs with different service areas based on geographic areas used by the U.S. Census Bureau. As explained further in the full instructions to the Tool, the standard data that HUD will provide may not always be the most relevant from a fair housing perspective. For PHAs and all other program participants under the AFFH rule, the Assessment Tool is framed so that it can be applied to Public Housing-only or HCV-only PHAs and combined PHAs with various types of Publicly Supported Housing (PSH) [3] under their inventory with a wide variety of populations of different agency types and geographies with unique fair housing issues. Note that in completing the Assessment Tool, program participants must use the HUD-provided data, as well as local data and local knowledge, and information received in the community participation process.

Disparities in Access to Opportunity. In order to reduce burden while still eliciting a meaningful fair housing analysis, HUD has clarified that for PHAs that do not administer the Housing Choice Voucher Program (HCV), the regional analysis part of this section is not required. However, if PHAs receive information during community participation about regional disparities in access to opportunities, which is relevant to the PHA's service area, such information must be considered. Due to data limitations for PHAs and QPHAs in rural areas outside of CBSA regions, program participants can request technical assistance for additional guidance on how local data and knowledge may be used to respond to questions on disparities in access to opportunity in PHA service areas.

Assessment of Past Goals, Actions and Strategies: HUD has clarified when PHAs must complete this section. This section may be inapplicable for PHAs that have not previously submitted AFHs or an Analysis of Impediments. However, PHAs are to indicate what fair housing goals were selected by the PHAs in past Analyses of Impediments (if prepared jointly with a local government) or Assessments of Fair Housing, if applicable.

Fair Housing Analysis of Rental Housing. The questions in this section have been streamlined and revised to reduce burden while still eliciting a meaningful fair housing assessment.

Other Publicly Supported Housing Programs. The questions and structure of this section have been edited to tailor the analysis to PHA program operations and reduce burden while still obtaining a meaningful fair housing analysis. HUD has clarified which types of other publicly supported housing the PHA must analyze.

Local Data and Local Knowledge. HUD has clarified the instructions in the Tool regarding local data and local knowledge—including where local data and local knowledge is particularly useful because HUD data is not provided or is limited. It has reiterated in the instructions to the Tool that the phrase ''subject to a determination of statistical validity by HUD'' is included to clarify that HUD may decline to accept local data that HUD has determined is not valid but not that HUD will apply a rigorous statistical validity test for all local data. In addition, HUD will provide additional further guidance to PHAs on potential sources of additional information or options for partnering with outside agencies, for example in relation to disparities in access to opportunity.

Maps and Tables. The accompanying instructions have been revised to reflect the appropriate Map and Table numbers of HUD-provided data that program participants must use in answering each question of the Assessment Tool. Descriptions of HUD-provided maps are available in Appendix B of the Assessment Tool instructions, and descriptions of HUD-provided tables are available in Appendix C.

Segregation. In the Assessment Tool, HUD has clarified the definition of ''segregation'' by referencing the regulatory definition and has noted that in identifying areas that may be segregated or integrated, program participants should take care to ensure they are focusing on all protected characteristics, and not solely focus on minority populations in their jurisdictions and regions. HUD has also included instructions related to analyzing segregation in so-called ''majority-minority'' communities and where there are concentrations of particular national origin, ethnic, or religious groups in their jurisdictions and regions.

Answering Questions in Collaborations. HUD has added language to the instructions to the Tool which reminds PHAs that are collaborating to note which contributing factors apply to which or all of the program participants. HUD has also added language that reminds PHAs that are collaborating that each program participant is responsible for answering the Assessment of Past Goals, Actions, and Strategies questions (as discussed above).

C. Responses to Significant Issues Raised by Public Commenters on the 30-Day Notice

1. Specific Questions Posed by HUD in the 30-Day Notice

In the 30-day notice, HUD posed a series of questions for which HUD specifically sought comment.

[1] All references to counties include counties or statistically equivalent areas (*e.g.,* parishes).

[2] HUD acknowledges that there are other PHAs, including regional PHAs, that may have differing or unique geographies from the categories in this table. HUD may provide data in the AFFH Data and Mapping Tool for such PHAs appropriate for their geographies based on administrative and data considerations. All program participants are required to conduct an analysis of their jurisdiction and region consistent with the AFFH Final Rule.

[3] The term ''publicly supported housing'' refers to housing assisted, subsidized, or financed with funding through Federal, State, or local agencies or programs as well as housing that is financed or administered by or through any such agencies or programs. HUD is currently providing data on five specific categories of housing: Public Housing; Project-Based Section 8; ''Other Multifamily Housing'' (including Section 202—Supportive Housing for the Elderly and Section 811—Supportive Housing for Persons with Disabilities); Low Income Housing Tax Credit (LIHTC) housing; and Housing Choice Vouchers (HCV). Other publicly supported housing relevant to the analysis includes housing funded through state and local programs, other federal agencies, such as USDA and VA, or other HUD-funded housing not captured in the five categories listed above.

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.

In response to this question, there were commenters who stated that completion of the Assessment Tool is not necessary for the proper performance of agency functions and will not have practical utility, because the commenters are already committed to and practicing deconcentration efforts under the HCV Program. Commenters stated that the Tool was a burden, particularly on small PHAs which lack the staff capacity and expertise to complete the Assessment and on small rural PHAs. A commenter was concerned that their agency would become ''troubled.'' Commenters expressed concern that nothing would be done with the information collected and that the Tool required PHAs to become reporting services. The commenters stated that they lack the funding to complete the Assessment, and High Performing PHAs should be exempt from the regulation until funding is returned and increased. A commenter noted that the approach ignores proportionality and local context, and in smaller communities with only one high school, there are no disparities in access to opportunity. Commenters stated that QPHAs in particular have little influence over factors in the region. Another commenter noted that some questions and terminology are broad and vague.

HUD Response: HUD continues to submit that the Assessment Tool has substantial utility for program participants in assessing fair housing issues, identifying significant contributing factors, formulating meaningful fair housing goals, and ultimately meeting their obligation to affirmatively further fair housing. One of the primary purposes of the Assessment Tool is to consider a wide range of policies, practices, and activities underway in a program participant's jurisdiction and region and to consider how its policies, practices, or activities may facilitate or present barriers to fair housing choice and access to opportunity, and to further consider actions that a program participant may take to overcome such barriers. The series of questions in the Assessment Tool enables program participants to perform a meaningful assessment of key fair housing issues and contributing factors and set meaningful fair housing goals and priorities. The Assessment Tool also clearly conveys the analysis of fair housing issues and contributing factors that program participants must undertake. In essence, HUD submits that the Assessment Tool, and the entire AFH approach, better implements the AFFH mandate under the Fair Housing Act than the Analysis of Impediments to Fair Housing Choice (AI).

In terms of resource limitations, HUD is aware that PHAs may be limited in the actions that they can take to overcome barriers to fair housing choice and that the AFH process does not mandate specific outcomes. The purpose of the AFH is for PHAs to identify fair housing issues and develop local solutions based on available resources. However, that does not mean that the PHA cannot take any action, or that the PHA should not strive to first understand the fair housing issues facing their communities and then work to overcome barriers to fair housing choice or disparities in access to opportunity. HUD has taken steps to streamline the Assessment Tool to reduce burden, while still maintaining a meaningful fair housing analysis. HUD has issued guidance on how program participants may establish appropriate goals to address contributing factors and fair housing issues that are beyond their direct control or PHA expertise. HUD has added clarifying instructions regarding prioritization of contributing factors and setting goals, consistent with the AFFH Final Rule and AFFH-related guidance. These edits state that, ''Program participants have discretion, within the requirements of the AFFH Rule, to analyze and interpret data and information, identify significant contributing factors, and set goals and priorities using the Assessment Tools provided by HUD. As more fully discussed in the guidance on HUD's review of AFHs, HUD will consider local context and the resources the program participant has available.'' It is HUD's stated policy that PHAs should be able to complete the assessment tool using their own available staff without the need to hire or contract for outside consultants. For instance, a cost limitation is one factor built directly into the regulatory definition of the term, ''local data.'' HUD has also issued a public guidance document providing further information on the standards HUD will use to review AFH submissions. As stated in this guidance, ''HUD does not expect program participants to hire statisticians or other consultants to locate and analyze all possible sources of local data.'' Furthermore, the guidance states, ''HUD's review of AFHs will likewise take into consideration the different circumstances of individual program participants and their varying locales and available resources.'' *See* ''Guidance on HUD's Review of Assessments of Fair Housing'' available at: *https://www.hudexchange.info/resources/documents/Guidance-on-HUDs-Review-of-Assessments-of-Fair-Housing-AFH.pdf.* As discussed above, HUD has tailored questions to PHAs' programmatic operations. HUD has also made key changes to the instructions to clarify issues raised by the commenters including the scale and scope of the service area and regional analysis that is required. For example, PHAs that do not administer the Housing Choice Voucher Program would not be required to conduct the regional analysis part of the Disparities in Access to Opportunity section. However, if PHAs receive information during community participation about regional disparities in access to opportunities, which is relevant to the PHA's service area, such information must be considered. HUD has also provided further instructions about the HUD-provided data in maps and tables and where local data and local knowledge may be most important, such as the Disparities in Access to Opportunity and Disability and Access sections of the analysis. These clarifications include that, ''The questions in the Assessment Tool are written broadly by HUD to enable PHAs in many different parts of the country to identify the fair housing issues that are present in their service areas and regions. PHAs should provide an analysis based on the HUD-provided data with respect to the fair housing issues analyzed in the AFH, as opposed to providing an inventory of what the data show.'' HUD also expects that PHAs will have the benefit of local data and local knowledge, including information obtained through the community participation process, to conduct an appropriate AFH.

PHAs are required to identify the fair housing issues that are present in their service areas and regions, as even issues beyond the PHA's control can affect the population that the PHA serves and the PHA's operations, and influence the PHA's actions to affirmatively further fair housing within its own programs. HUD recognizes that some of these issues are outside of the PHA's control, and as more fully discussed in HUD guidance, the AFH planning framework, including prioritization of significant contributing factors and setting goals, allows for program participants to match their goals to their local circumstances and to set goals within the PHA's unique control. The AFFH process also envisions the possibility of

adopting innovative and collaborative goals and priorities as a way of attempting different approaches that may yield positive fair housing outcomes. This may be useful in helping PHAs to address disparities in access to opportunity (access to proficient schools, transportation, employment clusters) and contributing factors, particularly at the regional level. HUD encourages PHAs and all program participants to work within their communities to develop cooperative approaches to fair housing issues.

2. The accuracy of the agency's estimate of the burden of the proposed collection of information.

Commenters disagreed with HUD's burden estimate and suggested that HUD conduct a more thorough analysis. One commenter estimated that the burden is likely three or four times HUD's estimate of 240 hours. Numerous commenters stated that HUD's estimate of burden was an underestimate of the actual burden that would be required, both for individual PHA respondents and for the total overall estimate. Numerous commenters stated that their PHA did not have adequate staffing or funding that would be needed to complete the assessment tool.

HUD Response: HUD appreciates the comments provided on HUD's burden estimate. HUD has made a number of improvements to reduce burden on program participants while conducting a meaningful fair housing assessment that will result in appropriate fair housing outcomes. These steps include the addition of the streamlined analysis (insert) as part of all three assessment tools and the commitment to develop a separate standalone assessment tool for QPHAs. Through this Notice, HUD is also announcing the expansion to the threshold number of units for a PHA to use the insert from 550 units to 1,250 units.

HUD intends to continue to monitor and assess the impact and burden and implementation costs of the AFH process on PHAs, including on the range of different program participants. This will include working directly with PHAs and other program participants and through the provision of technical assistance. It will also include conducting a process and implementation study based on actual program participant experience, including a review of costs and staff burden as well as barriers or obstacles faced by PHAs and other program participant across different types, sizes and locations. HUD expects to prepare revised workload and costs estimates as PHAs prepare and submit actual AFH plans in the future. Going forward, HUD will review the appropriateness of this threshold and the possibility of increasing the 1,250-unit threshold in the future it based on experience with AFH submissions. HUD will also assess actual burden on all program participants in order to consider the need for additional improvements and prior to the renewal of the assessment tool at the end of the 3-year PRA approval period.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

A commenter suggested that instead of using a separate Assessment Tool, HUD should expand the requirements of Consolidated Plans to include fair housing, as the Assessment Tool is duplicative of the CDBG entitlement community's AFH. Another commenter suggested that HUD ask PHAs what their service area is, as this will not be an additional burden for PHAs. A commenter noted that HUD should further enhance HUD-provided maps to allow PHAs to accurately and clearly view their data.

HUD Response: HUD appreciates commenters' suggestions for enhancing the quality, utility, and clarity of the information to be collected. The Assessment Tool, and the entire AFH approach, implements the AFFH mandate under the Fair Housing Act. The Tool facilitates program participants' meaningful analysis of key fair housing issues and contributing factors to fair housing issues, and that analysis is intended to lead them to set meaningful fair housing goals and priorities. This meaningful analysis of fair housing issues is not captured as fully in other HUD planning documents that have different purposes than Affirmatively Furthering Fair Housing.

As part of the development of the AFFH Data and Mapping Tool (AFFH–T) changes for PHAs, HUD will be gathering information on PHA service areas and will add this significant new information to the AFFH–T as it becomes available. With respect to enhanced ways to make maps and data easily accessible to program participants, HUD continues to work to make the HUD-provided data and maps easily accessible and easily readable to its program participants, including unique functionality for PHAs, such as the ability to view only the PHA's housing stock and vouchers.

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.

Commenters provided a number of suggestions to HUD to minimize the burden of collection of information from PHAs. A commenter suggested that HUD create and provide a sample completed AFH for different sized PHAs. A commenter stated that HUD should provide suggestions for defining R/ECAPs in rural areas. A commenter noted that HUD should simplify the Assessment Tool to the greatest extent possible so that PHAs would not have to rely on expensive consultants. Multiple commenters stated that the Assessment Tool asked for information beyond a PHA's mission, expertise, or influence, such as a regional analysis and analysis of access and barriers to transportation, schools, and work. Commenters recommended that HUD not require a regional analysis outside of a PHA's service area or where data is not provided by HUD. Another commenter suggested that PHAs that serve more than two counties—*i.e.,* the case of regional PHAs—should define their own regions.

A commenter expressed concern that HUD is using an online system for the Assessment Tool, because the agency must successfully implement web-based information collecting and keep its reporting systems up to date. Another commenter found electronic submissions of AFH responses helpful, and requested that HUD report back data that it has already collected in other formats from PHAs to reduce burden.

A commenter is encouraged by HUD's application of the rental housing analysis to only PHAs that operate voucher programs, but thinks the analysis is still too broad because the data is not readily available. A commenter noted that HUD should not require program participants to analyze demographics because HUD already has this information. Instead, HUD should provide PHAs with the comparison of the demographics of occupants of the PHA's housing to the community. HUD also has thorough demographic information of RAD properties and should provide it to PHAs, instead of requiring PHAs to again provide it to HUD. HUD requires PHAs to submit data to HUD on the location of assisted housing in the locality and the region, but HUD should provide that to PHAs. HUD should provide data to support analysis of the change in the location of rental housing over time, or eliminate it from the tool. HUD should not require PHAs to identify the location of LIHTC, but HUD should instead identify the locations. The commenter states that the analysis of access to opportunity for other assisted housing is duplicative.

The commenter also notes that the Fair Housing Enforcement section requires an inventory of fair housing laws, and HUD already has this information and instead should provide it to PHAs.

Commenters appreciated that HUD removed public housing from the analysis of rental housing, as well as the inclusion of the QPHA insert and drafting of a separate QPHA tool, as this will minimize burden for PHAs with smaller operations.

HUD Response: HUD thanks commenters for their suggestions for minimizing burden. HUD has worked to streamline the Assessment Tool and provide clarifying instructions to simplify the process for program participants that are completing the AFH, while providing a meaningful framework in which program participants can analyze the fair housing issues and contributing factors in their communities and set meaningful goals and priorities. This notice clarifies that the regional analysis across multiple sections is not meant to be interpreted as an inventory of local policies and practices in all of the local governments throughout the region. The Tool emphasizes that the solicitation of information on whether there are any demographic trends, policies, or practices that could lead to higher segregation in the jurisdiction or region in the future, is not to be read as HUD seeking an inventory of local laws, policies, or practices. Understanding the demographic patterns and trends of a PHA's service area contextually within the PHA's region is important to identify fair housing issues and related contributing factors affecting the PHA's operations and inform goal setting designed to affirmatively further fair housing, especially for portability and increasing choice in the housing choice voucher program. Fair housing issues and contributing factors are often not bound by geographic or political boundaries. PHAs are not expected to conduct a neighborhood-by-neighborhood or jurisdiction-by-jurisdiction analysis, but instead are asked to identify patterns and trends over time. PHAs are advised to begin the regional analysis starting with areas immediately surrounding the PHA service areas. This analysis will cover residential living patterns, segregated and R/ECAP areas more integrated areas of opportunity (with access to proficient schools, public transportation and employment opportunities) in the immediate jurisdictions outside of their service area where there is adequate rental supply available for lease-up and utilization by voucher holders. The regional analysis will also use integrated areas of opportunity that are feasible for new construction of affordable housing that will enhance mobility and decrease concentration of protected class while adding to the supply of affordable, low-income housing. HUD will continue to provide data through the AFFH–T as it becomes available.

HUD is exploring options for posting AFHs as an online resource for program participants and the public.

HUD appreciates comments regarding simplifying analysis and believes in this final version of the Assessment Tool designed for PHAs that it has undertaken significant steps to do so, including tailoring of questions, instructions, and contributing factor descriptions to the public housing and Housing Choice Voucher operations of PHAs. Regarding the comment on regional analysis and analysis of transportation, schools, and work to reduce disparities in access to opportunity for protected classes and recipients of publicly supported housing, HUD believes that such analyses are important to achieving meaningful fair housing outcomes. In particular, a PHA's regional analysis provides a contextual baseline for PHAs to understand the residential living patterns, rental market, and the unique fair housing issues and challenges facing their operations and service areas. In addition, such a regional analysis is important for understanding fair housing outcomes in the broader region related to mobility, portability, and collaborative efforts and goals with neighboring organizations, including other PHAs, such as the use of shared waitlists, landlord lists, and other collaborative efforts designed to address barriers to meaningful fair housing choice involving voucher mobility or production of affordable housing in areas of opportunity throughout a region. To achieve these types of goals, regional analysis and collaboration or information sharing is necessary among PHAs and local governments. With respect to analysis of transportation, schools, and work, HUD notes that disparities in access to such opportunities affect the PHA's assisted residents, and waitlisted residents, but also have significant importance from a fair housing perspective when considering goals such as how to increase voucher utilization in areas of opportunity to overcome disparities by protected classes in accessing such opportunities and when siting affordable housing. HUD has taken steps to streamline this analysis, while maintaining efforts at appropriate fair housing outcomes. Analysis of disparities in access to opportunity for the PHA's service area can be helpful for considering how the PHA's own assets (and HCVs where applicable) are positioned and in identifying places in the surrounding area that might be appropriate for additional new affordable housing opportunities when possible. Some of these issues may be beyond the scope of expertise for PHA staff, but consultation and cooperation with government agencies may be helpful. HUD acknowledges that staffing and funding realities may limit the level of inter-governmental and inter-agency interaction that is possible, as well as the availability and cooperation of other agencies or organizations to participate or to engage in information sharing, mutual analysis, or goal setting. Nonetheless, shared information and resources may assist PHAs and other agencies with meeting fair housing objectives. In support of this goal of PHAs performing a fair housing analysis and to address the workload concerns of PHAs, this Notice clarifies that HUD has increased the threshold for PHAs with 1,250 or fewer combined units to use the insert.

HUD appreciates the comment regarding the unique service areas of regional PHAs and has provided a baseline set of data and expectations as far as regional analysis for such entities. The instructions and this notice provide more information to PHAs on how to identify the required regional analysis based on their different geographic areas. HUD notes that all program participants may conduct analysis beyond the baseline required by the Assessment Tool.

HUD appreciates the comments regarding the provision of data. HUD continues to evaluate methods of reliably providing additional nationally available sources of data, including data that may be provided in other HUD programs, to program participants.

5. Are there other ways in which HUD can further tailor this Assessment Tool for use by PHAs? If so, please provide specific recommendations for how particular questions may be reworded while still conducting a meaningful fair housing analysis, or questions that are not relevant for conducting a meaningful fair housing analysis, or other specific suggestions that will reduce burden for PHAs while still facilitating the required fair housing analysis.

Commenters noted ways in which HUD could further tailor the Assessment Tool for PHA use. One commenter suggested that HUD create a shorter guidance document specifically from the PHA's perspective. Commenters noted that HUD should

tailor the Tool to focus more on housing preservation strategies and HUD should eliminate the analysis of rental housing, since it is not applicable to PHAs. Another commenter stated that HUD should provide a streamlined set of questions for QPHAs that choose not to collaborate.

HUD response: HUD thanks commenters for their suggestions. HUD will issue further guidance to assist program participants, including PHAs, in completing their AFHs. HUD appreciates the suggestion to specifically release a streamlined guidance document for smaller PHAs. HUD will continue to provide guidance involving the balanced approach and mobility and comprehensive community revitalization strategies to address areas where PHAs engage in preservation and new construction of affordable housing in their jurisdictions. HUD added a question to the insert for PHAs to identify areas where PHAs engage in comprehensive community revitalization strategies and to address fair housing and disparities in access to opportunity issues. HUD has committed to developing a fourth Assessment Tool specifically for use by QPHAs who choose to conduct and submit an individual AFH or that collaborate with other QPHAs to conduct and submit a joint AFH.

6. Whether HUD should include any other contributing factors or amend any of the descriptions of the contributing factors to more accurately assess fair housing issues affecting PHAs' service areas and regions. If so, please provide any other factors that should be included or any additional language for the contributing factor description for which changes are recommended.

A number of commenters provided other contributing factors that they believe HUD should add to the Assessment Tool. A commenter suggested adding adverse housing decisions and policies based on criminal history as a factor. Another suggestion was to add landlords exiting the HCV program into the description of the contributing factor, ''displacement of residents due to economic pressures.'' A commenter proposed that lack of public and private investment should not be merged into one contributing factor, but suggested that HUD add ''and/or'' between the two if it does merge the factors. The commenter also mentioned that HUD should add ''discrimination on the basis of limited English proficiency'' to the ''lack of meaningful language access'' contributing factor, and this should make reference to HUD and USDA's LEP guidance and Title VI. A commenter suggested adding lead-based paint to the environmental health hazards factor, editing the factor regarding ''survivors of domestic violence'' to be consistent with the Violence Against Women Act by including survivors of sexual assault, dating violence, and stalking, adding in a factor for displacement and lack of housing support for victims of harassment based on membership in a protected class, and including individuals with disabilities under the ''nuisance laws'' factor. The commenter applauded HUD's addition of ''Policies related to payment standards, FMR, and rent subsidies,'' but suggested that it also include PHA's policies and procedures for determining rent reasonableness for the Housing Choice Voucher program. A commenter suggested that ''Private Discrimination'' should not have been omitted, and that HUD should add it back into the Assessment Tool. Another commenter mentioned that contributing factors that are only addressed in some sections, such as lack of meaningful language access, should be included in all sections. The commenter suggested adding ''limitations of federal regulations,'' ''low vacancy cities,'' and place-based nature of public housing as contributing factors. Another commenter noted that ''access to reliable automobile transportation'' should be added to the Disparities in Access to Opportunity section. A commenter noted that HUD should remind Program Participants that ''PHAs are required to identify contributing factors that are not listed if that contributing factor creates, perpetuates, contributes to, or increases the severity of at least one fair housing issue.''

Other commenters suggested that HUD limit contributing factors in the Assessment Tool. Commenters noted that contributing factors should be limited to those that are ''housing related.'' A commenter mentioned that in the segregation section of the tool, the contributing factor related to admissions and occupancy policies and procedures should be limited to a discussion of only the PHA's policies and procedures, because otherwise it is too broad and requires PHAs to collect and analyze policies from hundreds of properties.

HUD Response: HUD thanks commenters for their suggestions. In the final version of the Assessment Tool, HUD has tailored the descriptions of the contributing factors so that they better apply in the context of a PHA's analysis. HUD will continue to update and provide guidance to assist PHAs as they consider contributing factors of fair housing issues in completing their AFHs.

While HUD has amended some contributing factors descriptions so that they are better tailored to meet the ways in which PHAs operate, HUD reminds program participants that they must identify contributing factors for their service area and region if that factor significantly creates, contributes to, perpetuates, or increases the severity of one or more fair housing issues. HUD acknowledges that program participants may need to identify contributing factors that are outside of their control or the boundaries of their service areas. If the program participant has met its planning requirements by identifying such factors, but addressing those factors is outside that program participant's control, the program participants are expected to undertake appropriate, good faith collaborative and outreach efforts with local government, private sector and other applicable governmental entities related to goal-setting to address the identified fair housing issue. HUD notes that addressing these types of contributing factors may require a collaborative approach that includes local, state, and private sector entities, and HUD encourages such collaboration.

HUD appreciates the suggestions from commenters of other contributing factors that may create, contribute to, perpetuate, or increase the severity of one or more fair housing issues in the PHA's service area or region. HUD agrees with the commenter that suggested that vacancy rates in cities may contribute to, perpetuate, or increase the severity of one or more fair housing issues, and has noted this in the updated definition of ''lack of access to opportunity due to high housing costs.'' HUD accepts the comment to add ''and/or'' between ''private'' and ''public'' in the contributing factor related to investment. HUD thanks the commenter for the recommendation to revise the ''domestic violence'' contributing factor so that it is consistent with VAWA, and has accepted this recommendation. HUD has also added a definition of ''private discrimination'' into the tool, in combination with ''lack of fair housing laws.''

7. Whether the inclusion of the ''insert'' for Qualified PHAs (QPHAs) will facilitate collaboration between QPHAs and non-qualified PHAs, and whether these entities anticipate collaborating to conduct and submit a joint AFH. Please note any changes to these inserts that (a) would better facilitate collaboration; (b) provide for a more robust and meaningful fair housing analysis; and (c) encourage

collaboration among these program participants that do not anticipate collaborating at this time.

Commenters support the inclusion of the QPHA insert and commended HUD for reducing administrative burden, and some suggested that HUD go even further. Commenters noted that all PHAs should be able to use the QPHA insert, as this will facilitate PHAs to collaborate with States, and the QPHA insert should be the approach for all program participants, regardless of whether they are collaborating. A commenter noted that the insert should not require QPHAs to conduct a regional analysis. Commenters believe that the QPHA insert will facilitate collaboration, and offered suggestions for how to further facilitate this collaboration. One commenter noted that a way to do this is to integrate data from multiple agencies across tables and maps. Another commenter asked HUD to provide assurances that PHAs will be able to certify under their State's plan.

Other commenters appreciated HUD's efforts to reduce burden on small entities, but suggested that the QPHA insert be eliminated or revised in order to ensure a meaningful analysis. A commenter warned that the QPHA insert could send a message to QPHAs that they will be held to a different standard of analysis and it risks creating confusion. The commenter was particularly concerned that HUD combined all of the opportunity indicators into one question in the insert. The commenter suggested that the policies and practices section of the Publicly Supported Housing section should ask the QPHA to consider its Admission and Continued Occupancy Plan (ACOP) and Administrative Plans more broadly, as this merely requires QPHAs to evaluate aspects of their current policies and will not increase burden. PHAs should report on grounds for denial of admission, evictions, or terminations of subsidies, policies regarding accessibility for persons with disabilities and to LEP persons.

HUD Response: HUD thanks commenters for their responses to the insert. By allowing the inserts for some PHAs, HUD has sought to reduce burden on smaller program participants, while still facilitating a robust analysis of fair housing issues that will allow these PHAs to set meaningful fair housing goals and priorities. The approach adopted attempts to address the issue of burden for these smaller agencies, by organizing the identification of contributing factors for the four fair housing issues (Segregation, R/ECAPs, Disparities in Access to Opportunity, and Disproportionate Housing Needs) in one step. This is intended to reduce any unnecessary duplication of effort and to better focus the analysis and identification steps to help produce meaningful fair housing goals. HUD has decided to reduce the burden for PHAs with 1,250 or fewer combined public housing and Housing Choice Voucher units by permitting them to also use the insert. At this time, HUD declines to extend the use of the insert to include all program participants but will continue to explore ways to reduce burden, regional HCV mobility planning and execution, and synchronization of AFH and PHA Agency planning, while appropriate analysis of fair housing issues is undertaken. HUD will continue to consider ways to incentivize and expand collaborations among PHAs to establish regional HCV mobility and portability efforts to increase tenant choice and utilization, PHA cooperation, and landlord outreach across multiple PHA service areas and regions. However, HUD has designed Assessment Tools that allow for collaboration between local governments and PHAs with 1,250 or fewer units and States and PHAs with 1,250 or fewer units. HUD has also committed to developing an additional Assessment Tool specifically for use by Qualified PHAs (QPHAs) who choose to conduct and submit an individual AFH or that collaborate with other QPHAs to conduct and submit a joint AFH.

With respect to the comment about PHAs certifying under their State's plan, HUD notes that PHAs will be able to partner with States when the State acts as the lead entity in the Assessment Tool designed for States, but that each program participant is ultimately responsible for its own assessment of fair housing and certifications. HUD will continue to seek ways to flexibly allow for collaborations by PHAs with other program participants.

HUD disagrees with the comment that the addition of streamlined Assessment Tool inserts for smaller program participants might inadvertently send a message that such smaller program participants are being held to a different standard of analysis. As HUD stated in the Preamble to the AFFH Final Rule, ''. . . HUD commits to tailor its [Assessment Tools] to the program participant in a manner that strives to reduce burden and create an achievable AFH for all involved. HUD intends to provide, in the Assessment Tool, a set of questions in a standard format to clarify and ease the analysis that program participants must undertake. The Assessment Tool, coupled with the data provided by HUD, is designed to provide an easier way to undertake a fair housing assessment.'' 80 FR 42272, at p. 42345 (July 16, 2015). Moreover, the inclusion of the inserts is also intended to facilitate joint and regional partnerships with smaller program participants. Such partnerships can result not only in improved planning and fair housing analysis but in intergovernmental and interagency cooperation and collaboration in goal setting, program operations, and results.

HUD has revised the Policies and Practices question in the insert, as it did in the Local Government tool, to elicit a more meaningful fair housing analysis by prompting PHAs of the types of policies and practices to consider with a focus on HCV portability, mobility, balanced approaches and comprehensive community revitalization strategies.

8. Whether HUD's change to the structure and content of the questions in the Disparities in Access to Opportunity section with respect to the protected class groups that PHAs must analyze is sufficiently clear and will yield a meaningful fair housing analysis. Additionally, HUD specifically solicits comment on whether an appropriate fair housing analysis can and will be conducted if the other protected class groups are assessed only in the ''Additional Information'' question at the end of the section, as opposed to in each subsection and question in the larger Disparities in Access to Opportunity section. HUD also requests comment on whether it would be most efficient for PHAs to have the protected class groups specified in each question in this section. If so, please provide an explanation. Alternatively, HUD requests comment on whether each subsection within the Disparities in Access to Opportunity section should include an additional question related to disparities in access to the particular opportunity assessed based on all of the protected classes under the Fair Housing Act.

Commenters expressed concern that the Assessment Tool does not require program participants to consider local data and local knowledge in completing the Disparities in Access to Opportunity section. Commenters suggested that PHAs should consider other protected classes under the Fair Housing Act and other fair housing laws, including sex and disability. Since the questions currently instruct program participants to answer based on HUD-provided data, and national data on disabilities is limited, commenters noted that this section excludes persons with disabilities. Commenters suggested that program participants use local data and

local knowledge, to the extent available, in the context of the opportunity indicator at issue to consider other protected classes.

HUD Response: HUD thanks commenters for their suggestions. Note, the regional analysis in the Disparities in Access to Opportunity section is only applicable to PHAs that administer HCVs. HUD believes that the structure of this section of the Tool in the version of the Tool that accompanied the 30-day PRA notice presents the appropriate questions to yield a meaningful analysis. HUD notes that in the final version of the Assessment Tool designed for PHAs, the instructions clarify for which questions and which protected classes HUD is currently providing data and for which questions local data and local knowledge, including community participation, will be used to answer questions regarding other protected classes. With respect to access to opportunity for individuals with disabilities, the instructions note that the second question in each section of the Disparities in Access to Opportunity section notes that disability may be identified either in such responses or in the responses related to disparities in access to opportunity in the Disability and Access section, or both, provided all required aspects are analyzed.

9. What sources of local data or local knowledge do PHAs anticipate using with respect to their analysis? Please specify which sections of the Assessment Tool PHAs anticipate using local data and local knowledge. For example, what sources of local data or local knowledge, including information obtained through the community participation process and any consultation with other relevant governmental agencies, do PHAs anticipate using for the service area as compared to the region regarding disparities in access to opportunity? Are there any different sources of local data or local knowledge for the question on disparities in access to opportunity in the publicly supported housing section?

Commenters noted a number of sources of local data and local knowledge that they anticipate using. These sources include their own internal demographics data collected through the annual review process for its public housing and Section 8 programs; data through a specific PHA's open portal on transportation, education and schools, environment, housing and development, and health and human services; community outreach to stakeholders, local service providers, local government agencies, program participants, and advocates; and internal information systems. A commenter noted it would use information from the PHA's housing and vacancy survey, as conducted by the Census Bureau, which enables PHAs to conduct extensive analysis of the locality's residential population and households, race/ethnicity, household composition and types, crowding and doubling-up, immigration, incomes and labor market, education, homeownership, the housing inventory, vacancies and vacancy rates, rent levels, affordability, and conditions of housing and neighborhoods including trends. A commenter mentioned that it will use local data and local knowledge in analyzing factors that prevent clients from accessing housing or constitute other barriers to opportunity. One commenter expressed concern that using local data and local knowledge will divert agency staff from completing their housing-related duties.

HUD Response: HUD thanks commenters for their responses. As HUD provides continued guidance and information on how program participants can use local data and local knowledge to facilitate a meaningful analysis of fair housing issues and goal setting and priorities, it will consider how to use this helpful information from commenters. HUD anticipates that it will continue to update guidance materials to identify potential sources of local data and local knowledge, including sources identified by public commenters through the various public comment periods associated with the Paperwork Reduction Act process associated with the various Assessment Tools. HUD also encourages commenters and other stakeholders to participate in and provide information during community participation when PHAs and other program participants in their communities are preparing to submit their AFHs.

(10) Whether the instructions to the Assessment Tool provide sufficient detail to assist PHAs in responding to the questions in the Assessment Tool. If not, please provide specific recommendations of areas that would benefit from further clarity.

A commenter requested that HUD provide a streamlined guidance document to assist in completing the Assessment Tool and using the instructions.

A commenter stated that instructions on goals and priorities are not sufficient, and it is unclear what factors would not meet the standards for prioritization.

HUD Response: In this final version of the PHA Assessment Tool, HUD has tailored the instructions to provide PHAs with more guidance as they complete the Assessment Tool, including instructions related to contributing factors, prioritization, goal-setting and the scope of regional analysis in the AFH. HUD will continue to explore options for further guidance beyond the instructions. HUD will provide additional guidance for specific questions where local data and knowledge can be used to respond to specific questions due to HUD data limitations.

(11) How can HUD best facilitate the analysis PHAs must conduct with respect to disparities in access to opportunity? For example, are questions based on the overall service area and region of the various opportunity indicators the best way for PHAs to identify access to opportunity with respect to their residents, including voucher holders? With regards to disparities in access to opportunity, how might the PHA identify contributing factors and set goals for overcoming disparities in access to opportunity?

Some commenters suggested that HUD make this section optional for PHAs because these questions are not relevant to a PHA's operations. They note that PHAs have little control over transportation, employment, and schools in a large metropolitan area. One commenter stated that in particular, PHAs should not be required to analyze job training data. Another commenter noted that the analysis of disparities in access to opportunity affecting individuals with disabilities is burdensome because data is not available and it should be deleted.

HUD Response: HUD disagrees with commenters who stated that the questions asked in the Disparities in Access to Opportunity section of the Tool are not relevant to a PHA's operations. PHAs are required to identify the fair housing issues and disparities in access to opportunities that are present in their service areas and regions, as even issues beyond the PHA's control can affect the residents that the PHA serves. Indeed, some PHAs may have little influence over education, transportation, and job-related activities. HUD notes, however, that PHAs are responsible for ensuring that their programs and activities are administered in a manner to affirmatively further fair housing, and that PHAs are responsible for ensuring the administration of such programs and activities do not perpetuate, contribute to, or exacerbate fair housing issues. HUD recognizes that some of these issues may be outside of the PHA's control and staff expertise, and as more fully discussed in HUD guidance and in this notice, the AFH planning

framework, including prioritization of significant contributing factors and setting goals, allows for program participants to match their goals to their unique local circumstances. HUD notes that while PHAs should identify all relevant contributing factors, even if they are outside of the PHA's control, PHAs should select goals that are within the control of the PHA, and that are realistically designed to affirmatively further fair housing.

HUD notes that addressing certain types of contributing factors may require a collaborative approach that includes local, State, and private sector entities. Program participants are expected to identify contributing factors regardless of their ability to exert control over a contributing factor or their proximity to the contributing factor identified if that factor significantly creates, contributes to, perpetuates, or increases the severity of one or more fair housing issues. However, if the program participant has met its planning requirements by identifying such factors, but addressing those factors is outside that program participant's control, the program participants are expected to undertake good faith collaborative and outreach efforts in the form of appropriate goals with local government, private sector, and other applicable governmental entities to address the identified fair housing issue and related contributing factors.

(12) What additional guidance would be useful to PHAs to assist in conducting the fair housing analysis in the Assessment Tool? In particular, which fair housing issues and contributing factors would benefit from additional guidance? For example, in the disparities in access to opportunity section, what guidance would PHAs benefit from?

A commenter suggested that to provide guidance, HUD should publish sample AFHs from various size program participants. Another commenter stated that HUD should provide additional guidance on the prioritization of contributing factors and goals.

HUD Response: HUD thanks commenters for their suggestions and will continue to explore ways to facilitate meaningful AFHs by issuing further guidance. HUD is exploring options for posting AFHs as an online resource for program participants and the public. HUD has provided additional guidance in the Tool's instructions about prioritization of contributing factors and goals.

(13) In the publicly supported housing section, there are several questions related to assisted housing programs that are not owned or operated by the PHA. Are these questions sufficiently clear, or would additional instructions beyond those that are provided be helpful to PHAs in answering these questions? Are there other or different questions that would facilitate the PHAs' analyses of publicly supported housing, specifically for the other categories of publicly supported housing included in this Assessment Tool?

A number of commenters had specific suggestions for improving this section. A commenter suggested questions to be added to the Assessment Tool regarding the Housing Choice Voucher (HCV) program and geographic mobility. The commenter urged HUD to include these questions in the main Assessment Tool and not only in the QPHA insert, because this is HUD's largest assisted housing program, and persons receiving HCV assistance often face barriers to mobility. Another commenter suggested that HUD ask about waiting list demographics. A commenter suggested that the word ''voucher'' be added to the phrase ''project-based developments'' in Question V.D.1.b.i. to clarify that this refers to properties where the PHA has entered into a contract to provide project-based voucher assistance. A commenter suggested adding to the end of Question V.D.2.b.iv.A, which asks about LIHTC, ''and whether there are differences in the neighborhood attributes of LIHTC developments where the PHA's vouchers are in use by members of protected classes.'' A commenter stated that PHAs participating in RAD should be asked whether their tenants are informed of their Choice/Mobility options and are offered moving assistance. Another commenter expressed that PHAs should not have to analyze housing stock outside of its control.

A commenter noted that it supported HUD's balanced approach, but was concerned that PHAs will not make meaningful changes, and therefore requested that HUD keep the balanced approach in perspective when it revises the Guidebook.

HUD Response: HUD appreciates commenters' responses. HUD accepted the commenter's suggestion to add the word ''voucher'' to the phrase ''project-based developments'' in Question V.D.i.2.a (previously question V.D.1.b.i). HUD has also revised the Tool to help PHAs to better analyze the fair housing impacts on persons in the HCV program by encouraging program participants to do outreach to HCV holders while conducting community participation, and by asking about HCV holders in the questions within this section.

HUD disagrees with commenters who noted that PHAs should only analyze housing stock in its control. Issues beyond the PHA's express control can affect the participants that the PHA serves.

In a broader context related to the balanced approach to affirmatively furthering fair housing, HUD has made a number of modifications to the Assessment Tool to recognize the importance of preserving existing affordable housing in connection with affirmative fair housing goals and strategies in connection with community revitalization, as well as modifications with respect to mobility. The balanced approach does not relieve PHAs of their duties to set meaningful goals and priorities to overcome fair housing issues in their jurisdictions and regions. As HUD's own studies on worst case needs for affordable housing make clear, there is an ongoing national crisis in housing affordability that particularly affects lower income families. In many local and regional housing markets, low income households are priced out of the market altogether with some form of income support or housing subsidy being needed to access decent, safe and affordable housing. This makes the preservation of the existing limited supply of long-term affordable stock a key component of any balanced approach to addressing the fair housing issues and contributing factors identified in assessments of fair housing. At the same time, HUD maintains the importance of mobility solutions in connection with affirmative fair housing goals and strategies, and notes that such strategies are not mutually exclusive.

In support of HUD's commitment to the balanced approach to addressing fair housing issues, a number of key changes have been made to the Assessment Tool:

(1) Added the contributing factor on the ''Loss of Affordable Housing.'' This factor was previously released for public comment as part of the Assessment Tool for States and Insular Areas. This contributing factor notes that, ''The loss of existing affordable housing can limit the housing choices and exacerbate fair housing issues affecting protected class groups.'' This factor, along with the contributing factor on ''displacement of residents due to economic pressures,'' allows program participants to recognize the need to preserve affordable housing in areas undergoing economic improvement as a way of maintaining access to opportunity assets for low-income residents and protected class groups as these areas experience increased opportunity.

(2) The Assessment Tool has strengthened the connection between the analysis of disproportionate housing

needs and the analysis in the publicly supported housing section. These changes include adding an instruction noting that the analysis in these sections can be compared to each other, as well as by clarifying the analysis questions in the insert to compare the demographics of who is receiving housing assistance with disproportionate housing needs. The instructions to the insert have also been clarified to note the policy linkage between this analysis and the overriding housing needs analysis required in the PHA Plan as one possible practical application of the AFH analysis.

(3) Adding instructions on LIHTC. The instructions indicate that program participants may distinguish between nine percent and four percent tax credits and the different uses that each can be used for, while analyzing the relation of such tax credit properties to fair housing issues and related contributing factors, including distinguishing for rehabilitation and preservation of affordable housing and for the various priorities available to state allocating agencies in meeting unique housing needs in their jurisdictions, in the context of identifying fair housing issues and related contributing factors.

(4) Adding more detail to the instructions for the additional information questions in the Publicly Supported Housing section. These questions provide an opportunity for program participants to reference or highlight efforts intended to preserve affordability in order to meet unmet and disproportionate housing needs in the context of fair housing issues and related contributing factors. The added instructions state that, ''Program participants may describe efforts aimed at preserving affordable housing, including use of funds for rehabilitation, enacting tenant right to purchase requirements, providing incentives to extend existing affordable use agreements and preventing Section 8 opt-outs, encouraging the use of RAD conversion and the PBRA transfer authority. Program participants may also describe positive community assets and organizations, including community development corporations, non-profits, tenant organizations, community credit unions and community gardens.''

(14) There have been new questions added to the Disability and Access Analysis section, under ''Housing Accessibility'' (Questions 2(d) and 2(e)). Are these questions sufficiently clear, or would additional instructions beyond those that are provided be helpful to PHAs in answering these questions? Are there other or different questions that would facilitate the PHAs' analyses of disability, specifically related to housing accessibility?

A commenter noted that questions in this section regarding disability and access should direct PHAs to consider local data and local knowledge, and HUD should instruct program participants that information gathered in community participation may provide valuable insight into the efficacy of the PHA's actions to engage in effective communications with persons with disabilities. Commenters stated that instructions should provide greater clarity to program participants regarding local data and local knowledge. The commenter noted that instead of instructing program participants to ''supplement'' HUD-provided data with local data and local knowledge, HUD should instruct program participants that local data and local knowledge ''will likely be particularly useful'' and PHAs should be required to contact Centers for Independent Living (CILS), provide evidence of the efforts they made to collect local data and local knowledge, and note a lack of local data and local knowledge if there is none available.

A commenter offered suggestions for questions that would further facilitate the PHA's analysis of disability. The commenter stated that in its current form, the Assessment Tool does not consider individuals with disabilities in relation to other barriers and it should consider intersectionality of disability and other protected classes. In this section, the Assessment Tool should ask about low poverty neighborhoods, environmentally healthy neighborhoods, and patterns in disparity in access to opportunity. The commenter offered the example that questions about effective communication should also include LEP.

Another commenter noted that it disagreed with the Assessment Tool's requirement to analyze integration of individuals with disabilities in the regions, and felt it required PHAs to assess *Olmstead* plans developed by other entities.

HUD Response: HUD has considered the public comments and has removed Question 2(e) under ''Housing Accessibility'' from the Assessment Tool, and instead explains in instructions that program participants should ''consider policies and practices that impact individuals' ability to access the housing, including such things as wait list procedures, admissions or occupancy policies (*e.g.,* income targeting for new admissions), residency preferences, availability of different accessibility features, and Web site accessibility'' when responding to Question 2(b) in that section.

HUD encourages PHAs and all program participants to seek the input of stakeholders, such as civil rights and disability rights groups, when conducting its community participation. Stakeholder groups are valuable sources of information and they can provide program participants with local data and local knowledge that will assist the PHA in completing its AFH and conducting a meaningful analysis of fair housing goals and priorities.

HUD thanks commenters for their suggestion that the Assessment Tool consider intersectionality of disability and other protected classes. In the instructions to the Tool, HUD notes that ''individuals can be members of more than one protected class, for instance, race, ethnicity, national origin often overlap, as will persons with disabilities with other protected characteristics. PHAs are expected to analyze fair housing issues with respect to individuals with disabilities who are also members of additional protected classes.''

(15) Are there other ways HUD can clarify the questions in the Assessment Tool, for example, through the provision of additional instructions, or different instructions from those that have been provided? Additionally, are there other or different questions or instructions that would better assist State PHAs in conducting their fair housing analysis? Please specify whether a particular section, question, or set of instructions requires clarification.

Commenters suggested that the Assessment Tool should more clearly define the definitions of service area and region. This will help PHAs to understand the exact regional area that must be covered and the data necessary to complete the analysis.

HUD Response: In response to commenters' request for more information regarding the service area and region that PHAs must analyze when completing their AFHs, HUD has added a chart identifying applicable regions for various size PHAs in terms of geography and operations and language to the instructions of the Assessment Tool. Appendix A at Part V: Fair Housing Analysis, explains these definitions in detail. The PHA's region varies based on its service area. The revised instructions to the Assessment Tool now include: (1) A description of the service area, also known as the jurisdiction, of various size PHAs in terms of their authorized geographic operations; (2) a description of the PHA's region for purposes of analysis

under the AFFH rule; (3) a description of the HUD-provided data for the PHA's applicable region; (4) instructions related to use of data and identification of fair housing issues and related contributing factors for different size PHAs; and (5) instructions related to rural PHAs, State PHAs, Regional PHAs, and PHAs in Insular Areas.

2. Other Issues Raised by the Public Commenters

PHA Control Over Contributing Factors

Commenters expressed concerns regarding legal exposure resulting from program participants' identification of contributing factors and goals set to address fair housing issues in the AFH. Specifically, commenters were concerned that many contributing factors address issues beyond the program participants' control and/or outside of the program participants' jurisdiction or service area for PHAs. Some commenters have expressed concern about potential litigation and expressed reluctance with regard to identifying contributing factors and developing goals that are primarily outside of their control or under the jurisdiction of the State or other local governments. These commenters have asked whether HUD acceptance of their AFH goals would shield program participants from litigation.

The commenters requested that HUD take into account whether past goals may not be achieved due to a lack of external support, a lack of collaborative action from State or local government entities, or private sector investment when reviewing submitted AFH plans.

Commenters have requested that HUD shield program participants from stakeholder litigation if a program participant fails to achieve a collaborative AFH goal when that program participant exerts good faith efforts to achieve collaborative AFH goals.

HUD Response: HUD recognizes the concerns of these commenters. HUD notes that the AFH is a planning tool. By providing data and information intended to inform local planning and decision making. The AFFH process is intended to assist program participants in meeting their legal obligation to affirmatively further fair housing, which continues beyond the submission of the AFH. Program Participants have an ongoing obligation to comply with the Fair Housing Act and other civil rights requirements.

Regarding the requirement that program participants, including PHAs, must identify significant fair housing issues and contributing factors that may be outside of their control to influence, HUD notes that doing so is still important for planning purposes. Even if they may not have the direct ability to impact or exert control over contributing factors, identifying these factors can, for example, provide context for the barriers facing the eligible populations that the PHA serves. HUD acknowledges that program participants may identify contributing factors that are outside of their control or the boundaries of their service areas. The AFH is a planning document, and a basic tenet of planning and performance management is recognition of ''external factors'' and other barriers to achieving goals, which sometimes are beyond an organization's control (*See, e.g.,* the Federal Government Performance and Results Act). The final AFFH rule requires grantees to identify such barriers. Included in such considerations is the identification of resources such as staffing and funding. HUD notes that addressing these types of contributing factors may require a collaborative approach that includes action by local, State, and private sector entities. Identifying contributing factors outside the control of a program participant may also be useful for considering interagency or public-private collaborative efforts. Program participants are expected to identify contributing factors regardless of their ability to exert control over a contributing factor or their proximity to the contributing factor identified if that factor significantly creates, contributes to, perpetuates, or increases the severity of one or more fair housing issues. However, if the program participant has met its planning requirements by identifying such factors, but addressing those factors is outside that program participant's control, the program participants are expected to undertake good faith collaborative and outreach efforts with local government, private sector, and other applicable governmental entities to address the identified fair housing issue. When these type of substantive collaborative actions are undertaken to address contributing factors outside of their direct sphere of influence or the service area of PHAs, HUD monitoring and oversight actions will take into consideration that there may be extenuating circumstances when there is a lack of collaboration by partnering program participants or private sector entities. Therefore, although collaborating program participants are responsible for any joint goals that are set, each collaborating program participant is only accountable for meeting its own planning requirements in addressing the contributing factors and related fair housing issues.

HUD encourages program participants to set fair housing goals that are within their sphere of influence that can be reasonably expected to be achieved. Goals and priorities in the AFH should be meaningful, realistic, and focus on changes that are achievable. HUD understands that achievement of certain goals may depend on what resources are available or will become available within the timeframe set for achievement. Program participants have latitude in setting goals to account for available resources and to prioritize strategies and actions that are more likely to be successful and to achieve the greatest impact. A program participant need not, and indeed should not, set a goal over which it maintains no control. There may be instances where a program participant's efforts to address contributing factors it has control over will assist another program participant with a goal it has set.

HUD recognizes public commenters' concerns regarding their ability to control contributing factors and their proximity to these contributing factors. HUD recommends program participants distinguish between significant contributing factors they control, and those they do not, as well as how they might respond to contributing factors they do not control, but can address in the context of their own operations. PHAs, in particular, are advised to consider these issues as they prioritize contributing factors and establish meaningful goals to overcome the effects of the fair housing issues they can control.

HUD has included instructions in the Assessment Tools, and has issued additional guidance to clarify how program participants, including PHAs, may set collaborative goals to address contributing factors and fair housing issues that are beyond their direct purview, control, or expertise. HUD anticipates including further guidance, including in an updated version of the AFFH Rule Guidebook, on identifying contributing factors, prioritizing them, and setting appropriate goals.

HUD Provided Data

Several commenters provided feedback on HUD-provided data that is to be used to complete the AFH. A number of commenters noted that the data currently provided by HUD is not sufficient to assist them in deciding whether to collaborate. Another commenter noted that some of the PHA's units were not included in HUD-provided data. Another commenter was

concerned that the data is not user-friendly enough, and may be outside the skillset of PHA staff. A commenter stated that the disparities in access to opportunity section should include Table 12, which HUD has made optional.

Other commenters requested that HUD provide more data, or different data. A commenter requested that HUD provide data at a more granular level. The commenter noted that in order to advance fair housing, public policies must be adopted at the municipal level, but HUD does not provide relevant block-group level data by municipality. The commenter noted that Census tract-based data obscure concentrations of poverty and other characteristics within small cities where census tracts cross municipal boundaries. The commenter requested that HUD provide census data for the portion of the Census Tract within each municipality, or if it not reliable at the block group level within a portion of the Census Tract, HUD should provide data from multiple block groups of adjoining census tracts within the same municipality. Commenters requested that HUD provide additional data about individuals with disabilities, including Medicaid home and community-based waiver programs, Money Follows the Person program, disability, and individuals in nursing homes, and suggested that HUD should instruct program participants to seek supplemental information from Aging and Disability Resource Centers (ADRCs) and Centers for Independent Living (CILs). Commenters requested that HUD provide more information and demographic data on LIHTC properties, as HUD already collects data pursuant to the 2008 Recovery Act, and if HUD is unable to provide data, it should instruct PHAs to use their own demographic data for any LIHTC-assisted PHA properties. Some commenters suggested that until HUD provides data on disabilities and LIHTC, it should not ask about these subjects.

A commenter appreciated that HUD provides data in its raw format because PHAs otherwise cannot collect this raw data.

HUD Response: HUD appreciates the commenters' suggestions. HUD is continuing to work to increase the ease of electronic availability of the Assessment Tool, maps, and tables. The agency will continue to improve upon the HUD-provided data and maps to strive to make them easily accessible and easily readable to its program participants. HUD will continue to explore options for making improvements to the User Interface, to data provided and the functionality of the data tool, and for providing additional guidance on using the HUD-provided data in the instructions to the Assessment Tool, as well as through other guidance materials. As HUD assesses longer-term improvements to the Assessment Tool data, HUD will continue to consider the comments received that recommended significant changes.

As to the comments about LIHTC data, HUD continues to administer and improve the LIHTC data on projects placed-in-service and LIHTC tenant demographic data. HUD will work to provide data for AFFH–T at an appropriate level of geography (*e.g.,* State, County, City, development and in rural areas outside of CBSA regions, etc.) as the data becomes available and verified for consistency and reliability. These data may be available in a variety of formats external to the AFFH–T Data and Mapping Tool. It is not expected that development level tenant data will be available in the near term due to current data quality issues. Additionally, compliance with federal privacy requirements will limit certain development-level data that will be available in the future. For background on data that are currently available, please see HUD's report, ''Data on Tenants in LIHTC Units as of December 31, 2013'' which is available at *https://www.huduser.gov/portal/publications/data-tenants-LIHTC.html.* HUD will also continue to pursue additional guidance on potential sources of readily and easily accessible information that may be useful as supplementary local data.

Reducing Burden Through Technical Assistance and Funding

One commenter noted that HUD has stated that Technical Assistance will be provided to PHAs, but the commenter urges that HUD make this a priority. Commenters also encouraged HUD offices throughout the country to be knowledgeable about AFFH.

Other commenters expressed concern about funding and hiring consultants. Some commenters urged HUD to request additional funding from Congress for PHAs to complete their AFHs.

HUD Response: HUD thanks commenters for their responses. HUD is committed to providing program participants with the resources they need to complete their AFHs, and encourages program participants to review existing HUD guidance, notices, and responses. HUD will continue to explore opportunities for providing greater guidance, training and technical assistance to program participants.

Community Participation

Some commenters stated that HUD should encourage more robust community participation. A commentator stated that program participants should be asked if they consulted stakeholders working in areas of public health, education, workforce development, environmental planning, or transportation so that program participants take an expansive view of their community members. Another commenter stated that HUD should inquire about the extent to which program participants effectively engaged in communications with persons with disabilities. A commenter noted that HUD's outreach to the RAB and other residents are positive improvements, and HUD should include additional language to reach residents of public housing, Section 8 HCV households, and persons eligible to be served by the PHA, including those currently on a PHA-administered waitlist. HUD should also require descriptions of how documents were provided to the community and require PHAs to include solicitation of feedback on preservation of properties, and resident relocation and mobility from R/ECAPs. The commenter agreed that PHAs should be given guidance that they can solicit feedback through surveys, but as a supplement, not a substitute, to that which community participation requires. Another commenter stated that HUD should remind program participants that collaboration does not relieve individual PHAs of the duty to engage in the community participation process.

A commenter requested that ''HUD should note that HUD will not apply a rigorous statistical validity test for all local data when discussing 'subject to statistical validity.' This is important so important local data and local knowledge is not dismissed by the PHA during community participation.''

Other commenters urged HUD to lessen the requirements of the community participation process. One commenter suggested that HUD should tell program participants that they do not need to ''expend excessive or unreasonable staff time and cost to review data received during the community participation process beyond what is necessary to adequately consider the data in accordance with the AFFH rule.'' Other commenters stated that community participation should be limited to RABs and applicable community partners, and another stated that program participants should not be required to consult with other government agencies.

HUD Response: The final rule strengthened the community participation requirements by directing each program participant to employ communications methods that are designed to reach the broadest audience. As HUD stated in the 30 Day PRA notice for the PHA Assessment Tool, ''HUD also notes that the community participation process that is part of conducting an AFH may yield important information from members of the community about [fair housing] issues for the PHA to consider as it conducts its AFH.'' 81 FR 64475, at p. 64481 (Sept. 20, 2016). HUD encourages program participants to consult stakeholders including fair housing groups, civil rights groups, disability rights groups, and other organizations in order to collect robust information through the community participation process that will provide valuable assistance to program participants in identifying contributing factors, prioritizing these factors, and setting meaningful goals that are designed to overcome fair housing issues. In the broader context, HUD notes that the area of encouraging and incorporating public involvement in planning activities is a growing field of interest and that there are likely to be technological ideas and solutions that may be worthy of additional interest and inquiry over time.

With respect to the commenter who requested that HUD note that it will not apply a statistical validity test for all local data, as HUD noted in the preamble to the final AFFH rule, ''The phrase 'subject to a determination of statistical validity by HUD' is included to clarify that HUD may decline to accept local data that HUD has determined is not valid but not that HUD will apply a rigorous statistical validity test for all local data.'' 80 FR 42272, at p. 42306 (July 16, 2015). HUD has revised the instructions to the Assessment Tool in the definition of ''local data and local knowledge'' to reiterate this.

Specific Suggestions for the Assessment Tool

A commenter noted that HUD should clarify timelines for collaborations.

Another commenter suggested that HUD reduce the segregation section to not require a segregation/integration analysis since PHAs are not experts. The commenter also suggested that HUD combine demographic analysis with the Publicly Supported Housing section and remove transportation, education, and employment from the disparities section. The commenter also stated that the instructions should be shortened.

A commenter stated that the question that asks, ''Describe the waitlist(s) policy of the PHA to include preferences, placement determination (*e.g.,* first-come, first-served vs. lottery), program selection (*e.g.,* agency-wide waitlist or by development), application method, length of time application window is open, and average wait time list'' in the ''Disability and Access Analysis'' section should also be included in the Segregation and R/ECAPs sections because these practices also affect access for other protected groups. Another commenter objected to the question because HUD already requires waitlist policies and practices in five-year and Annual Plans. Another commenter was opposed to this question because of the number of individuals on the waitlist in some PHAs. Commenter suggested that instead, HUD should include one or more questions focused on a PHA's waiting list policies and administration from a fair housing perspective, including any PHA proposals to improve its processes to further fair housing goals.

A commenter noted that the Housing Enforcement section should ask about pending fair housing or other civil rights complaints, which may be helpful in noticing emerging fair housing issues. Another commenter found this section to be vague.

A commenter stated that the Assessment Tool should incorporate comprehensive consideration of sex, gender, and fair housing challenges experienced by women in the analysis, as well as address the fair housing barriers experienced by survivors of domestic violence and sexual assault. The commenter also suggested that the Tool ask for an analysis of barriers to fair housing choice by local nuisance laws.

A commenter noted that HUD should eliminate reviews of Analyses of Impediments (AIs) in the Assessment Tool, and HUD should revert back to the AI process.

A commenter suggested that HUD should modify the threshold for QPHAs.

A commenter noted that limitations on use of local data and local knowledge should be included in notes to the public about use of local data and local knowledge.

A commenter noted that asking PHAs to analyze trends that may influence segregation in the future is speculative, and the Assessment Tool should not ask this. The commenter also noted that the Tool should not require inventories of local laws, policies, and practices. The commenter suggested that the additional information questions be eliminated because they are redundant, and PHAs should not be required to conduct regional analysis of admissions and occupancy policies and procedures including preferences in publicly supported housing or to analyze regional analysis of nuisance laws, land use and zoning laws, a complete inventory of all assisted housing, policies related to rents and FMRs, and source of income discrimination. The commenter stated that it believed the occupancy codes and restrictions questions should not be included because it conflicts with HUD policies and practices. The commenter also objected to questions that asked for an analysis of R/ECAPs and noted that a regional analysis of R/ECAPs is not useful to PHAs.

A commenter suggested removing the Disproportionate Housing Needs analysis because it is duplicative and is covered in other analysis.

A commenter stated that instructions for the assessment of Past Goals, Actions, and Strategies should explain that ''other relevant planning documents'' include ACOPs, Administrative Plans, past PHA Plans (including Five Year and Annual Plans), and Language Assistance Plans to the extent the PHA has adopted policies, practices, or procedures that implicate fair housing choice.

A commenter noted that HUD should change ''transforming R/ECAPs'' to ''expanding opportunity into R/ECAPs.''

A commenter stated that the Assessment Tool should acknowledge the Equal Access Rule and should explore the denial of housing choice due to sexual orientation, gender identity, or marital status, and steps that PHAs and other HUD funded entities have taken to implement the Equal Access Rule.

A commenter suggested that each section of the Assessment Tool should require PHAs to ask questions about disparities in access to services and infrastructure for members of protected classes who are (1) farmworkers, (2) mobile home residents, and (3) living in disadvantaged rural areas in the PHA's service area or region, using local data and local knowledge.

HUD Response: HUD thanks commenters for their specific suggestions to improve the Assessment Tool.

As to the first comment, HUD encourages program participants to consult § 5.156 of the final rule for the rule's requirements for Joint and Regional AFHs.

As to commenters who suggested eliminating sections or questions of the Assessment Tool and noted that the

Tool requires an inventory, HUD reiterates that the Tool does not require an inventory of laws, policies, and practices, and the Tool is a planning tool designed to create solutions and goals that respond to the fair housing and disparities in access issues identified. HUD thanks commenters for their suggestions, and remains committed to providing Program Participants with a Tool that will allow them to conduct an analysis of fair housing issues facing their services areas, jurisdictions, and regions that will inform meaningful goal setting and priorities.

HUD also thanks commenters who suggested additional questions or areas to ask about in the Tool. HUD agrees that the Tool should ask about mobile home residents, and this is included in the final version of the Tool along with manufactured housing in the definition of the contributing factor, Land Use and Zoning Laws. HUD has also noted in the instructions to the Fair Housing and Enforcement section that program participants may discuss other protected classes covered by state and local fair housing and civil rights ordinances. While the final version of the Tool does not include Nuisance Laws as its own Contributing Factor, it adds the new factor, ''Displacement of and/or lack of housing support for victims of domestic violence, dating violence, sexual assault, and stalking.'' HUD has revised the Assessment Tool to better capture the nuances of nuisance laws by incorporating this into both the new abovementioned factor, and in the ''Land Use and Zoning Laws'' contributing factor. HUD also revised the Assessment Tool to ask about the PHA's policies and practices, including those in the Admission and Continued Occupancy Policy (ACOP) and Administrative Plan, relating to fair housing.

As to the commenter who believed HUD should revert back to the AI process, HUD notes that since the AI process was not as effective as envisioned, the new AFFH process is intended to provide a more robust fair housing analysis and to help program participants to select meaningful goals and priorities to meet their statutory obligation to Affirmatively Further Fair Housing.

As to the comment seeking clarification about local data and local knowledge, HUD has clarified in the instructions that there may be limited nationally-uniform data available for the regional analysis for PHAs in rural areas, and such data limitations may be present in the AFFH Data and Mapping Tool. In cases where data is unavailable, HUD expects that PHAs in rural areas will consult local data and local knowledge, including information obtained through the community participation process, to complete this analysis.

HUD has adopted the suggested change to modify the threshold of those PHAs that may use the insert, and has modified the threshold from QPHAs (550 units) to PHAs with 1,250 units or fewer. HUD will also continue to consider efforts to reduce administrative burden on all program participants, including PHAs.

Miscellaneous

A commenter asked whether the Tool raises the level of scrutiny for housing above *Lindsey* v. *Normet's* minimum level of scrutiny. The commenter stated that *Lindsey* v. *Normet,* held: (1) There is no fairness component of housing because there is no fairness component of property, and (2) there is homelessness. The commenter stated that in the Tool and the policies underlying it, the Government finds that fairness is a component of property and housing; further, dignity is the essence of the Tool and a component of housing. The commenter noted that in the Government's statement of interest in the *Boise* homelessness case, the government found that homelessness does not exist as homeless people are housed people whose housing is assaulted. The government's policies show that housing has a higher level of scrutiny than minimum scrutiny, and the Supreme Court in the same-sex marriage case found that dignity is an individually enforceable right with a higher level of scrutiny than minimum scrutiny. The commenter asked: Does housing enjoy a level of scrutiny higher than minimum scrutiny? According to *West Virginia* v. *Barnette,* a fact is an individually enforceable right in court, and the level of scrutiny is raised, if, inter alia, the fact is ''unaffected by assaults upon it.'' Does the government deny that this is the test? Has the government found that housing passed this test? Who has the power to enforce the Rule in court and pursuant to what right? What parts of these policies are individually enforceable?

A commenter noted that it felt its area did not lend itself to completing the Assessment Tool because the area is 99% white, with a 1% Native American population, and there is no segregation and schools are as integrated as they can be. The commenter noted that the government should stop trying to track differences.

A commenter stated that using race to lead decision making has serious constitutional questions, and cited to *Tex. Dep't of Hous. & Cmty. Affairs* v. *Inclusive Cmtys. Project, Inc.,* 135 S. Ct. 2507 (2015).

A commenter suggested that HUD create a working group to test the PHA Tool before implementation. HUD should require PHAs to conduct assessments as part of a demonstrations program before pursuing implementation.

A commenter noted that HUD's new HUD Environmental Review Online System (HERO) requires a partial AFFH analysis of environmental factors, and this is duplicative and uncoordinated with the AFFH Tool submission. The commenter recommended relying on the AFH process, not HERO for this analysis.

HUD Response: HUD has carefully reviewed the commenters' suggestions. As to the first commenter, HUD reviewed the case law cited by the commenter and has concluded that the cases are not applicable to the obligation to affirmatively further fair housing under the Fair Housing Act and under the AFFH rule. HUD continues to assert that the AFFH rule and the Assessment Tool implementing the requirements contained in the regulation will better facilitate compliance with the AFFH mandate under the Fair Housing Act.

HUD notes that in the Assessment Tool, in the instructions, that in identifying areas of segregation and integration program participants should not only focus on areas of minority concentration in their jurisdictions and regions, but also areas of majority concentration. HUD notes that segregation and integration are defined in the AFFH regulation at 24 CFR 5.152 and apply to minority concentration and majority concentration, no matter the protected class. HUD has also included instructions related to analyzing segregation in majority-minority communities and where there are concentrations of particular national origin, ethnic, or religious groups.

HUD thanks commenters for their suggestions regarding testing the PHA Tool. HUD submits that it has given commenters sufficient time to comment on the Assessment Tool through the PRA process, with both the 60-day and 30-day notices.

Program Participants are reminded that they must apply with all applicable laws, including Fair Housing Laws and the Privacy Act.

As to the last commenter, HUD notes that the AFFH rule requires fair housing planning and describes the required elements of the fair housing planning process. The first step in the planning process is completing the fair housing

analysis required in the AFH. The rule establishes specific requirements program participants will follow for developing and submitting an AFH and for incorporating and implementing that AFH into subsequent Consolidated Plans and Public Housing Agency (PHA) Plans in the form of strategies and actions. This process will help to connect housing and community development policy and investment planning with meaningful actions that affirmatively further fair housing. The new approach put in place by this rule is designed to improve program participants' fair housing planning processes by providing data and greater clarity to the steps that program participants must take to assess fair housing issues and contributing factors, set fair housing priorities and goals to overcome them, and, ultimately, take meaningful actions to affirmatively further fair housing. A goal of the AFFH rule is to make sure states and insular areas, local communities, and PHAs understand their responsibilities in the area of fair housing planning. As the Department works to foster effective fair housing planning, goal setting, strategies, and actions, it recognizes that the people who are most familiar with fair housing issues in cities, counties, and states are the people who live there and deal with these issues on a daily basis.

D. Summary

In issuing this Public Housing Agency Assessment Tool, approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, HUD has strived to reach the appropriate balance in having program participants produce a meaningful assessment of fair housing that carefully considers barriers to fair housing choice and accessing opportunity and how such barriers can be overcome in respective service areas and regions without being unduly burdensome. HUD has further committed to addressing program participant burden by providing data, guidance, and technical assistance, and such assistance will occur throughout the AFH process. While HUD is not specifically soliciting comment for another prescribed period, HUD welcomes feedback from HUD grantees that use this Tool on their experience with this Tool.

Dated: January 9, 2017.

Gustavo Velasquez,

Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. 2017–00713 Filed 1–12–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5173–N–10]

Affirmatively Furthering Fair Housing: Announcement of Renewal of Approval of the Assessment Tool for Local Governments

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice.

SUMMARY: This notice announces that the Office of Management and Budget (OMB) has approved HUD's request to renew for approval under the Paperwork Reduction Act (PRA), the Assessment Tool developed by HUD for use by local governments that receive Community Development Block Grants (CDBG), HOME Investment Partnerships Program (HOME), Emergency Solutions Grants (ESG), or Housing Opportunities for Persons with AIDS (HOPWA) formula funding from HUD when conducting and submitting their own Assessment of Fair Housing (AFH). This Assessment Tool, referred to as the Local Government Assessment Tool, is used for AFHs conducted by joint and regional collaborations between: (1) Such local governments; (2) one or more such local governments with one or more public housing agency (PHA) partners, including qualified PHAs (QPHAs); and (3) other collaborations in which such a local government is designated as the lead for the collaboration. Through the notice and comment process required by the PRA, HUD did make changes to the Local Government Assessment Tool approved by OMB in 2015. HUD's Web page at *https://www.hudexchange.info/programs/affh/* highlights the differences between the 2015 Local Government Assessment Tool and this 2016 Local Government Assessment Tool. This notice also highlights significant issues raised by commenters on the 30-day notice published in the **Federal Register** on August 23, 2016.

FOR FURTHER INFORMATION CONTACT: Krista Mills, Deputy Assistant Secretary, Office of Fair Housing and Equal Opportunity, Department of Housing and Urban Development, 451 7th Street SW., Room 5246, Washington, DC 20410; telephone number 866–234–2689 (toll-free) or 202–402–1432 (local). Individuals who are deaf or hard of hearing and individuals with speech impediments may access this number via TTY by calling the toll-free Federal Relay Service during working hours at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2015, at 80 FR 42357, HUD published in the **Federal Register** its Affirmatively Furthering Fair Housing (AFFH) final rule. The AFFH final rule provides HUD program participants with a new approach for planning for fair housing outcomes that will assist them in meeting their statutory obligation to affirmatively further fair housing as required by the Fair Housing Act. To assist HUD program participants in improving planning to achieve meaningful fair housing outcomes, the new approach involves an ''assessment tool'' for use in completing the regulatory requirement to conduct an assessment of fair housing (AFH) as set out in the AFFH rule. Because of the variations in the HUD program participants subject to the AFFH rule, HUD has developed three separate assessment tools: One for local governments, which is the subject of this notice, the Local Government Assessment Tool; one for public housing agencies (PHAs), the PHA Assessment Tool; and one for States and Insular Areas, the State and Insular Areas Assessment Tool. HUD is currently developing all tools to allow for a joint or regional collaboration with local governments of all sizes and public housing agencies. All three assessments tools, because they are information collection documents, are required to undergo the PRA notice and comment process. HUD has also committed to developing a fourth Assessment Tool specifically for use by QPHAs who choose to conduct and submit an individual AFH or that collaborate with other QPHAs to conduct and submit a joint AFH.

II. Local Government Assessment Tool

A. The PRA Process

The Local Government Assessment Tool was approved by OMB under the Paperwork Reduction Act (PRA) in December 2015, and HUD announced the approval of this tool and the availability of its use by notice published in the **Federal Register** on December 31, 2015, at 80 FR 81840. The Local Government Assessment Tool was approved by OMB for a period of one year and in 2016, HUD began the process for renewal of the Local Government Assessment Tool.

On March 23, 2016, at 81 FR 15546, HUD published its 60-day notice, the first notice for public comment required by the PRA, to commence the process for renewal of approval of the Local Government Assessment Tool. Although

HUD made no changes to the Local Government Assessment Tool approved by OMB in December 2015, HUD specifically solicited public comment on 6 issues (inadvertently numbered as 7 in the March 23, 2016 publication). The 60-day public comment period ended on May 23, 2016. HUD received 18 public comments.

On August 23, 2016, at 81 FR 57602, HUD published its 30-day notice under the PRA. In the 30-day notice, HUD addressed the significant issues raised by the commenters on the 60-day notice. HUD received 28 public comments in response to the 30-day notice. HUD appreciates the comments received in response to the 30-day notice, and, in developing this final version of the Assessment Tool all comments were carefully considered. The significant issues commenters raised and HUD's responses to these issues are addressed in Section II.C. of this notice. All comments submitted on the August 23, 2016, notice can be found on *www.regulations.gov* at *https://www.regulations.gov/docketBrowser?rpp=50&so=ASC&sb=docId&po=0&dct=PS&D=HUD-2016-0090.*

In addition, and as noted earlier in this notice, HUD has posted on its Web site at *http://www.huduser.gov/portal/affht_pt.html* and *https://www.hudexchange.info/programs/affh/,* a comparison of the Local Government Assessment Tool approved by OMB in 2016 and that approved by OMB in 2015.

B. Differences in the Local Government Assessment in 2016

This section highlights the key changes between the approved 2015 Local Government Assessment Tool and this 2016 Local Government Assessment Tool that differ from the approved 2015 Local Government Assessment Tool. A comparison draft of the 2016 Local Government Assessment Tool to the 2015 Local Government Assessment Tool that shows all of the differences can be found at *https://www.hudexchange.info/programs/affh/.*[1] The following lists the more significant differences:

• The most significant difference between the 2016 and 2015 Assessment Tools is that in the 2016 Assessment Tool, HUD has included two inserts designed to facilitate collaboration between different types of program participants that choose to conduct a joint or regional AFH with a local government as the lead entity, and to reduce burden for smaller program participants choosing to enter into joint or regional collaborations.

○ The first is an insert for use by PHAs with 1,250 or fewer units, which are PHAs with a combined unit total of 1,250 or fewer public housing units and Section 8 vouchers. PHAs that collaborate with local governments are still required to complete an analysis of their service area and region, as required by the AFFH rule, but the insert is designed to make the analysis less burdensome. For PHAs with service areas in the same core-based statistical area (CBSA) as the local government, the analysis required in the insert is intended to meet the requirements of a PHA service area analysis, and it is expected that the local government's analysis of the CBSA would satisfy the PHA's regional analysis. For PHAs whose service area extends beyond, or is outside of, the local government's CBSA, the analysis in the insert must cover the PHA's service area and region. See table below:

PHA jurisdiction/service area	HUD-provided data for PHA region
Metropolitan and Micropolitan (CBSA) PHAs: PHA jurisdiction/service area is located within a CBSA.	Maps and Tables for the CBSA.
Sub-County Rural PHAs: PHA jurisdiction/service area is outside of a CBSA and smaller than a county.	Tables for the county. Maps are available for the county and if patterns of segregation, R/ECAPs, disparities in access to opportunity extend into a broader area, maps are also available to identify such patterns, trends, and issues.
County-Wide or Larger Rural PHAs:[2] PHA jurisdiction/service area is outside of a CBSA and boundaries are consistent with the county or larger.	Tables include data for all contiguous non-CBSA counties, in the same state, and inclusive of the PHA's county (or counties). Maps are available for all counties and if patterns of segregation, R/ECAPs, disparities in access to opportunity extend into a broader area, maps are also available to identify such patterns, trends, and issues.
Statewide PHAs: The PHA's jurisdiction/service area is the State	HUD will generally provide data consistent with that provided to the State. Maps may be used to analyze fair housing issues that extend beyond the state's borders, where applicable, but tables are provided with data within the state's borders.

○ The second insert is for use by local government consolidated plan program participants that received a CDBG grant of $500,000 or less, including HOME consortia whose members collectively received $500,000 or less in CDBG funds or whose members received no CDBG funds, in the most recent fiscal year prior to the due date of the joint or regional AFH.

• The 2016 Assessment Tool emphasizes that the solicitation of information on whether there are any demographic trends, policies, or practices that could lead to higher segregation in the jurisdiction or region in the future, is not to be read as HUD seeking an inventory of local laws, policies or practices. A similar instruction has been added noting that the regional analysis across multiple sections is not meant to be interpreted as an inventory of local policies and practices in all of the local governments throughout the region.

• In the Disparities in Access to Opportunity section of the 2016 Assessment Tool, HUD identifies where it provides data for each of the opportunity areas to be assessed, while the instructions make clear which protected class groups the HUD-provided data includes. HUD also clarifies which questions in the Disparities in Access to Opportunity

[1] In addition to the redline/strikeout version of the assessment tool that provides a compare of the 2016 tool to the 2015 tool, HUD also provides at *https://www.hudexchange.info/programs/affh/* a redline/strikeout of the Assessment Tool that accompanied the 30-day PRA notice and this final version.

[2] HUD acknowledges that there are other PHAs, including regional PHAs, that may have differing or unique geographies from the categories in this table. HUD may provide data in the AFFH Data and Mapping Tool for such PHAs appropriate for their geographies based on administrative and data considerations. All program participants are required to conduct an analysis of their jurisdiction and region consistent with the AFFH Final Rule.

section require a jurisdictional and regional analysis.

- In the Publicly Supported Housing analysis of the 2016 tool, HUD changed the list of contributing factors that may affect the jurisdiction and region that should be considered.
- In the Disability and Access analysis of the 2016 Assessment Tool, HUD clarifies that the analysis should cover both the jurisdiction and the region as identified in the Assessment Tool.
- The accompanying instructions have been revised to reflect the changes to questions in the Assessment Tool, changes made to the HUD-provided data, and to provide additional guidance to assist program participants in conducting the AFHs.

C. Responses to Significant Issues Raised by Public Commenters on the 30-Day Notice

1. Specific Questions Posed by HUD in the 30-Day Notice

In the 30-day notice, HUD posed a series of questions for which HUD specifically sought comment.

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.

In response to this question, there were commenters that stated completion of the Assessment Tool is not necessary for the proper performance of agency functions and will not have practical utility, because agencies must already comply with income deconcentration to help eliminate R/ECAPs, and that racial and ethnic concentrations are analyzed and measures taken to eliminate segregation. The commenters stated that for many small grantees, much of the collection of information will be superfluous and will have little utility because grantees do not have the resources or capacity to address issues identified in the analysis. The commenters stated that providing additional time and ''inserts'' to small CDBG grantees is an inadequate response to the burden. The commenters stated that AFH is a complicated and burdensome process, and HUD should have corrected deficiencies in the comparatively simple process for Analysis of Impediments. Commenter stated that submitters have the burden of analyzing a broad set of variables, many of which they have little or no control over, such as the regional analysis over territory where they do not exercise control. Core-based statistical areas (CBSAs) often cover multiple states/counties/jurisdictions/school districts/special districts—which include urban cores, inner and outer suburbs, exurban communities, and rural jurisdictions. The commenters stated that the analyses will be time-consuming, likely unsupported by data, and provide little benefit to the Fair Housing Act goals.

HUD Response: HUD continues to submit that the Assessment Tool has substantial utility for program participants in assessing fair housing issues, identifying significant contributing factors, formulating meaningful fair housing goals, and ultimately meeting their obligation to affirmatively further fair housing. One of the primary purposes of the Assessment Tool is to consider a wide range of policies, practices, and activities underway in a program participant's jurisdiction and region and to consider how its policies, practices, or activities may facilitate or present barriers to fair housing choice and access to opportunity, and to further consider actions that a program participant may take to overcome such barriers. The series of questions in the Assessment Tool enables program participants to perform a meaningful assessment of key fair housing issues and contributing factors and set meaningful fair housing goals and priorities. The Assessment Tool also clearly conveys the analysis of fair housing issues and contributing factors that program participants must undertake. In essence, HUD submits that the Assessment Tool, and the entire AFH approach, better implements the AFFH mandate under the Fair Housing Act.

In terms of resource limitations, HUD is aware that program participants may be limited in the actions that they can take to overcome barriers to fair housing choice and notes that the AFH process does not mandate specific outcomes. However, that does not mean that no actions can be taken, or that program participants should not strive to first understand the fair housing issues facing their communities and then work to overcome barriers to fair housing choice or disparities in access to opportunity. HUD has issued guidance on how program participants may establish appropriate goals pertaining to outreach, collaboration, etc. to address contributing factors and fair housing issues that are beyond their direct control or expertise. HUD has added clarifying instructions regarding prioritization of contributing factors and setting goals, consistent with the AFFH Final Rule and AFFH-related guidance. These edits state that, ''Program participants have discretion, within the requirements of the AFFH Rule, to analyze and interpret data and information, identify significant contributing factors, and set goals and priorities using the Assessment Tools provided by HUD. As more fully discussed in the guidance on HUD's review of AFHs, HUD will consider local context and the resources the program participant has available.''

HUD has also made key changes to the instructions to clarify issues raised by the commenters including the scale and scope of the analysis that is required. These clarifications include that, ''The questions in the Assessment Tool are written broadly by HUD to enable program participants in many different parts of the country to identify the fair housing issues that are present in their jurisdictions and regions.'' These and similar clarifications are intended to note that the Assessment Tool is intended to be scalable to meet the needs of a wide variety of different local governments and potential joint and regional partners. Program participants may choose to set goals and priorities based on the level of impact they can have; for example, whether the goal will have a greater impact in the short-term versus the long-term, or vice versa. HUD also recognizes that efforts involving the need for cooperation between different agencies or between different local governments may often be dependent on having effective intergovernmental coordination.

The AFH planning framework, including prioritization of significant contributing factors and setting goals allows for program participants to match goals and policy options to different local circumstances and the different types of fair housing issues communities face. For instance, different approaches and goals may be needed in high cost versus low cost markets, housing markets with higher vacancy versus lower vacancy rates, in areas with different patterns of single family versus mixed use development, or in areas experiencing economic or population growth versus longer-term decline. Applying place-based, mobility, preservation and rehabilitation or incentives for new construction, affordable rental or single family approaches may be appropriate as described in the balanced approach and depending on fair housing issues and related contributing factors as identified in the AFH. The AFFH process also envisions the possibility of adopting innovative and experimental goals and priorities as a way of attempting different approaches that may yield positive fair housing outcomes.

With respect to smaller program participants, HUD continues to strive to find ways to better enable these entities to comply with their obligation to affirmatively further fair housing while recognizing their resource limitations.

In this regard, HUD published a notice in the **Federal Register** on October 24, 2016, at 81 FR 73129, in which HUD announced that it moved the AFH submission deadline for grantees that receive less than $500,000 in CDBG who would otherwise be due to submit based on the program year that begins on or after January 1, 2018, for which a new 3 to 5-year consolidated plan is due, to the program year that begins on or after January 1, 2019, for which a new 3 to 5-year consolidated plan is due. HUD believes that the one-year delay in the submission deadline will not only help program participants that receive smaller CDBG grants, but will give HUD additional time to find ways to reduce burden for program participants that receive relatively small CDBG grants, as well as for qualified public housing agencies (QPHAs) that will also begin submitting based on their first planning cycle beginning on or after January 1, 2019.

2. The accuracy of the agency's estimate of the burden of the proposed collection of information.

Several commenters stated that they could not advise whether HUD's estimate of 240 hours is accurate, but that they could advise that completion of the assessment tool is an insurmountable financial and physical burden, especially because the consolidated planning process immediately follows. A few commenters stated they had to hire consultants to do their 2015 consolidated plan (using city money, because they would have gone over the 20 percent cap using CDBG money); listed salaries and other costs. Other commenters stated that it is difficult to know what the burden will be, as administrative burdens have been doubled for early submitters because training is just now being offered and changes to the tool have been issued while participants are doing the assessments. A commenter stated that large local governments and joint/regional AFHs cannot quantify the amount of community engagement required.

Other commenters stated that the estimate of 240 hours is too low. A commenter stated that HUD's estimate is ''grossly underestimated,'' particularly for participants that have not previously completed robust AIs. Another commenter stated that the 240 hour estimate is inadequate, due to the time required to plan and run public meetings, translate notices, interpret information; obtain and analyze supplementary data that is not included in the tool; and to review and to coordinate with several city departments, other cities in the region, the county, and the housing authority. A commenter stated that one grantee documented over 600 staff hours, and another documented 250 hours solely for community engagement. Another commenter adds that grantee staff cannot complete the AFH due to other required reports and administrative duties associated with the CDBG program—Citizen Participation Plan, 5-Year Consolidated Plan, Annual Action Plan, Semi-Annual Labor Reports, Consolidated Annual Performance and Evaluation Report (CAPER), quarterly financial reports, Section 3 reporting, Minority Business Enterprise (MBE)/Women Business Enterprise (WBE) report, Integrated Disbursement and Information System (IDIS) input and environmental review for each activity, sub-recipient monitoring, Federal Funding Accountability and Transparency Act (FFATA), Central Contractor Registration (CCR)/Data Universal Numbering System (DUNS), Davis-Bacon, OMB directives, and Office of Inspector General (OIG) Bulletins.

A commenter stated that the estimate should be revised after participants complete AFHs. Another commenter stated that the AFH should ask grantees to track the hours and cost for preparing the AFH.

HUD Response: HUD appreciates the comments provided on HUD's burden estimate. HUD agrees with the commenter that a more accurate estimate of the time and cost involved in preparing the AFH may not be known until program participants submit their AFHs. HUD also appreciates the suggestion made by the commenter that the AFH should ask grantees to advise of hours and costs involved in preparing their AFH. HUD intends to also continue to monitor and assess the impact and burden of implementation of the AFH process on program participants, including on the range of different fair housing outcomes.

3. Ways to enhance the quality, utility, and clarity of the information to be collected.

Commenters stated that in the segregation section, participants are asked to identify areas in the jurisdiction and region that are segregated and integrated, and referred to Table 3 (dissimilarity index). The commenters stated that the dissimilarity index calculates values for the jurisdiction and region as a whole, does not indicate spatial patterns, and provides no values for areas within the jurisdiction and region. The commenters asked that HUD make available values for each jurisdiction within the region and a comparison. The commenters stated that the segregation section asks for tenure data, which is not provided. The commenters stated that tract-by-tract tenure data is available on HUD's Comprehensive Housing Affordability Strategy (CHAS) site but is unlikely to be accessed unless it is part of the data for which HUD requires consideration.

Commenters stated that gaps in HUD-provided data will impede assessment of needs of individuals with disabilities. Specifically, HUD should provide Federal data from (1) the Money Follows the Person program, and the Medicaid home and community-based waiver programs and options from the Center for Medicare and Medicaid Services (CMS); (2) data on persons with disabilities living in nursing facilities and intermediate care facilities for individuals with development disabilities from CMS (including data about answers by individuals in nursing facilities to a question about whether they want to leave the facility and return to the community); and (3) data on people with disabilities experiencing homelessness (from the HUD Homeless Management Information System (HMIS) and/or Annual Homeless Assessment Report (AHAR) databases). The commenters stated that despite the lack of uniform data about people with disabilities, the lack of data is not a reason to exclude consideration of the information. One of the commenters stated that the data provided on persons with disabilities should be further broken down by income and renter status. Another commenter stated that if HUD is unable to provide data on access issues for people with disabilities, and local data is unavailable, this analysis should not be required.

Other commenters stated that the focus on R/ECAPs is misplaced without similar analysis of areas of concentrated white affluence; that identifying these areas and factors contributing to their creation and perpetuation is important to further fair housing, address segregation, and promote mobility.

Another commenter stated that HUD should explore the possibility of including more questions that would prompt a discussion within communities and regions that may have considerable concentrations of wealth, but low instances of integration, to better facilitate goal-setting for purposes

of expanding fair housing choice for members of protected class groups.

Another commenter stated that HUD should provide data underlying maps as maps can help spot issues but the maps are worthless for making objective, quantitative comparisons. A commenter stated that in the disproportionate housing needs section, Tables 9 and 10 contain no data for areas within the jurisdiction and the maps are useless for quantitative analysis. The commenter stated that HUD should provide tables underlying every map. Another commenter stated that HUD's failure to provide a data mapping tool for housing authorities means that participants may need to decide whether to collaborate without adequate information, as the map examples are insufficient.

A commenter suggested that HUD provide grantees with proposed assessments that they may accept or modify to develop locally tailored approach to affirmatively further fair housing. Another commenter stated that ''region'' must be better defined. The commenter added that although regional assessment is a core element of the assessment, this assessment using existing HUD data will be difficult, and that it is unclear what is required, and should be optional.

HUD Response: HUD appreciates the suggestions of the commenters. The 2016 Assessment Tool addresses some of these concerns, but not all at this time. In the 2016 Assessment Tool HUD has provided, in the instructions, that in identifying areas of segregation and integration program participants should not only focus on areas of minority concentration in their jurisdictions and regions, but also areas of majority concentration. With respect to enhanced ways to make maps and data easily accessible to program participants, HUD continues to work to make the HUD-provided data and maps easily accessible and easily readable to its program participants. HUD believes it has made considerable progress in this area, and acknowledges it has more work to do here. HUD will continue to provide updates to the AFFH Data and Mapping Tool (AFFH–T) as more current data becomes available.

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.

Commenters recommended that the AFH tool should be accessible through IDIS and eliminate redundancies and overlap between the AFH and the consolidated plan. A commenter stated that electronic submission is the only practical and logical method. Another commenter stated that there should be an option to download the maps and tables that are pre-populated with HUD-provided data (similar to the Action Plan and CAPER in the eCon Planning Suite).

A commenter stated that data should be available through the portal directly, so that it is accessible to stakeholders without specialized training. Another commenter stated that there should be a way to download shape files and data in tabular format from the Assessment Tool for additional in-house geographic information system (GIS) analysis.

A commenter stated that it is concerning that to participate in a less-cumbersome process smaller communities must participate with another eligible community. The commenter stated that partnering to write the AFH would force the community to spend money the community does not have, particularly because HUD's new rules related to grant-based accounting have limited the administrative dollars the city can ''tap into each grant.''

Another commenter recommended that program participants only be required to conduct an AFH every 10 years, prior to the consolidated plan that follows the decennial census.

HUD Response: As stated in HUD's response to comments on question 3, HUD appreciates the commenters' suggestions. This 2016 version of the Assessment Tool has made progress in this area over the 2015 tool. HUD is continuing to work to increase the ease of electronic availability of the Assessment Tool, maps and data. HUD continues to work to make the HUD-provided data and maps easily accessible and easily readable to its program participants. HUD will continue to explore options for making improvements to the User Interface, to data provided and the functionality of the data tool, and providing additional guidance on using the HUD-provided data in the instructions to the Assessment Tool, as well as through other guidance materials. As HUD assesses longer-term improvements to the Assessment Tool data, HUD will continue to consider the comments received that recommended significant changes.

In determining the frequency in which an AFH should be prepared, HUD determined that every 5 years was an appropriate time period, similar to the time period for the PHA 5-year plan and the 5-year consolidated plan (although some consolidated plans are submitted every 3 years at the election of the program participant).

5.[3] *Whether the inclusion of the ''inserts'' for Qualified PHAs (QPHAs) and small program participants will facilitate collaboration; whether entities anticipate collaborating; (a): Any changes to inserts that would facilitate collaboration; (b): Changes that would provide more robust fair housing analysis; (c): Any changes that would encourage collaboration.*

In response to this question, commenters had a variety of suggestions. Several commenters stated that QPHA inserts will facilitate collaboration and that inclusion of the inserts is headed in the right direction. The commenters, however, suggested removing regional analysis by QPHAs so QPHAs can focus on areas for which they have control, and local governments can focus on larger regional control areas. The commenters stated that adoption of this proposal would reduce duplicative analysis for overlapping areas, but if not adopted, HUD must clarify when QPHAs and small program participants must conduct a regional analysis.

Another commenter recommended that to facilitate collaboration, the assessment tool should allow focus on ''known'' areas of concentration and on ''known'' locations of R/ECAPs and protected class groups, and HUD should provide data on protected class groups in PHA service area as this information is not readily known to QPHAs.

A commenter stated that HUD should substantially restructure the questions and accompanying instructions for the inserts. The commenter stated that it understood HUD's efforts to streamline the process for program participants with fewer resources, but stated the questions run the risk of sending a message to these program participants that they are being held to a different standard of analysis. The commenter stated that the AFFH rule already provides flexibility to smaller program participants when conducting joint or regional collaborations by allowing them to ''divide work as they choose,'' and the inserts may inhibit community participation, as the analysis of these program participants will be separated from the rest of the fair housing analysis in the Assessment Tool. The commenter recommended that the inserts explicitly instruct these program participants to consider the sections of the assessment tool outside of the Fair Housing

[3] The prior Notice inadvertently numbered this question as question 6. For clarity, this and the following questions have been renumbered in this summary.

Analysis section, such as community participation and the assessment of past goals, actions, and strategies. The commenter stated that if HUD retains these inserts, HUD must provide instructions at the beginning of each section of the insert that cross reference the remaining pieces of the analysis in the main portion of the Assessment Tool.

A commenter stated that in the QPHA insert, HUD should include a question regarding the QPHA's service area using geographic boundaries and other indicators commonly known in the community. The commenter stated that this will help place the maps in the HUD-provided data into context for the QPHA analysis and better facilitate community participation on the QPHA insert.

Another commenter stated that the disparities in access to opportunity question in the insert combines several questions, which is not conducive to a meaningful analysis. The commenter stated that the instructions in the QPHA insert are unclear as to whether QPHAs would have to review Table 12 (opportunity indices), which implies QPHAs are being held to a different standard. Other commenters recommended that the disparities in access to opportunity section of the QPHA insert be made optional for QPHAs because they do not have the skill set to meaningfully analyze transportation or education policies. Another commenter stated that program participants should be required to identify contributing factors in the inserts and that the disparities in access to opportunity section of the insert should include the same sub-questions as the main Assessment Tool. The commenter stated that the ''secondary'' participants should identify whether their own policies and processes contribute to segregation, lack of access to opportunity indices, or other fair housing issues.

A commenter stated that the ''policies and practices'' section of the QPHA insert should ask the QPHA to consider its admissions and occupancy policies more broadly, including grounds for denial of admission, as well as grounds for eviction or subsidy termination. The commenter stated that the grounds for which the QPHA decides to admit or evict a family, or terminate a subsidy can raise fair housing concerns. The commenter also recommended that this section ask the QPHA to outline its policies regarding providing access to persons with disabilities and LEP persons.

Another commenter stated that the list of programmatic barriers is too cursory and PHAs should examine a more comprehensive list of programmatic barriers, and that the list should include source of income and other discrimination, availability of landlord outreach programs, low payment standards, portability restrictions, inspection delays, refusal to extend search times, lack of notice to families of their choices, lack of assistance in locating housing in opportunity areas, and geographic concentration of apartment listings provided to Housing Choice Voucher (HCV) families by the PHA.

Other commenters recommended that joint participants should adopt explicit measures to ensure that the community participation process includes the focused solicitation of information and recommendations pertinent to each individual participant, as well as the combined AFH.

A commenter stated that some small grantees are located outside of metropolitan statistical areas (MSAs), and the commenter suggested working with the National Community Development Association (NCDA) to reduce the scope of the proposed insert.

Other commenters stated that the insert does not provide enough of an incentive for small grantees to collaborate. The commenters stated that providing additional time and offering these inserts is an inadequate response to the burden small entities face in conducting an AFH.

A commenter did not propose changes to the inserts but recommended that HUD raise the threshold of those PHAs that may use the QPHA insert to PHAs with 2,000 total units instead of 550 total units. The commenter also recommended that HUD raise the threshold for small program participants that may use the insert to those that receive a CDBG grant of (at least) $1 million or less, stating that this would reduce administrative burden and would benefit HUD staff by reducing the number of separate AFH submissions. Another commenter requested that HUD provide an additional 60-day comment period on the inserts since they were not introduced until the 30-day notice.

HUD Response: As noted earlier in this notice, HUD has raised the threshold for use of the insert from QPHAs with 550 or fewer units to PHAs with 1,250 or fewer units, which is reflected in the redline/strikeout version of the Assessment Tool that provides a comparison of the 2016 tool to the 2015 tool, HUD also provides at *https://www.hudexchange.info/programs/affh/* a redline/strikeout of the Assessment Tool that accompanied the 30-day PRA notice and this final version. This redline/strikeout version reflects the many changes that HUD made in response to public comment. The accompanying instructions for the insert also address questions of the commenters seeking clarification about certain aspects of the inserts.

With respect to additional time to comment on the inserts, HUD submits that 30 days was sufficient time to comment, and PHAs and grantees that received a CDBG grant of $500,000 or less are not required to undertake the analysis provided by the inserts. They may use the inserts or the main portions of the Assessment Tool to undertake the required analysis.

HUD disagrees with the comment that the addition of streamlined Assessment Tool (inserts) for smaller program participants might inadvertently send a message that such smaller program participants are being held to a different standard of analysis. As HUD stated in the Preamble to the AFFH Final Rule, ''. . . HUD commits to tailor its AFHs to the program participant in a manner that strives to reduce burden and create an achievable AFH for all involved. HUD intends to provide, in the Assessment Tool, a set of questions in a standard format to clarify and ease the analysis that program participants must undertake. The Assessment Tool, coupled with the data provided by HUD, is designed to provide an easier way to undertake a fair housing assessment.'' 80 FR 42345 (July 16, 2015). Moreover, the inclusion of the inserts is also intended to facilitate joint and regional partnerships with smaller program participants. Such partnerships can result not only in improved planning and fair housing analysis but in intergovernmental and interagency cooperation and collaboration in goal setting, program operations and results.

Also, in the inserts for smaller program participants, HUD has adopted a modified approach in the final Assessment Tool for identifying contributing factors. The approach adopted also attempts to address the issue of burden for these smaller agencies, by combining the identification of such factors for the four fair housing issues assessed in the Assessment Tool (Segregation, R/ECAPs, Disparities in Access to Opportunity, and Disproportionate Housing Needs) in one step. This is intended to reduce any unnecessary duplication of effort and to better focus the analysis and identification steps to help produce meaningful fair housing goals.

HUD notes that all program participants using the full Assessment Tool also have the option of completing

the analysis and identification of contributing factors steps in a variety of ways that make the most sense to them. HUD has added general instruction to the Assessment Tool to clarify this. For instance, program participants may choose to complete several of the analysis sections first and then consider and identify contributing factors as a next step for those sections. HUD acknowledges that contributing factors can often affect more than one fair housing issue. Some program participants may find it beneficial for them to identify contributing factors in combination across fair housing issues after completing the analysis for those sections first. The User Interface is set up in a way to allow for this approach.

As noted above, HUD has raised the threshold of those PHAs that may use the insert to PHAs with 1,250 total units instead of 550 total units. HUD will continue to consider efforts to reduce administrative effort on all program participants, including PHAs and local governments. As lessons are learned, in the future, there may be opportunities to consider further enhancements to the Assessment Tool. HUD will continue to enhance the instructions and guidance on the analysis of jurisdictions and regions where there are new construction, rehabilitation of existing housing, mobility, and community revitalization, supporting program participants in conducting their AFH.

Regarding the public comment that the PHA insert should ask the PHA to ''consider its admissions and occupancy policies more broadly,'' HUD has made revisions to instructions and the contributing factors definitions that clarify the demographic analysis of protected classes living in public housing, Housing Choice Vouchers residences, and other publicly supported housing developments as related to the fair housing concerns on the concentration due to admissions, income targeting, and the demographic composition and protected class characteristics of applicants on the array of publicly supported housing waiting lists.

Regarding the public comments on PHA service areas and the need for HUD to provide accurate data for these important agencies, HUD reiterates its commitment to provide data that is useful for their AFHs. HUD's statements on the known limitations of national level data, maps and tables when applied in rural areas is intended as an acknowledgement of the need for flexibility for these agencies in conducting an AFH. Local data and local knowledge can often be useful or more readily applied to the questions and issues raised by the Assessment Tool. For instance, dot density maps may have limitations for large geographic areas with low population densities. In addition, as stated HUD will be providing data for individual PHA service areas as this information becomes available. Although, HUD has provided clearer instructions in the Assessment Tool related to the PHA Regional Analysis required regional analysis for PHAs in different geographic areas, which includes multiple parts to this explanation: (1) A description of the service area, also known as the jurisdiction, of various size PHAs in terms of their authorized geographic operations; (2) a description of the PHA's region for purposes of analysis under the AFFH rule; (3) a description of the HUD-provided data for the PHA's applicable region; (4) instructions related to use of data and identification of fair housing issues and related contributing factors for different size PHAs; and (5) instructions related to rural PHAs, State PHAs, and PHAs in Insular Areas.

6. Clarity of changes in content/structure of questions in Disparities in Access to Opportunity with respect to protected classes. Also, whether appropriate analysis can be conducted if other protected classes are assessed only in ''Additional Information'' questions. Should protected classes be specified in each question? Additional question in Disparities in Access to Opportunity about all protected classes?

A commenter stated that an analysis of disparities in access to environmentally healthy neighborhoods is necessary for CDBG program participants, as grantees must do environmental review for each CDBG activity. The commenter stated that applying this to each protected class would be difficult, and that small entitlements do not have the financial capability to use CDBG funds to effect significant change with respect to this area of analysis.

Another commenter stated that the question relating to environmental policies should ask about siting and permitting processes, cumulative impact analyses, legislative or regulatory protections such as health impact assessments, and funding distribution processes that impact activities such as remediation. The commenter stated that these structural factors contribute to cumulative impacts of environmental burdens and should be included in the index and contributing factors appendix. The commenter stated that participants should assess, using local data and local knowledge, a range of environmental health factors (in addition to air quality), including soil and water toxins, mold, standing water and water-borne illnesses due to inadequate drainage, violence, and inequitable distributions of benefits such as park space.

Other commenters stated that HUD has provided more structure and clearer directions for the disparities in access to opportunity section, and that such restructuring and clarity have made it sufficient to conduct the analysis for additional protected classes within the ''Additional Information'' question if there is sufficient space in that field. The commenters stated, however, that HUD should include the protected class groups within each question in this section to facilitate responses.

Another commenter stated that the questions in the disparities in access to opportunity section are clear and will yield a meaningful analysis, but that the data provided is provided only by race/ethnicity, national origin, and familial status. The commenter stated that it would be helpful if HUD provided data for other protected classes (sex, disability, age), and if HUD provided a more detailed breakdown of ethnicity (*i.e.,* ''Asian'' broken into subcategories), and to cross-tabulate the categories with housing cost burden and median income by census tract—to facilitate meaningful analysis in large, diverse cities. The commenter stated that, if HUD cannot provide such data perhaps HUD can provide guidance on obtaining custom tabulations.

A commenter stated that an appropriate analysis would include an assessment of all protected classes in each section; specification of protected class groups would ensure that participants address each group without considering whether groups were not included or inadvertently omitted. Another commenter similarly recommended that HUD include questions in each subsection of the disparities in access to opportunity section about other protected classes, not just those for which HUD is providing data, stating that doing so would provide for a fuller analysis within each subsection without requiring the program participant to revisit the topic in the ''additional information'' section. The commenter expressed concern about waiting until the ''additional information'' section to conduct such an analysis could result in the exclusion of this portion of the analysis.

Another commenter recommended that HUD restructure the disparities in access to opportunity section, stating that the questions in each subsection should, ask program participants to

examine HUD-provided data, local data, and local knowledge for all protected classes under the Fair Housing Act, and describe: (1) Disparities in access to opportunity for the given opportunity indicator; (2) how disparities regarding that opportunity indicator ''relate to residential living patterns in the jurisdiction and region''; and (3) ''programs, policies, or funding mechanisms that affect disparities'' in access to a particular opportunity indicator. The commenter stated that if this structure is not feasible, HUD should, at a minimum, include questions about all protected classes under the Fair Housing Act in each subsection.

A commenter stated that HUD should not add additional questions about disparities in access to particular opportunities because these questions will be addressed within the primary text. Another commenter similarly stated that an additional question related to disparities to the particular opportunity based on all protected classes would be redundant and too general.

A commenter stated that the education questions do not assess students' actual access to proficient schools, and whether residential segregation results in educational segregation. The commenter stated that the questions must assess student presence or participation, and should ask: (1) The distribution of children by race/ethnicity attending proficient schools in the jurisdiction/region; (2) racial segregation in public schools in the jurisdiction/region; and (3) economic segregation of public schools in the region/jurisdiction.

Another commenter stated that HUD should delete ''participant's own'' in qualifying ''local data and knowledge'' as participants should not only use local data and knowledge available within their own departments when assessing disparities in access to opportunity.

A commenter stated the term ''access'' is vague and risks confusion or evasion by program participants, and recommended that HUD clarify that access is measured by both the physical proximity to employment, educational, environmental, and transportation assets, and actual rates of participation in programs and institutions (such as actual rates of enrollment in proficient schools). The commenter further stated that the quality of transportation to these assets may be relevant in assessing access.

Another commenter stated that program participants should use local data and local knowledge to evaluate transportation policy, as well as cost and access, as transportation can drive revitalization/gentrification, or can bypass poorer communities. The commenter stated that program participants should assess the approval, financing, and civil rights oversight of transportation policies.

HUD Response: The redline/strikeout draft of the tool that compares this final version to the 2015 tool reflects the many changes that HUD made to the 2015 approved version, primarily in response to comments that HUD received on the 60-day PRA notice. HUD made some additional minor changes in response to the 30-day notice, but believes that the structure of this section of the tool in the version of the tool that accompanied the 30-day presents the appropriate questions to yield a meaningful analysis.

2. Other Issues Raised by the Public Commenters

Contributing Factors

Several commenters offered suggestions on contributing factors. A commenter stated that the contributing factor of ''Land use and zoning laws'' (for segregation, R/ECAPs, disparities in access to opportunity, and disproportionate housing needs) is too narrow a categorization of local public policies affecting housing choice for lower income households. The commenter suggested replacing with: ''public policies that limit or promote production of affordable housing.'' Commenters stated that important categories of policies include: permitted project scale and density, provision of local financial resources, assistance with site selection, reduction of unnecessary parking requirements, fee reductions or waivers for affordable housing, reduction of administrative delays, permitted manufactured housing, and inclusionary housing policies. The commenter stated that ''Lack of support for developing and preserving affordable housing'' is a critical contributing factor for disproportionate housing needs section of the Assessment Tool.

Another commenter asked under what circumstances HUD expects program participants to identify the contributing factor of ''displacement of residents due to economic pressures.'' The commenter recommended that the analysis of housing be limited to the jurisdiction.

Commenters stated that the contributing factor of ''lack of source of income protection'' fails to account for the different nature of housing voucher programs. The commenters stated that at the Federal level, Congress has not enacted a law to require private development owners to participate in any voucher programs.

Several commenters thanked HUD for including barriers to fair housing choice faced by victims of domestic violence and harassment, and requested that HUD make certain changes to how this is accomplished based on VAWA and HUD's recent final Harassment Rule. One of the commenters stated that the contributing factor ''Lack of housing support for victims of sexual harassment, including victims of domestic violence'' should be divided into two factors because, as drafted, the factor conflates two distinct concepts that should be considered separately: (1) Displacement of and/or lack of housing support for victims of domestic violence, dating violence, sexual assault, and stalking (additions due to VAWA); and (2) sexual and other forms of harassment. Harassment includes quid pro quo and hostile environment—and harassment due to membership in any protected class gives rise to FHA liability. The commenter stated that the first contributing factor should be included in Disparities in Access to Opportunity, Disproportionate Housing Needs, and Publicly Supported Housing, and recommended that the second factor be included in Disparities in Access to Opportunity, Disproportionate Housing Needs, and Publicly Supported Housing. The commenter proposed descriptions for both contributing factors to add to Appendix C.

A commenter suggested adding ''Eviction policies and practices in the geographic area'' to the list of contributing factors in the following sections of the Assessment Tool: R/ECAPs, disparities in access to opportunity, and disproportionate housing needs. The commenter stated that eviction causes poverty, makes it difficult for such tenants to find housing, and tenants are unlikely to report habitability problems. The commenter stated that people living in R/ECAPs, minorities, and individuals with disabilities disproportionately experience eviction. Commenter stated that Appendix C includes ''eviction policies and procedures'' as part of a list relating to public housing, but that discussion of eviction should not be limited to public housing.

Another commenter stated that HUD has provided a sufficient array of contributing factors, and should allow participants the flexibility to identify other factors relevant to the jurisdiction and region (rather than requiring analysis of additional inapplicable factors). Another commenter stated that the instructions on contributing factors

should make clear that program participants are required to identify contributing factors that are not listed in the HUD-provided lists if that contributing factor creates, perpetuates, contributes to, or increases the severity of at least one fair housing issue.

A commenter recommended that HUD add the contributing factor of ''Adverse housing decisions and policies based on criminal history'' to the list of contributing factors based on HUD's recently issued guidance on this subject. The commenter stated that the analysis should not be confined to the publicly supported housing section, but should be assessed more broadly, and include the private housing market. The commenter also recommended HUD include a new contributing factor of ''Lack of meaningful language access for individuals with limited English proficiency'' and stated that it should be included in all sections of the assessment tool, except the disability and access section. The commenter also suggested that in the description of ''community opposition,'' HUD include ''lack of political will'' that results from successful community opposition.

HUD Response: Both redline/strikeout versions provided at *https://www.hudexchange.info/programs/affh/* reflect the changes made in response to public comment received during 2016. In the instructions provided to the final approved Assessment Tool, HUD clarifies that while program participants are required to identify those factors that significantly create, contribute to, perpetuate, or increase the severity of one or more fair housing issues, program participants are not required to conduct separate statistical or similar analyses to determine which factors to identify and need only rely on the information considered in the community participation process, assessment of past goals and actions, and fair housing analysis sections of the Assessment Tool, including information obtained through the community participation process to meet its obligations to identify contributing factors under the AFFH Rule.

In addition, the instructions highlight that program participants have flexibility in how they choose to prioritize significant contributing factors, so long as they give highest priority to those factors that limit or deny fair housing choice, access to opportunity, or negatively impact fair housing or civil rights compliance. Once fair housing issues and contributing factors have been identified and prioritized, the program participant has options in how to set goals for overcoming the effects of contributing factors and related fair housing issues. In setting goals, relevant considerations for doing so may include the resources, the likely effectiveness of the policy options that are available to the program participant, and collaborative goals among joint or regional partners.

Also, HUD agrees with the commenter regarding the scope of the land use and zoning laws contributing factor. Specifically, HUD has responded to the comment by adding language to the contributing factor on ''Land Use and Zoning.'' Additional language was added to clarify that this contributing factor might include, ''[the lack] of support for development and preservation of affordable housing (may include efforts for neighborhood stabilization, green building, transit oriented development, and smart growth development).'' HUD also agrees with the commenter on this issue and the relationship between the analysis of ''disproportionate housing needs'' and potential policy goals. Additional clarification on this subject are discussed in this Notice, below in the HUD responses to comments related to publicly supported housing.

User Interface

A commenter stated that user Interface is difficult to navigate. Another commenter stated that, within the Assessment Tool, it would be helpful to be able to view and print the entire document (the AFH tool webinar indicated each section would need to be printed separately). Other commenters recommended that HUD migrate the assessment tool from the User Interface to the existing IDIS e-Con planning suite which grantees are already familiar with, and this would enable closer integration of the AFH with Consolidated Plans and Action Plans.

HUD Response: During the year since the Local Government Assessment Tool was approved in 2015, HUD has spent considerable time striving to make the User Interface easier to navigate. HUD believes that the current version is easier but acknowledges additional work is still needed. HUD will continue to further improve the User Interface, as well as the AFFH Data and Mapping Tool, to meet the needs of different program participants.

AFFH–T & HUD-Provided Data

Several commenters stated that the data and mapping tool has often failed to load, and has crashed various browser. A commenter stated that when the AFFHT does work, it loads each map and changes to the map very slowly when it works. The commenter expressed concern about the utility of the tool when multiple agencies are using it. The commenter stated that HUD must ensure that the data is accurate, for example the geocoding from IMS/PIC. Another commenter requested that the loading speed for the maps be increased.

Several commenters raised concerns about the dots in the dot density map. Commenters stated that the following: The size of the dots in the dot density maps should be adjustable to see them more clearly; when you zoom in the dot-size stays constant; if one adjusts the monitor, one loses portions of the map; there is insufficient contrast between colors at that size; the remaining dots shift if one is in the Table of Contents (TOC) and deselect a category; and that if one re-selects a category, the dots shift again, but not to their original position. The commenters stated that all of these issues should be corrected.

Commenters also raised issues about the maps and tables. With respect to maps, a commenter asked why the R/ECAP on Map 2 is different from the other maps, and another commenter stated that there are data errors in Map 5 as several Public Housing locations are missing, and several multifamily markers come up with Null, and some are misidentified, *e.g.,* a hotel is listed as multifamily, and some markers are not active. Other commenters recommended that the HCV maps be layered with the publicly supported housing maps to comprehensively understand all subsidized housing in an area. Another commenter stated that currently, the assessment tool allows only 17 different maps to be displayed and indices can generally only be layered with demographic data. The commenter suggested that participants be able to choose from a menu of layers to use in one map and participants be able to layer more than one set of data over the indices (higher levels of user customization), and further stating that it should be easier to find the data sources for the 17 maps to facilitate verification and in-house analysis.

With respect to tables, a commenter stated that Tables 9 and 10 do not provide a useful basis for comparing the needs of families with children with publicly supported units, as the tables do not distinguish renter from homeowner needs and do not contain income group information available in the CHAS data (those with incomes less than 30 percent of area median income (AMI) need different policies than those at 60–80 percent of AMI). Another commenter stated that Tables 5, 6, 8, and 11 for use in the publicly supported housing section do not include low-income housing tax credits (LIHTC)

units (although the instructions indicate that Map 5 produces LIHTC data and the data documentation incorrectly lists it as on Table 8). The commenter stated that, without LIHTC data, answers to the questions in this section have little value, as the data does not show current affordable housing. The commenter stated that Table 6 is misleading as ''Housing Type'' counts households by race/ethnicity, but the next section shows race/ethnicity for the total population, and stated that note 2 in the table is wrong.

Other commenters recommended that HUD add LIHTC projects, and provide separate breakouts of elderly and family public housing, and Section 202 and 811 developments. A commenter urged HUD to add demographic data for individual LIHTC developments to the AFFHT, stating that given the prevalence of the LIHTC program, it is imperative to have this information in order for communities to conduct a robust assessment of fair housing choice in a jurisdiction and region. The commenter also expressed support for differentiating between 4 percent and 9 percent tax credits in the AFFHT.

Commenters stated that HUD should clarify: (1) How scattered site public housing is shown on the map and in the tables; (2) how units removed from the PIC as part of RAD will be shown on the map and in tables; and (3) how units with more than one subsidy (LIHTC, Section 8) are shown on the map and in tables. Another commenter stated that because the distribution of Section 8 vouchers may be different than project-based, it may be helpful to understand how multifamily rental stock is distributed (in addition to landlords' acceptance of Section 8 vouchers). The commenter further suggested that HUD provide data on additional tenant characteristics including national origin, limited English proficiency (LEP), age, etc.

Other commenters asked if there is an assumption that all analysis of segregation and integration will be at the census tract level. A commenter stated that voucher data should be available on the census tract level. Another commenter suggested that AFH downloadable data be available at census tract level (rather than jurisdictional level) to aid local data analysis, as it would be helpful for participants to be able to select areas on the map and obtain data for that selection—whether census tract or group of census tracts—to approximate neighborhoods and planning districts.

Commenters stated that on May 18, HUD stated that the R/ECAP map data was updated from 2006–2010 to 2009–2013 American Community Survey (ACS); however, the commenter stated that it is unclear which maps HUD was referring to and whether the rest of the ACS data in the maps and tables is 2006–2010 or 2009–2013. Commenters recommended that each table specify which ACS data is used. Another commenter stated that all data provided by HUD should be current ACS data in map and table format for accurate analysis and interpretation.

A commenter recommended that HUD provide standardized calculations of the changes in demographic and other trends over time and of comparisons between the community and CBSA region, so grantees do not need to do the calculations themselves. The commenter stated that HUD should provide national data related to schools and education and allow grantees to supplement as needed with local data and knowledge. The commenter also stated that an analysis of fair lending is more central to a fair housing analysis than some of the opportunity index measures. HUD should provide data on home purchase loans by race/ethnicity and trends, and data on HECM loans.

A commenter stated that HUD did not decide whether to exclude college students from the poverty rate in R/ECAPs, and asked that HUD reconsider excluding college students from the poverty rate calculation or calculate the poverty rate with and without college students. Another commenter expressed concern about how to appropriately define R/ECAPs in rural areas, stating that HUD should provide suggestions for how QPHAs should define R/ECAPs in rural areas, and notes that these suggestions could be included in the instructions to the assessment tool or in additional guidance.

A commenter recommended that HUD provide data on evictions and subsidy terminations in the AFFHT, stating that this will allow program participants and members of the community to be able to evaluate the extent to which members of protected class groups are experiencing evictions and subsidy terminations.

A commenter stated that HUD-provided data about disability has a variety of limitations and suggests requiring local governments to supplement with local data, and suggested that data on disability that is available to HUD be made available to localities, such as national data on disabilities among veterans. The commenter stated that HUD should obtain more data from local governments about the needs and opportunities for people with disabilities at a more granular level; the data and analysis should differentiate between physically accessible units for people with mobility and sensory disabilities, and the need for independent, supported, and shared housing options for people with disabilities including mental health and intellectual disabilities, and people with traumatic brain injuries.

Another commenter stated that it is pleased that HUD advised that it would provide additional data on homeownership and rental housing but asks when this data will be available.

Commenters stated that HUD should provide a schedule of planned data updates in advance to minimize mid-stream revisions of the AFH. A commenter stated that some data is over 5 years old and that data sets should be updated annually.

HUD Response: HUD continues to thank all of the public commenters for their valuable and ongoing feedback on the AFFH Data and Mapping Tool, both via these public comments and through the HUD Exchange ''Ask A Question'' portal (*https://www.hudexchange.info/get-assistance/my-question/*).

HUD offers the following responses to specific comments as follows:

Regarding comments on the display of map information, HUD will continue to monitor and implement ways to improve performance, including improving the visual display of information and options for users to make adjustments according to their needs. Also, HUD is adopting a change in the maps for publicly supported housing by combining two separate maps into one map that can display Housing Choice Vouchers along with other housing programs simultaneously.

HUD continues to work with program participants to improve geocoding accuracy of HUD administrative data. In addition, HUD will review and revise the data documentation and its footnotes and provide other explanatory language.

Regarding comments on how current the HUD-provided data is and the frequency of updates, HUD will schedule regular updates and will provide notice of any updates on the HUD Exchange Web site. HUD will also provide guidance clarifying that program participants that have started conducting an AFH will not be required to use all newly updated data. HUD is also working on making improvements to the AFFH Data and Mapping Tool to minimize the effects of data updates on program participants while they are completing their AFH.

Regarding the provision of additional types and formats for data, HUD notes that raw data is available for download directly from the HUD Exchange site,

where all other AFFH guidance and materials are also provided. HUD is planning to make the raw geo-enabled data available in GIS Open Data site where it can be downloaded in multiple open formats including GIS format.

Regarding LIHTC related data, HUD continues to administer and improve the LIHTC data on projects placed-in-service and LIHTC tenant demographic data. HUD will work to provide data for AFFH–T at an appropriate level of geography (*e.g.,* State, County, City, development, etc.) as the data becomes available and verified for consistency and reliability. These data may be available in a variety of formats external to the AFFH–T Data and Mapping tool. It is not expected that development level tenant data will be available in the near term due to current data quality issues. Additionally, compliance with federal privacy requirements will limit certain development-level data that will be available in the future. For background on data that are currently available, please see HUD's report, ''Data on Tenants in LIHTC Units as of December 31, 2013'' which is available at *https://www.huduser.gov/portal/publications/data-tenants-LIHTC.html.* HUD will also continue to pursue additional guidance on potential sources of readily and easily accessible information that may be useful as supplementary local data.

Regarding the specific comment on scattered site public housing developments, HUD confirms that such developments are included in the maps and tables when they are listed as a single development in the HUD PIC administrative data system. HUD has added an instruction to the Assessment Tool noting this and advising program participants to use caution when considering such developments, particularly as it relates to census tract demographics. HUD intends to address this issue over time, as needed, but advises that this may involve addressing the issues on a case by case basis. Program participants are empowered to use local data and local knowledge in this and other cases where such information is superior to the HUD-provided data.

In regard to the public comment regarding the use of data for joint collaborations between multiple agencies, HUD notes that the User Interface currently allows individual program participants to access the maps and tables that are relevant for their own jurisdiction. HUD is making further improvements to gather information on PHA service areas and will add this significant new information to the AFFH–T as it becomes available. Specifically regarding information relevant to PHAs, HUD is adding additional tables and functionality for maps to provide information on the assisted housing stock and residents served by individual PHAs. Also, HUD is exploring options for posting AFHs as an online resource for program participants and the public.

Regarding comments on whether to exclude college students from the calculation of R/ECAPs, HUD is taking the comments into consideration and has not made any changes at this time. Any changes to the methodology in the future will be communicated through updates on HUD Exchange.

Publicly Supported Housing Section

A commenter stated that there is no data on publicly supported housing by ''bedroom size'' and until the data is available, HUD should delete the question referencing bedroom size. The commenter stated that the analysis of comparing the demographics of publicly supported housing occupants to the demographics of the areas in which they are located implies that when the demographics comport with one another, this represents a positive fair housing outcome, but HUD has barred this approach. Other commenters recommended removing the new question added in the publicly supported housing section, stating that the comparison of the demographics of the types of publicly supported housing between the jurisdiction and region is not the right approach to the AFH.

A commenter requested that HUD clarify the categories it expects participants to compare and what ''same category in the region'' means. The commenters expressed concern that the question implies a causal relationship that is difficult or impossible for localities to assess, and further stated that the various programs have different requirements and eligible populations, and without controlling for this, the comparisons may be incorrect or misleading. A commenter stated that the comparison would not take into account critical factors that limit participation in publicly supported housing—including federal requirements such as income limits (rather than the jurisdiction's choices). The commenter also stated that the data sets and responses required are unreasonable, as reliable data is unavailable and in many subsidized projects, data gathering and reporting is not required.

HUD Response: HUD appreciates the comments received on the new question asking for a regional comparison of publicly supported housing. Specifically, this question asks for a comparison of the demographics of assisted housing in separate publicly supported housing program categories to the regional demographics for that same program category. Based on feedback, HUD has decided to retain this question in the final Assessment Tool and has made several clarifications in the instructions. The instructions clarify the specific comparisons that are being asked. HUD has also added an instruction that is generally applicable to all regional publicly supported housing questions providing additional context. Consistent with the balanced approach, there are a myriad of public policy options available to program participants involving preservation, mobility and siting of new housing opportunities when appropriate in relation to fair housing issues and related contributing factors. As with all questions in the Assessment Tool, on a continuing basis, HUD will consider and assess the utility of this question as it relates to conducting a meaningful fair housing analysis.

The added instruction states, ''Conducting a regional analysis can help identify fair housing issues in a broader context, for instance if fair housing issues in the jurisdiction are affected by regional factors, and can inform regional solutions and goal setting. For example, depending on what the regional analysis shows, and always dependent on local conditions, regional solutions could include coordinated or merged waitlists, increasing HCV portability opportunities, affirmative marketing across jurisdictional lines, administering Section 8 vouchers on a regional basis with active mobility counseling, landlord recruitment (including sharing of landlord lists across PHAs) to provide greater access to housing in areas with opportunity or the need for the preservation of affordable housing. This regional analysis can also be compared to the Disproportionate Housing Needs conducted above.''

In a broader context related to the balanced approach to affirmatively furthering fair housing, HUD has made a number of modifications to the Assessment Tool to recognize the importance of preserving existing affordable housing in connection with affirmative fair housing goals and strategies in connection with community revitalization. As HUD's own studies on worst case needs for affordable housing make clear, there is an ongoing national crisis in housing affordability that particularly affects lower income families. In many local and regional housing markets, low

income households are priced out of the market altogether with some form of income support or housing subsidy being needed to access decent, safe and affordable housing. This makes the preservation of the existing limited supply of long-term affordable stock a key component of any balanced approach to addressing the findings drawn from assessments of fair housing. At the same time, HUD maintains the importance of mobility solutions in connection with affirmative fair housing goals and strategies, and notes that such strategies are not mutually exclusive.

In support of HUD's commitment to the balanced approach to addressing fair housing issues, a number of key changes have been made to the Assessment Tool.

(1) Added the contributing factor on the ''Loss of Affordable Housing.'' This factor was previously released for public comment as part of the Assessment Tool for State and Insular Areas. This potential contributing factor notes that, ''The loss of existing affordable housing can limit the housing choices and exacerbate fair housing issues affecting protected class groups.'' This factor, along with the contributing factor on ''displacement of residents due to economic pressures'' allows program participants to recognize the need to preserve affordable housing in areas undergoing economic improvement as a way of maintaining access to opportunity assets for low-income residents and protected class groups as these areas experience increased access.

(2) The Assessment Tool has strengthened the connection between the analysis of disproportionate housing needs and the analysis in the publicly supported housing section. These include adding an instruction noting that the analysis in these sections can be compared to each other, as well as by clarifying the analysis questions in the inserts for PHAs with 1,250 units or fewer and smaller local governments to compare the demographics of who is receiving housing assistance with disproportionate housing needs. The instructions to the 1,250 units or fewer PHA insert have also been clarified to note the policy linkage between this analysis and the overriding housing needs analysis required in the PHA Plan as one possible practical application of the AFH analysis.

(3) Adding instructions on LIHTC. The instructions indicate that program participants may distinguish between nine and four percent tax credits and the different uses that each can be used for, while analyzing the relation of such tax credit properties to fair housing issues and related contributing factors, including distinguishing for rehabilitation and preservation of affordable housing and for the various priorities available to state allocating agencies in meeting unique housing needs in their jurisdictions, in the context of identifying fair housing issues and related contributing factors.

(4) Adding more detail to the instructions for the additional information questions in the Publicly Supported Housing section. These questions provide an opportunity for program participants to reference or highlight efforts intended to preserve affordability in order to meet unmet and disproportionate housing needs in the context of fair housing issues and related contributing factors. The added instructions state that, ''Program participants may describe efforts aimed at preserving affordable housing, including use of funds for rehabilitation, enacting tenant right to purchase requirements, providing incentives to extend existing affordable use agreements and preventing Section 8 opt-outs, encouraging the use of RAD conversion and the PBRA transfer authority. Program participants may also describe positive community assets and organizations, including community development corporations, non-profits, tenant organizations, community credit unions and community gardens.''

HUD thanks the commenter that stated that the ''analysis of comparing the demographics of publicly supported housing occupants to the demographics of the areas in which they are located implies that when the demographics comport with one another, this represents a positive fair housing outcome, but HUD has barred this approach.'' However, HUD notes that this analysis can assist in understanding who is being served in the housing programs, where they have housing opportunities, and how the location impacts the residents' access to opportunities. Thus, the same demographics in the public housing project in the census tract it is in may or may not represent a fair housing issue.

Community Participation

A commenter stated that the requirement to describe how communications were designed to reach ''the broadest audience possible'' should be deleted as participants are submitting other information about community participation. The commenter stated that asking grantees to evaluate why there was low attendance is irrelevant and asks grantees to impute meaning without substantive information.

Another commenter stated that there should be substantive community participation questions in the tool (not only suggestions in the Guidebook) in order to show its importance, communicate what constitutes the parameters of meaningful participation, and enable HUD, community members, and participants to understand what constitutes sufficient community participation. The commenter recommended that HUD include more substantive content in the tool's community participation process and direct participants to assess whether engagement has occurred to multiple groups, stakeholders, and protected classes for information relevant to each section of the tool. The commenter stated that stakeholders from multiple sectors should be actively solicited early on and throughout the AFH process, as stakeholders may be unaware of housing planning processes and localities with the most severe fair housing issues may suffer the most severe deficits in equitable public engagement. The commenter further stated that the assessment tool should ask, for example, that participants ''Describe efforts to include persons or organizations with local knowledge relating to public health, education, transportation, workforce development, or environmental quality.'' The commenter also recommended that the tool require documentation of compliance with regulatory consultation requirements. See, *e.g.,* 24 CFR 91.100.

Another commenter stated that effective, robust community participation is fundamental to the successful implementation of the AFFH regulation. The commenter commended HUD for retaining the question regarding low participation, as this question is crucial in assessing the extent to which efforts were made to ''give the public reasonable opportunities for involvement in the development of the AFH.'' The commenter recommended that the first question in the community participation section be amended to include other PHA resident outreach. The commenter also recommended that the instructions for the second question in the community participation section be improved by adding a checklist for the types of organizations that local governments and PHAs should consider consulting (see, *e.g.,* 24 CFR 91.100). The commenter further recommended that HUD consider adding examples of organizations that may fit within the broader categories, such as legal services organizations, which are community-based organizations that serve protected

class members. The commenter requested that the instructions also remind program participants that they must explain why any comments from the community participation process were not accepted by the program participant.

A commenter suggested that HUD ask program participants, in the community participation section of the tool to describe how it ensured accessibility including physical accessibility, effective communications, accessible Web sites and electronic materials, materials in alternate formats, and reasonable accommodations.

HUD Response: In response to public commenters who were concerned that the question on levels of participation would require the program participant to speculate on possible reasons for low participation, HUD has revised that specific question and accompanying instruction. In the broader context, HUD notes that the area of encouraging and incorporating public involvement in planning activities is a growing field of interest and that there are likely to be technological ideas and solutions that may be worthy of additional interest and inquiry over time.

Local Data/Local Knowledge

A commenter stated that HUD should require local governments to use local data and local knowledge (rather than allowing program participants to state that such data is unavailable) about individuals with disabilities in home or community-based settings (including Medicaid and local government funded services), those in institutional settings (nursing homes, board and care homes (''adult homes'' or ''adult care homes''), assisted living facilities, and individuals ready for discharge from psychiatric hospitals). The commenter stated that if HUD does not require participants to use local data and local knowledge, AFH plans may have disparate and disadvantageous consideration of people with disabilities. Another commenter stated that HUD should provide additional guidance as to the types of local data and local knowledge that are likely available.

Other commenters stated that HUD should require (or at least encourage) participants to consult and coordinate with other public agencies and other entities, such as academic institutions. A commenter stated that participants will not interpret ''reasonable amount of search'' to include consultation and coordination, and suggests adding: ''However, the requirement to engage in a reasonable amount of searching means that a reasonable effort should be made to consult and coordinate with public agencies and public entities with access to relevant local data and local knowledge'' to the instructions for the tool.

A commenter urged HUD to include a section that substantively guides participants' efforts to include local data and local knowledge, and requires participants to document strategies such as outreach to other government agencies. The commenter recommended that HUD issue guidance on institutionalizing informational pipelines among agencies and enforcement entities, and collaborations with local stakeholders, and provide lists of common resources to consult.

A commenter recommended that HUD add a section within the tool that requires program participants to evaluate their efforts and processes to incorporate local data and local knowledge (similar to the community participation section).

Another commenter recommended that program participants should encourage members of the community and other stakeholders to submit local data as part of the community participation process, and this should be added to the instructions to the tool. The commenter recommended that HUD include examples to provide some clarity on HUD's expectations with respect to the program participant's obligation to review local data received during the community participation process.

A commenter stated that the instructions regarding local data, specifically the language telling program participants that they ''need not expend extensive resources,'' should be qualified and should depend on factors such as the size of the program participant and the division of responsibilities in a joint or regional collaboration.

HUD Response: HUD did not agree to the suggestion to remove language from the Assessment Tool noting that program participants are not required to expend extensive resources in reviewing or validating complex reports or studies submitted by outside parties during the community participation process. The language states, ''[program participants] are required to consider the information received during the community participation process, but need not expend extensive resources in doing so.'' This is consistent with past HUD statements on the topic. For example, as HUD stated in the PRA Notice on the initial Local Government Assessment Tool on September 26, 2014:

''In addition, local knowledge may be supplemented with information received through the public participation process. In such cases, program participants retain the discretion to consider data or information collected through this process as well as the manner in which it may be incorporated into the AFH, whether in the Analysis section of the Assessment or in Section III of the AFH with an option to include extensive or lengthy comments in appendices or attachments. In short, the receipt of extensive public comments may require staff effort to review and consider input but would not result in a mandate to incur substantial additional costs and staff hours to do so. To the contrary, the public participation process should be viewed as a tool to acquire additional information to reduce burden.''

HUD also notes that the requirements to conduct community participation and consultation are detailed for consolidated plan grantees in 24 CFR part 91, subpart B and 24 CFR 5.158.

Specific Suggestions for the Assessment Tool

A commenter expressed disagreement with the newly added sentence that states ''Participants should focus on patterns that affect the jurisdiction and region rather than creating an inventory of local laws, policies, or practices,'' stating that requiring a detailed list of policies and practices that encourage or discourage affordable housing and mobility of lower income households is useful. The commenter stated that each category in the disparities in access to opportunity section asks for jurisdiction and region, except for the third item, implying that the question only asks about the jurisdiction. The commenter recommended that the question should also ask about region, because suburbs should provide resources and remove barriers for affordable housing, and cities should identify needed regional changes.

Another commenter stated that HUD risks diluting housing patterns to peripheral matters not directly tied to segregation, stating that HUD should leave education to DOE, transportation to DOT, workforce development to DOL, health to HHS, and environment to EPA.

Other commenters recommended deleting the Assessment of Past Goals and Actions section because it duplicates information participants have previously submitted to HUD.

A commenter stated that parenthetical references to sections of the Code of Federal Regulations are confusing and recommended deleting such citations.

A commenter stated that conducting a trend analysis over 27 years with data available at only 10-year intervals is meaningless and should be deleted. The

commenter stated that certain questions require participants to make speculative assumptions about causality and should be deleted, and recommended that, before requiring an analysis of education, HUD and DOE should develop (and provide to grantees) data about the relationships between school attendance, school performance, and residency. The commenter stated that in many districts, school assignment is no longer connected to residency, policies differ among districts, students in one community may attend schools in other districts with different policies, and students in one R/ECAP may attend a broad array of schools with widely varying performance. The commenter recommended that the regional analysis of access to high performing schools should not include schools in communities up to 128 miles apart, stating that the regional assessment of access to transportation should only require localities to assess access to transportation in or near their jurisdiction, and that HUD should not be asking for a regional analysis in the ''additional information'' questions.

Other commenters stated that Olmstead planning is primarily a State activity, but that local governments also have Olmstead obligations, and in some States disability service systems are largely controlled by local government agencies. One of the commenters stated that the tool and Guidebook provide insufficient guidance about Olmstead and the relationship between States and local governments with respect to Olmstead planning. The commenter recommended HUD develop additional guidance to better ensure that connections are made between the States and local governments engaged in AFH planning.

Another commenter recommended that HUD include specific prompts aimed at assessing the jurisdiction's compliance with the Olmstead integration mandate, specifically ''To what degree do people with disabilities have meaningful access to integrated housing opportunities that are not solely in special needs housing, group homes, assisted living, and other congregate housing options? For persons with disabilities that require supportive housing, the commenter asked whether they are able to choose to receive the supports they need in housing of their choice; that is, are supportive housing options available within integrated housing developments.

A commenter stated that, in the Disability and Access section, HUD should provide a more specific definition of ''infrastructure,'' recommending limiting ''public infrastructure'' to the external physical environment and excluding buildings, consistent with the distinction in the AFH Desktop between infrastructure, accessible housing, and accessible government facilities.

Another commenter stated that with respect to the Assessment of Past Goals and Actions section, HUD must ensure that the AFH delivers concrete mechanisms for progress and accountability, stating that program participants should describe fair housing strategies, and whether they have institutionalized mechanisms (such as interagency partnerships) to facilitate implementation.

A commenter stated that the tool ask about civil rights enforcement (pending complaints, resources, and efficacy of protections, enforcement, and remedies). The commenter recommended that participants be specifically instructed to examine the sufficiency of enforcement infrastructure in related areas, such as Title VI and environmental protections.

Another commenter stated that HUD should revise the ''additional information'' sections throughout the tool. The commenter stated this should be done so that important considerations are not omitted from the core fair housing analysis, as this analysis informs the selection of contributing factors and goal setting.

A commenter recommended that HUD encourage local jurisdictions to share information about waiting list demographics and specifically solicit information about applicants' needs for accessibility (physical and sensory) in its waiting list applications. The commenter stated that this information should be used in determining the needs of the jurisdiction to create more accessible housing, offer a reasonable modifications fund, or otherwise offer low-cost loans for accessibility modifications.

Another commenter made several specific recommendations for revising the various sections of the tool. The commenter stated that, for example, the segregation analysis includes a reference to disability and that ''segregated setting'' be defined to include housing that is exclusively for persons with disabilities. The commenter recommended that certain contributing factors be added to other sections of the tool. The commenter also recommended that HUD ask jurisdictions to report on the loss of housing for persons with disabilities, particularly where developments have adopted tenancy preferences for senior citizens to the exclusion of persons with disabilities. The commenter stated that jurisdictions should evaluate the impact of the loss of housing for persons with disabilities in these situations and plan for how to mitigate them.

A commenter recommended that when referring to R/ECAPs, HUD not use the phrase ''transforming R/ECAPs by addressing the combined effects of segregation and poverty,'' and instead use the phrase ''expanding opportunity into R/ECAPs.'' The commenter stated that there are community assets that may exist within R/ECAPs that residents would like to retain, while still attracting investment, opportunity, and expanding fair housing choice in the community.

A commenter recommended that HUD include a question about the unequal provision of services and disparities in infrastructure in the jurisdiction.

Another commenter stated that ''mobility'' is used both to refer to geographic mobility and mobility disabilities, and suggested using terms ''geographic mobility'' and ''physical mobility.''

A commenter stated that local governments ensure that their own housing programs and facilities are accessible, and suggested that the tool ask local governments to state how they ensure accessibility throughout their own housing programs and the projects they fund. The commenter expressed appreciation for the emphasis given to the needs of people with disabilities by separating out the section on disabilities; however, many parts of the required analysis fail to require an analysis of disability needs and opportunities—either in the relevant or disability sections. The commenter recommended that the tool require local governments to include: (1) The number, location, and geographic distribution of Uniform Federal Accessibility Standards (UFAS) units with mobility and sensory disability accessibility in housing subsidized with federal funds; (2) how the locality informs people with disabilities about accessible units; (3) how the locality monitors the distribution of accessible units throughout each project subsidized with federal or other funds; (4) how the locality monitors the availability of accessible units including the number of individuals with disabilities on waiting and transfer lists; (5) how the locality monitors the marketing of accessible units to individuals with disabilities; and (6) how the locality insures that its building and permitting departments are requiring compliance with federal accessibility laws.

Another commenter suggested including questions about segregation of

people with disabilities in the Segregation and R/ECAP sections of the tool, including whether the lack of accessible housing contributes to concentrations in R/ECAP areas, and whether land use, zoning laws, occupancy codes and restrictions, or lack of investment contribute to segregation in facilities that only house people with disabilities or fail to provide housing in integrated settings. The commenter also recommended asking participants to provide data about the availability of accessible transportation throughout the locality. The commenter also suggested adding ''disability'' to the list of protected class groups in the disproportionate housing needs section, because such individuals often face high costs burdens. The commenter recommended adding the following question: ''Compare the needs of families with a member with a disability who needs accessible features to the available housing stock with such accessible features in each category of publicly supported housing for the jurisdiction and region'' in the disproportionate housing needs section.

This same commenter recommended that people with disabilities be included in all portions of analysis including the publicly supported housing section and in the disability section, and program participants should be required to discuss compliance with Section 504 and the Americans with Disabilities Act. The commenter stated that the questions in the disability and access section should more specifically distinguish between people with mobility and sensory disabilities and people who need supported and integrated housing. The commenter expressed concern that participants will not provide information about barriers, needs, and solutions for people with different types of disabilities. The commenter suggested that local governments separate out the locality's own compliance from general problems in the region. The commenter also suggested rewording the bullet that says: ''State or local laws, policies, or practices that discourage individuals with disabilities from being placed in or living in apartments, family homes, and other integrated settings'' to read: ''State or local laws, policies, or practices that discourage or prohibit individuals with disabilities from living in apartments, family homes, supported housing, shared housing, and other integrated settings.'' The commenter stated adoption of this language deletes ''placed in,'' which implies a lack of choice, and expands the options that should be, but often are not, available to people with disabilities; recent proposed ordinances in California have proposed restricting shared and supported housing, and sober living situations. In the fair housing enforcement section, the commenter suggested adding ''pending administrative complaints or lawsuits against the locality alleging fair housing violations or discrimination'' to the first question and asked HUD to add a question soliciting information on how localities handle discrimination in their respective jurisdictions.

HUD Response: HUD appreciates all of the commenters' specific suggestions. As to the first comment, HUD thanks the commenter but believes that the analysis of residential living patterns within a jurisdiction and region does not require an inventory of laws and policies under an assessment and planning tool to create solutions and goals that respond to the fair housing and disparities in access issues identified.

HUD appreciates the commenters' feedback related to the contributing factors, and notes that some of the definitions have been revised.

HUD recognizes the public commenters' feedback in regard to school proficiency, and notes that it will continue to evaluate and consider best practices involving school performance, attendance and residency issues that impact access of protected classes to proficient schools.

Regarding the comment that persons with disabilities be included in all portions of analysis including the Publicly Supported Housing section, HUD notes that the instructions state that: ''The Fair Housing Act protects individuals on the basis of race, color, religion, sex, familial status, national origin, or having a disability or a particular type of disability. HUD has provided data for [the Publicly Supported Housing] section only on race/ethnicity, national origin, familial status, and limited data on disability. Include any relevant information about other protected characteristics—but note that the analysis of disability is also specifically considered in Section V(D). Program participants may include an analysis of disability here, but still must include such analysis in Section V(D).''

Miscellaneous

One commenter asked whether the tool raises the level of scrutiny for housing above *Lindsey* v. *Normet's* minimum level of scrutiny. The commenters stated that it is clear that the Administration does not want to raise the level of scrutiny because that would move housing issues from the political process to the courts, nonetheless, the Administration has clearly concluded that *Lindsey* is no longer good law. The commenters stated that the tool proposes fairness and dignity components to property (whereas *Lindsey* did not raise the level of scrutiny because that would interfere with the right to property). The commenters stated the Administration's statement of interest in *Bell* v. *Boise* stated that homelessness is an individual who is ''assaulted, unconstitutionally, in her or his housing.'' The commenter asked the following questions: What is the relation between the statement of interest and the tool? According to *West Virginia* v. *Barnette,* a fact is an individually enforceable right in court (vs. a fact for the political process), and the level of scrutiny is raised, if, inter alia, the fact is ''unaffected by assaults upon it.'' Is it the position of the Tool that housing is such a fact? What is the relation of the Collection Financial Standards (CFS) housing component to the tool? The commenters stated that according to *Lindsey,* the level of scrutiny for housing cannot be raised, and that *Lindsey* was premised on there not being a fairness component to housing and that there is such a thing as homelessness (which is contradicted by the Boise Statement of Interest). The commenters stated the tool contradicts both of these premises. The commenter stated that the government should give an instruction in the Tool (or explain why it did not) stating that the Tool is premised on the policy that *Lindsey* is no longer good law, housing is an individually enforceable right, and the level of scrutiny is above the minimum level.

Other commenters recommended that HUD defer implementation of the AFH process until all elements applicable to each type of program participant are publicly available. Another commenter stated that HUD should revise submittal deadlines until after it has tested the HUD-provided data, incorporated final comments into the tool, and provided adequate training; otherwise, early submitters may submit AFHs with questionable or misunderstood data.

A commenter stated that HUD should extend the deadline for comments or solicit comments again to allow grantees to respond because most grantees are busy with CAPER submissions due September 30.

A commenter identified a city as one of the most highly segregated cities in the area by race, ethnicity, poverty, and housing choice. The commenter stated that it appears that, due to predatory lending practices that led to the

foreclosure crisis, homes in the city's predominantly minority working class neighborhoods that were previously family-owned have been purchased in foreclosure by slumlords and these neighborhoods are now the victims of predatory rental and eviction practices. The commenter stated that the city did not update its AI for approximately 20 years (although it finally completed an AI this year).

Another commenter requested notification from HUD when AFFH documents are published that impact local governments.

HUD Response: HUD appreciates the commenters' suggestions. HUD reviewed the case law cited by the commenter and has concluded that the cases are not applicable to the obligation to affirmatively further fair housing under the Fair Housing Act and under the AFFH rule. HUD continues to assert that the AFFH rule and the Assessment Tool implementing the requirements contained in the regulation will better facilitate compliance with the AFFH mandate under the Fair Housing Act.

In response to concerns raised regarding predatory lending and other single family and mortgage-related comments, HUD notes that these issues can be addressed in several ways in the existing Assessment Tool. The segregation section provides for an analysis of owner-occupied and rental housing, by location. The contributing factors that can be considered under this section include Private Discrimination, Lending Practices and Access to Financial Services. Issues raised by commenters related to landlord tenant and eviction policies and practices can likewise be considered, including through changes that HUD has made to the Assessment Tool in the final stage, for instance in the contributing factor on Private Discrimination.

III. Summary

In issuing this Local Government Assessment Tool, approved for renewal under the Paperwork Reduction Act, HUD has strived to reach the appropriate balance in having program participants produce a meaningful assessment of fair housing that carefully considers barriers to fair housing choice and accessing opportunity and how such barriers can be overcome in respective jurisdictions and regions without being unduly burdensome. HUD has further committed to addressing program participant burden by providing data, guidance, and technical assistance, and such assistance will occur throughout the AFH process. While HUD is not specifically soliciting comment for another prescribed period, HUD welcomes feedback from HUD grantees that use this tool on their experience with this tool.

Dated: January 5, 2017.

Bryan Greene,

General Deputy Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. 2017–00714 Filed 1–12–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5995–N–2]

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 possible 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), call the toll-free Title V information line at 800–927–7588 or send an email to *title5@hud.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 5, 2017.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

[FR Doc. 2017–00256 Filed 1–12–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2016–N242; FXES11130300000–178–FF03E00000]

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications for a permit to conduct activities intended to enhance the survival of endangered or threatened species. Federal law prohibits certain activities with endangered species unless a permit is obtained.

DATES: We must receive any written comments on or before February 13, 2017.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Carlita Payne, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458; or by electronic mail to *permitsR3ES@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Carlita Payne, (612) 713–5343.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), prohibits certain activities with endangered and threatened species unless the activities are specifically authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A permit granted by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of propagation or survival, or interstate commerce (the latter only in the event that it facilitates scientific purposes or enhancement of propagation or survival). Our regulations implementing section 10(a)(1)(A) of the ESA for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, Tribal, and Federal agencies and the public to comment on the following applications. Please refer to the permit number when you submit comments. Documents and other information the applicants have submitted with the applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit Applications

Proposed activities in the following permit requests are for the recovery and enhancement of survival of the species in the wild.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE02651A	Ohio Department of Transportation.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*), American burying beetle (*Nicrophorus americanus*).	Ohio	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, mist-net, trap, radio-tag, release.	Amend, renew.
TE07730A	Redwing Ecological Services, Inc.	Relict darter (*Etheostoma chienense*), Cumberland darter (*E. susanae*), Palezone shiner (*Notropis albizonatus*), Scioto madtom (*Noturus trautmani*), blackside dace (*Phoxinus cumberlandensis*), Big Sandy crayfish (*Cambarus callainus*), 30 mussel species.	Illinois, Indiana, Iowa, Kentucky, Minnesota, Missouri, Ohio, Pennsylvania, Tennessee, West Virginia, Wisconsin.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, evaluate impacts.	Capture, handle, release.	Amend, renew.

National Environmental Policy Act

The proposed activities in the requested permits qualify as categorical exclusions under the National Environmental Policy Act, as provided by Department of the Interior implementing regulations in part 46 of title 43 of the CFR (43 CFR 46.205, 46.210, and 46.215).

Public Availability of Comments

We seek public review and comments on these permit applications. Please refer to the permit number when you submit comments. Comments and materials we receive in response to this notice are available for public inspection, by appointment, during normal business hours at the address listed above in **ADDRESSES**.

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.

Authority: We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*).

Dated: January 9, 2017.

Lori H. Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2017–00663 Filed 1–12–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R6–ES–2015–0104; 4500030113]

Endangered and Threatened Wildlife and Plants; Status Review of the Northern Rocky Mountain Distinct Population Segment of the Fisher

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of status review.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the opening of an information gathering period regarding the status of the fisher (*Pekania pennanti*) throughout the range of its northern Rocky Mountain distinct population segment (DPS) in the United States. The status review will include analysis of whether the northern Rocky Mountain DPS of the fisher warrants listing as an endangered or a threatened species under the Endangered Species Act of 1973, as amended (Act). We encourage all interested parties to provide us information regarding the status of, and any potential threats to, the northern Rocky Mountain DPS of the fisher.

DATES: We will accept comments from all interested parties until February 13, 2017. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Time on this date.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* In the Search box, enter the FWS–R6–ES–2015–0104, which is the docket number for this action. Then click on the Search button. You may enter a comment by clicking on ''Comment Now!'' Please ensure that you have found the correct document before submitting your comment.
- *U.S. mail or hand delivery:* Public Comments Processing, Attn: Docket No. FWS–R6–ES–2015–0104, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Information, below, for more information).

FOR FURTHER INFORMATION CONTACT: Jodi Bush, Field Supervisor, U.S. Fish and Wildlife Service, Montana Ecological Services Field Office, 585 Shepard Way,

Helena, MT 59601; telephone 406–449–5225; or facsimile 406–449–5339. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Request for Information

This document solicits biological or other data or information on the status of, and potential threats to, the northern Rocky Mountain DPS of the fisher, a medium-sized mammal of the mustelid family. This information, along with other sources of data, will be used to determine if the northern Rocky Mountain DPS of the fisher warrants listing as an endangered or a threatened species under the Act (16 U.S.C. 1531 *et seq.*). We request any new information concerning the status of the northern Rocky Mountain DPS of the fisher. Information submitted since the 2011 status review (which culminated in our 12-month finding published on June 30, 2011, at 76 FR 38504) and the 2016 90-day petition finding (81 FR 1368; January 12, 2016) will be considered and need not be resubmitted. We will base our status review on the best scientific and commercial information available, including all information received as a result of this publication. We are soliciting information and supporting data on the northern Rocky Mountain DPS of the fisher; we specifically seek information on the following:

(1) Information regarding the species' historical and current population status, distribution, abundance, and trends; biology and ecology; and habitat selection.

(2) Information on the effects of potential threat factors that are the basis for a species' listing determination under section 4(a)(1) of the Act (16 U.S.C. 1533(a)(1)), which are:

(a) The present or threatened destruction, modification, or curtailment of the species' habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) Inadequacy of existing regulatory mechanisms; and

(e) Other natural or manmade factors affecting its continued existence.

(3) Scientific and commercial data to assist in development of any proposed critical habitat designation that we may make, including:

(a) Whether the designation of critical habitat for the northern Rocky Mountain DPS of the fisher would be beneficial to the conservation of the species or whether the identification of specific areas as critical habitat may increase threats to the species or its habitat;

(b) Habitat selection and use, and any changes or trends in the amount and distribution of habitat for the northern Rocky Mountain DPS of the fisher;

(c) Habitat requirements for feeding, breeding, and sheltering, including particular physical or biological features that are essential to the conservation of the species and where such physical or biological features are found;

(d) Whether any of these features may require special management considerations or protection;

(e) What areas that are currently occupied and contain the physical or biological features essential to the conservation of the species should be included in the critical habitat designation and why;

(f) What areas not currently occupied at the time of listing are essential for the conservation of the species and why; and

(g) The possible benefits and impacts (including probable economic impacts) of a possible critical habitat designation for the northern Rocky Mountain DPS of the fisher.

(4) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this species and regulations that may be addressing those threats.

(5) Any information on the biological or ecological requirements of the species and ongoing conservation measures for the species and its habitat.

(6) Information on land use designations and current or planned activities in the areas occupied by the northern Rocky Mountain DPS of the fisher or areas that may be important for its conservation, and possible impacts of these activities on this species and these areas.

(7) Information on the projected and reasonably likely impacts of climate change on the northern Rocky Mountain DPS of the fisher and its habitat.

(8) Information on any foreseeable economic, national security, or other relevant impacts that may result if we designate any area as critical habitat. We are particularly interested in any potential impacts on small entities, and the benefits of including or excluding areas from any possible future proposed designation that are subject to these impacts.

Please support submissions with documentation such as maps; bibliographic references; methods used to gather and analyze the data; or copies of pertinent publications, reports, or letters by knowledgeable sources. We request data from systematic surveys, studies, or analyses of data regarding population size or trends, biology or ecology of the species, effects of current land management on population distribution and abundance, current condition of habitat, and conservation measures that have been implemented to benefit the species. We also request information on the current distribution of populations and threats to the species in relation to the five listing factors (as defined in section 4(a)(1) of the Act).

Comments merely stating support for or opposition to a particular action without providing supporting data may not meet the standard of information required by section 4(b)(1)(A) of the Act, which directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Authors

The primary authors of this document are staff of the Montana Ecological Services Field Office.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: January 5, 2017.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2017–00656 Filed 1–12–17; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[178A2100DD/AAKC001030/A0A501010.999900 253G]

Reservation Proclamations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of availability of procedural guidance.

SUMMARY: The Bureau of Indian Affairs (BIA) has updated its Fee-to-Trust Handbook to include procedural guidance for its employees on processing reservation proclamations, including simultaneous requests for trust acquisition and reservation proclamations.

ADDRESSES: The updated Fee-to-Trust Handbook is available at the following link: *http://www.bia.gov/WhatWeDo/Knowledge/Directives/Handbooks/.*

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Office of Trust Services, Bureau of Indian Affairs, (202) 208–3615, *sharlene.roundface@bia.gov,* or Ms. Tana Fitzpatrick, Counselor, Assistant Secretary—Indian Affairs, (202) 208–7163, *tana.fitzpatrick@bia.gov.*

SUPPLEMENTARY INFORMATION: The BIA has updated its Fee-to Trust Handbook to establish procedures for BIA to process simultaneous requests for trust land acquisitions under 25 CFR part 151 and reservation proclamations under the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. 467). This Handbook revision will provide flexibility for Tribes who wish to submit their requests simultaneously. BIA has also updated the Handbook to include guidance for processing reservation proclamations where the land has already been acquired in trust.

Authority: 5 U.S.C. 301; 25 U.S.C. 2; 25 U.S.C. 9; 25 U.S.C. 467.

Dated: December 30, 2016.

Lawrence S. Roberts,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2017–00703 Filed 1–12–17; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO260000 L10600000.PC0000]

Renewal of Approved Information Collection; OMB Control No. 1004–0042

AGENCY: Bureau of Land Management, Interior.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Bureau of Land Management (BLM) has submitted an information collection request to the Office of Management and Budget (OMB) to continue the collection of information from those who wish to adopt and obtain title to wild horses and burros. The OMB previously approved this information collection activity, and assigned it control number 1004–0042.

DATES: The OMB is required to respond to this information collection request within 60 days but may respond after 30 days. For maximum consideration, written comments should be received on or before February 13, 2017.

ADDRESSES: Please submit comments directly to the Desk Officer for the Department of the Interior (OMB #1004–0042), Office of Management and Budget, Office of Information and Regulatory Affairs, fax 202–395–5806, or by electronic mail at *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to the BLM. You may do so via mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: jesonnem@blm.gov.

Please indicate ''Attn: 1004–0042'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Holle Hooks, at 405–234–1860. Persons who use a telecommunication device for the deaf may call the Federal Relay Service at 1–800–877–8339, to leave a message for Ms. Hooks. You may also review the information collection request online at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act (44 U.S.C. 3501–3521) and OMB regulations at 5 CFR part 1320 provide 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. In order to obtain and renew an OMB control number, Federal agencies are required to seek public comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on September 20, 2016 (81 FR 64502), and the comment period ended November 21, 2016. The BLM received two non-substantive public comments, which did not address, and were not germane to, this information collection. Therefore, the BLM has not changed the collection in responses to the comments.

The BLM now requests comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;

2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information to be collected; and

4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as directed under **ADDRESSES** and **DATES**. Please refer to OMB control number 1004–0042 in your correspondence. 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.

The following information pertains to this request:

Title: Protection, Management, and Control of Wild Horses and Burros (43 CFR part 4700).

Forms: Form 4710–10, Application for Adoption of Wild Horse(s) or Burro(s).

OMB Control Number: 1004–0042.

Abstract: This notice pertains to the collection of information that enables the BLM to administer its private maintenance (*i.e.,* adoption) program for wild horses and burros. The BLM uses the information to determine if applicants are qualified to provide humane care and proper treatment to wild horses and burros in compliance with the Wild Free-Roaming Horses and Burros Act (16 U.S.C. 1331–1340).

Frequency: On occasion.

Description of Respondents: Those who wish to adopt and obtain title to wild horses and burros.

Estimated Number of Responses Annually: 7,093.

Estimated Reporting and Recordkeeping ''Hour'' Burden Annually: 3,545.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden Annually: $2,400.

The estimated burdens are itemized in the following table:

Type of response A.	Number of responses B.	Time per response (minutes) C.	Total hours (Column B × Column C) D.
Application for Adoption of Wild Horse(s) or Burro(s) 43 CFR 4750.3–1 and 4750.3–2 Form 4710–10	7,000	30	3,500
Supporting Information and Certification for Private Maintenance of More Than Four Wild Horses or Burros 43 CFR 4750.3–3	6	10	1
Request to Terminate Private Maintenance and Care Agreement 43 CFR 4750.4–3	75	30	38
Request for Replacement Animals or Refund 43 CFR 4750.4–4	12	30	6
Totals	7,093		3,545

Mark Purdy,

Bureau of Land Management, Management Analyst.

[FR Doc. 2017–00757 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Bureau of Indian Affairs

[LLESM00000.L14400000.FR0000; MNES–058082]

Identifying Lands Subject to Secretarial Order of Restoration of February 22, 1945

AGENCY: Bureau of Land Management, Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: On February 22, 1945, the Secretary of the Interior issued an Order restoring to the Red Lake Band of Chippewa Indians of Minnesota (''Tribe'') certain lands that the Tribe had previously ceded to the United States for use by non-Indians. The lands restored to the Tribe by the 1945 Order are lands that were continuously held in trust by the United States since the cessions, that were never sold or otherwise disposed of, and for which the Tribe was never paid. This notice provides a partial list of the legal descriptions of lands restored to the Tribe by the 1945 Order. The Secretary included in the 1945 Order ''lands which have been assessed for drainage works by the State of Minnesota under the authority of the Volstead Act of May 20, 1908 . . . subject to any existing valid rights.'' The Department has reviewed and resolved title issues that arose regarding applicability of the Volstead Act. Thus, without further delay, these legal descriptions are published as representing lands among the lands restored to the Tribe as trust lands.

DATES: Restoration of lands was effective on February 22, 1945.

ADDRESSES: Bureau of Land Management, Eastern States, 20 M Street SE., Suite 950, Washington, DC 20003. Bureau of Indian Affairs, Midwest Regional Office, 5600 American Blvd., West, Suite 500, Bloomington, MN 55437. Detailed information concerning this action is available for review at these addresses.

FOR FURTHER INFORMATION CONTACT: Dominica VanKoten, Deputy State Director, Division of Geospatial Services, by telephone at (202) 912–7756, or by email at *dvankote@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 Nelson Act of January 14, 1889, ch. 24, 25 Stat. 642, created and authorized a Federal commission to negotiate a cession of lands in northern Minnesota from the Red Lake Band of Chippewa Indians of Minnesota to the United States. By agreement dated July 8, 1889, 2.9 million acres of land known as ''Royce 706'' were ceded by the Tribe to the United States for the benefit of the Tribe. The Tribe retained a much smaller area known as ''Royce 707.''

On March 10, 1902, another agreement was negotiated between the Tribe and the United States for the cession of an additional 256,152 acres of land in the western portion of Royce 707. This agreement was approved, with amendments, by Congress under the Act of February 20, 1904, ch. 161, 33 Stat. 46. Consistent with the provisions of the Nelson Act, the lands the Tribe ceded to the United States were opened for timber sales and homesteading, and most of the lands were disposed of by the 1930s.

The Indian Reorganization Act of 1934 (''IRA''), 25 U.S.C. 461 *et seq.,* authorized the Secretary of the Interior, if he found it to be in the public interest, ''to restore to tribal ownership the remaining surplus lands to any Indian reservation [that prior to June 18, 1934 were] opened, or authorized to be opened, to sale or any other form of disposal by Presidential proclamation, or by any of the public land laws of the United States[.]'' 25 U.S.C. 463(a).

On February 22, 1945, exercising this authority granted by the IRA, the Secretary of the Interior issued an Order of Restoration (''1945 Order''), 10 FR 2448 (1945). The 1945 Order ''Restored to tribal ownership all those lands of the Red Lake Indian Reservation which were ceded by the Indians under [the Nelson Act and the Act of February 20, 1904] and which were opened for sale or entry but for which the Indians have not been paid and which now are or hereafter may be classified as undisposed of.'' 10 FR at 2449. See also Act of December 4, 1942, ch. 673, 56 Stat. 1039 (''All right, title, and interest of the Minnesota Chippewa Tribe in and to the so-called Red Lake Indian ceded lands, including any administrative reserves, is hereby declared extinguished and title thereto vested in the Red Lake Band of Chippewa Indians.'').

On May 28, 1945, the Acting Commissioner of the General Land Office forwarded to the Commissioner of the Office of Indian Affairs a list of lands that satisfied the criteria of the 1945 Order and could be returned to the Tribe. On April 29, 1946, and January 9, 1947, amendments to the list of lands were made. The list of May 28, 1945, and the amendments of April 29, 1946, and January 9, 1947 (collectively, the ''1945 List'') totaled approximately 157,499 acres of noncontiguous lands. The 1945 List was to have been published in the **Federal Register** to provide public notice of lands that were subject to the 1945 Order. However, shortly after the 1945 List was completed, several title and legal description problems with lands on the list were discovered, and the 1945 List

was never published in the **Federal Register**.

From 1945 until 1988, the Department attempted to resolve many of the title and legal description problems with the lands on the 1945 List. On December 22, 1988, the Acting State Director of the Eastern States Office, Bureau of Land Management (''BLM''), forwarded to the Bureau of Indian Affairs a comprehensive list of lands totaling approximately 186,533 acres (''1988 List'') that the BLM had determined qualified for restoration to the Tribe under the 1945 Order. Many of the lands on the 1945 List were on the 1988 List. However, shortly after the 1988 List was completed, several additional title and legal description problems were discovered and the 1988 List was never published in the **Federal Register**.

In December 1997, the Department initiated a review of the lands on the 1945 and 1988 Lists. On February 2, 1999, the Department published in the **Federal Register** a list of lands totaling 86,685.89 acres which were determined to be eligible for restoration to the Tribe pursuant to the 1945 Order. 64 FR 5069 (1999). On November 15, 2001, the Department published in the **Federal Register** a list of lands totaling 34,578.58 acres which were also determined to be eligible for restoration to the Tribe pursuant to the 1945 Order. 66 FR 57479 (2001).

The Department has conducted an extensive review of one of the outstanding title and legal description problems. Specifically, the 1945 Order restored lands, including ''lands which have been assessed for drainage works by the State of Minnesota under authority of the Volstead Act of May 20, 1908 (35 Stat. 169, 43 U.S.C. secs. 1021–1028) . . . subject to existing valid rights.'' 10 FR 2449. In a 2015 M-Opinion (M–37031) entitled *Legal Status of the Red Lake Band of Chippewa Indians' Restored Lands Assessed for Drainage Works by the State of Minnesota Under the Authority of the Volstead Act of 1908* (May 1, 2015), the Department determined that the Volstead drainage liens do not constitute a valid existing right as to restored lands for the Tribe.

The Department has determined through a review of BLM records, in accordance with M–37031, that the lands described below were ceded by the Tribe to the United States in 1889 and 1902, were held in trust by the United States subject to sale for the benefit of the Tribe, were not disposed of by the United States, and were restored to the Tribe by the 1945 Order. The descriptions include lands previously published as restored by the 1945 Order if such lands were also assessed with Volstead drainage liens. Descriptions of any additional lands that were restored by the 1945 Order may be published as they are confirmed.

Lands restored to the Tribe by the 1945 Order include the following described tracts and their respective acreages:

FIFTH PRINCIPAL MERIDIAN, MINNESOTA

T. 159 N., R 27 W.,	
Sec. 15, NE¼SW¼	40
T. 157 N., R 28 W.,	
Sec. 6, Lots 5 and 6, SE¼NW¼	126.92
Sec. 7, W½SE¼	80
Sec. 27, E½NE¼, SW¼NE¼, NW¼, SW¼, SE¼	600
Sec. 29, SW¼	160
Sec. 32, Lots 1 thru 4, NE¼, N½SW¼, N½SE¼	468.84
Sec. 34, E½, SW¼	480
Sec. 35, All	640
T. 158 N., R 28 W.,	
Sec. 1, SW¼, SE¼SE¼	200
Sec. 2, S½	320
Sec. 3, S½SE¼	80
Sec. 5, SE¼	160
Sec. 6, S½NE¼, N½SE¼, SW¼SE¼	200
Sec. 7, Lots 1 and 2, E½NW¼	158.60
Sec. 12, SE¼SW¼	40
Sec. 13, SE¼	160
Sec. 15, SW¼SW¼	40
Sec. 16, SW¼NE¼	40
Sec. 17, W½NE¼, W½SE¼	160
Sec. 18, E½	320
Sec. 21, NE¼NE¼, S½SW¼, E½SE¼, SW¼SE¼	240
Sec. 22, W½NW¼, S½	400
Sec. 23, E½, E½NW¼, SW¼NW¼, SW¼	600
Sec. 24, E½NE¼, SW¼NE¼, W½NW¼, SE¼NW¼, SW¼, N½SE¼, SW¼SE¼	520
Sec. 25, N½NE¼, N½NW¼, NW¼SE¼	200
Sec. 26, N½NE¼, N½NW¼	160
Sec. 27, NE¼, N½NW¼	240
Sec. 28, N½NE¼, SE¼NE¼, NW¼	280
Sec. 29, E½NE¼	80
Sec. 32, SE¼NW¼, E½SW¼, SW¼SW¼	160
T. 159 N., R 28 W.,	
Sec. 5, SW¼NE¼	40
Sec. 6, Lot 4, SE¼SE¼	76.50
Sec. 7, N½NE¼	80
Sec. 8, SE¼NE¼, SE¼SW¼, SW¼SE¼	120
Sec. 9, N½NW¼	80
Sec. 12, E½SW¼, SW¼SW¼	120
Sec. 13, W½NW¼	80
Sec. 14, N½NE¼, SW¼NE¼	120
Sec. 17, NW¼NE¼, NE¼NW¼	80
Sec. 25, NW¼	160
Sec. 27, NW¼SW¼	40
Sec. 29, W½SW¼, E½SE¼	160
Sec. 30, Lot 1	38.67
Sec. 32, SW¼NE¼, NW¼SE¼	80
T. 160 N., R 28 W.,	
Sec. 31, Lots 3 and 4, NE¼SW¼	112.27
T. 154 N., R 29 W.,	
Sec. 16, NE¼SE¼	40
T. 155 N., R 29 W.,	
Sec. 16, SW¼NW¼	40
Sec. 36, Lot 2	19.40
T. 156 N., R 29 W.,	
Sec. 36, SE¼SW¼	40
T. 157 N., R 29 W.,	
Sec. 3, SW¼SE¼	40
Sec. 4, Lots 1 and 4, SW¼NW¼	120.04

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 5, Lot 1, SE¼NE¼	79.93
Sec. 6, Lots 3 thru 6, S½NE¼, SE¼NW¼, NE¼SW¼, NW¼SE¼	372.06
Sec. 11, E½NE¼, SW¼NE¼	120
Sec. 12, W½NW¼	80
Sec. 21, NE¼, W½NW¼	240
Sec. 22, NW¼	160
Sec. 26, SE¼	160
Sec. 36, E½SW¼, SE¼	240
T. 158 N., R 29 W.,	
Sec. 3, E½SE¼	80
Sec. 4, NW¼SW¼	40
Sec. 6, Lot 7, E½SW¼, SE¼	282.22
Sec. 8, W½NW¼, SE¼NW¼, SW¼	280
Sec. 19, NE¼NE¼	40
Sec. 25, E½NW¼	80
Sec. 29, W½NE¼, SE¼NE¼, NW¼SE¼	160
Sec. 32, SW¼NW¼	40
Sec. 33, SE¼SE¼	40
T. 159 N., R 29 W.,	
Sec. 3, S½SE¼	80
Sec. 6, SE¼NE¼, E½SE¼	120
Sec. 10, SW¼NE¼, SE¼NW¼, N½SE¼	160
Sec. 11, NE¼NE¼, W½NW¼	120
Sec. 12, S½NW¼, NW¼SE¼	120
Sec. 15, S½NE¼	80
Sec. 28, NW¼SE¼	40
Sec. 32, Lot 3, SE¼NE¼	80.70
Sec. 33, S½SW¼	80
Sec. 34, N½NW¼, SW¼NW¼, NW¼SW¼	160
Sec. 35, NE¼NW¼	40
T. 160 N., R 29 W.,	
Sec. 13, E½NE¼, E½SE¼	160
Sec. 15, SW¼NW¼	40
Sec. 16, NE¼NE¼	40
Sec. 28, NE¼SE¼	40
T. 153 N., R 30 W.,	
Sec. 14, SE¼SW¼	40
T. 156 N., R 30 W.,	
Sec. 36, SW¼	160
T. 157 N., R 30 W.,	
Sec. 3, Lots 1 and 2, S½NE¼, S½	478.86
Sec. 4, S½NW¼	80
Sec. 5, NE¼SW¼, N½SE¼, SE¼SE¼	160
Sec. 6, Lot 1	40.38
Sec. 7, NE¼	160
Sec. 13, NE¼, SW¼	320
Sec. 14, NE¼	160
Sec. 19, SE¼	160
Sec. 20, SW¼	160
Sec. 25, NE¼	160
Sec. 30, Lots 1 and 2, E½NW¼	159.55
T. 158 N., R 30 W.,	
Sec. 7, Lot 3, NE¼SW¼, N½SE¼	157.53
Sec. 10, SW¼SE¼	40
Sec. 14, N½SE¼, SE¼SE¼	120
Sec. 15, NW¼SW¼	40
Sec. 24, N½NW¼	80
Sec. 29, W½NW¼	80
Sec. 30, Lots 3 and 4, E½SW¼	158.16
Sec. 31, NW¼NE¼	40
Sec. 32, SE¼SE¼	40
Sec. 33, NE¼SW¼, S½SE¼	120
Sec. 34, SE¼NW¼, NE¼SW¼	80
T. 159 N., R 30 W.,	
Sec. 6, Lots 3 and 4	79.49
Sec. 24, SE¼SW¼	40
Sec. 35, SW¼NW¼	40
T. 160 N., R 30 W.,	
Sec. 31, E½SW¼	80
T. 153 N., R 31 W.,	
Sec. 36, W½NE¼	80
T. 157 N., R 31 W.,	
Sec. 2, Lot 4, SE¼NE¼, NE¼SW¼	119.79
Sec. 3, Lot 1	39.78
Sec. 8, NW¼SW¼	40
Sec. 9, SW¼NW¼, W½SW¼	120
Sec. 11, NE¼	160

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 12, SW¼	160
Sec. 15, SE¼NW¼	40
Sec. 20, NW¼NW¼	40
Sec. 22, NW¼	160
Sec. 31, Lots 1 and 2, E½NW¼	160.75
Sec. 32, SW¼NE¼	40
T. 158 N., R 31 W.,	
Sec. 19, Lot 3	43.08
Sec. 23, SW¼NE¼, SE¼NW¼, N½SW¼	160
Sec. 24, NW¼SE¼	40
Sec. 30, W½SE¼	80
Sec. 33, SW¼SE¼	40
Sec. 34, NE¼NW¼	40
T. 159 N., R 31 W.,	
Sec. 6, Lot 6	41.20
Sec. 30, SE¼NW¼	40
Sec. 32, S½NW¼	80
T. 155 N., R 32 W.,	
Sec. 1, Lots 1 thru 12, NW¼	612.64
Sec. 2, S½	320
Sec. 3, SE¼	160
Sec. 6, NW¼	160
Sec. 11, N½NW¼, SE¼NW¼, SW¼	280
Sec. 12, Lots 1 and 12	65.36
Sec. 20, N½	320
Sec. 21, NE¼	160
Sec. 22, NW¼NE¼, SE¼NE¼, NW¼	240
Sec. 23, SW¼NE¼	40
Sec. 26, SW¼NE¼, NW¼, NW¼SE¼	240
Sec. 27, NW¼SE¼	40
Sec. 28, NW¼, N½SW¼	240
T. 156 N., R 32 W.,	
Sec. 2, Lot 1	26.01
Sec. 7, SW¼	160
Sec. 16, NW¼	160
Sec. 17, NE¼	160
Sec. 19, SW¼	160
Sec. 22, SE¼	160
Sec. 23, SW¼	160
Sec. 24, Lot 12, SW¼	193.59
Sec. 25, Lots 1, 6, 7 and 12, SW¼	294.04
Sec. 26, NW¼	160
Sec. 30, W½	320
Sec. 31, NW¼	160
Sec. 35, NW¼	160
T. 157 N., R 32 W.,	
Sec. 1, NW¼SW¼	40
Sec. 13, Lot 4	40.03
Sec. 17, W½NW¼	80
Sec. 18, Lot 3, N½NE¼, SE¼NE¼	159.09
Sec. 19, Lots 3 and 4, E½SW¼	159.6
Sec. 22, N½NE¼, SW¼NE¼, NW¼SE¼	160
Sec. 24, E½NE¼, S½SE¼	160
Sec. 25, SW¼NE¼, SE¼SW¼, W½SE¼	160
Sec. 28, NW¼SW¼	40
Sec. 30, Lots 1 and 2, E½NW¼	159.7
T. 158 N., R 32 W.,	
Sec. 1, Lot 7, SW¼SW¼	72.54
Sec. 2, NE¼SW¼, SE¼SE¼	80
Sec. 14, NE¼SE¼	40
Sec. 15, NE¼SE¼, SW¼SE¼	80
Sec. 16, SE¼NW¼, SW¼	200
Sec. 17, SW¼NW¼, N½SW¼	120
Sec. 20, E½SE¼	80
Sec. 21, SW¼NW¼, SW¼SW¼	80
Sec. 22, NW¼SW¼	40
Sec. 25, Lot 4, NE¼SW¼	74.93
Sec. 26, SE¼NE¼	40
Sec. 27, SW¼SE¼	40
Sec. 28, NW¼NE¼, N½NW¼	120
Sec. 31, E½SE¼, SW¼SE¼	120
Sec. 35, NE¼NE¼, SW¼NE¼	80
T. 159 N., R 32 W.,	
Sec. 6, Lots 2 and 5, SW¼NE¼, SE¼NW¼	148.83
Sec. 8, NE¼SE¼	40
Sec. 9, NW¼SE¼	40
Sec. 13, NE¼NW¼	40
Sec. 15, SW¼NE¼	40

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 16, SW¼NE¼, W½NW¼, SE¼NW¼, SE¼SE¼	200
Sec. 25, NE¼NE¼	40
Sec. 26, NW¼NW¼	40
Sec. 28, SE¼SW¼	40
T. 160 N., R 32 W.,	
Sec. 23, NE¼	160
Sec. 24, W½	320
Sec. 32, SE¼	160
Sec. 36, NW¼	160
T. 155 N., R 33 W.,	
Sec. 14, N½	320
Sec. 23, SE¼	160
Sec. 26, NE¼	160
Sec. 28, NE¼	160
Sec. 35, S½	320
Sec. 36, NE¼	160
T. 156 N., R 33 W.,	
Sec. 16, SE¼	160
T. 157 N., R 33 W.,	
Sec. 7, Lot 1, SE¼NE¼	79.12
Sec. 8, E½SW¼, W½SE¼	160
Sec. 13, NE¼SE¼	40
Sec. 16, NE¼SW¼	40
Sec. 17, SW¼SE¼	40
Sec. 19, N½SE¼	80
Sec. 20, SW¼NE¼, NW¼SW¼	80
Sec. 21, NE¼NE¼, NW¼NW¼, SE¼NW¼	120
Sec. 22, W½NW¼, W½SE¼	160
Sec. 23, S½NE¼	80
Sec. 24, S½NW¼, N½SW¼, NW¼SE¼	200
Sec. 35, NE¼SW¼	40
T. 158 N., R 33 W.,	
Sec. 34, NE¼NE¼	40
T. 159 N., R 33 W.,	
Sec. 5, Lots 2 and 3, S½NE¼	159.32
Sec. 7, E½NE¼, NE¼SW¼, N½SE¼	200
Sec. 8, NW¼NE¼, W½NW¼, NE¼SE¼	160
Sec. 19, N½SE¼, SW¼SE¼	120
T. 160 N., R 33 W.,	
Sec. 8, NW¼SE¼	40
Sec. 23, S½NW¼	80
Sec. 25, SE¼NE¼, NE¼SE¼	80
Sec. 29, SE¼NE¼	40
Sec. 30, SE¼	160
Sec. 32, SE¼NE¼	40
T. 162 N., R 33 W.,	
Sec. 14, NW¼SE¼	40
T. 156 N., R 34 W.,	
Sec. 4, Lot 4, SW¼NW¼	63.69
Sec. 5, Lot 1, S½NE¼, SE¼	263.73
Sec. 6, Lot 1, SE¼NE¼	65.20
Sec. 7, Lots 3 and 4, E½SW¼	161.79
Sec. 9, W½NE¼, SE¼NE¼, NE¼NW¼	160
Sec. 18, Lots 1 and 2, E½NW¼	161.42
T. 157 N., R 34 W.,	
Sec. 1, Lots 3 and 4, S½NW¼	157.92
Sec. 5, SW¼SW¼	40
Sec. 8, NE¼NW¼	40
Sec. 10, SW¼NE¼, NW¼SW¼	80
Sec. 12, NW¼	160
Sec. 13, SE¼NW¼	40
Sec. 18, Lots 3 and 4, SE¼SW¼, SW¼SE¼	154.92
Sec. 20, SE¼	160
Sec. 21, S½SE¼	80
Sec. 22, E½SE¼	80
Sec. 23, W½SW¼, SE¼SW¼, S½SE¼	200
Sec. 24, W½SW¼, SE¼SW¼, SW¼SE¼	160
Sec. 27, N½	320
Sec. 28, N½NE¼, W½SW¼, SE¼SW¼, SW¼SE¼	240
Sec. 32, NW¼NW¼	40
Sec. 33, NW¼NE¼	40
T. 158 N., R 34 W.,	
Sec. 31, Lot 1	33.16

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 32, N½NE¼	80
T. 159 N., R 34 W.,	
Sec. 6, Lots 3, 5 and 6	120.06
Sec. 7, Lots 2 thru 4, SE¼NW¼, E½SW¼, NE¼SE¼	278.82
Sec. 8, S½SW¼, SE¼	240
Sec. 9, N½NE¼	80
Sec. 17, N½NE¼, N½NW¼	160
Sec. 18, Lots 1 thru 3, NW¼NE¼, E½NW¼, NE¼SW¼	279.10
T. 160 N., R 34 W.,	
Sec. 1, S½NW¼	80
Sec. 2, Lots 1 and 2, S½NE¼	165.11
Sec. 7, W½NE¼, W½SE¼	160
Sec. 8, Lot 3, SW¼NE¼, NE¼SW¼	118.80
Sec. 9, SE¼	160
Sec. 15, SE¼NW¼, SW¼SW¼	80
Sec. 16, NW¼SW¼	40
Sec. 17, Lot 1, W½NW¼, SE¼NW¼	157.70
Sec. 19, Lots 1, 2 and 4, E½NW¼, N½SE¼, SE¼SE¼	295.46
Sec. 20, W½SW¼	80
Sec. 21, SE¼	160
Sec. 22, NE¼SW¼, NE¼SE¼	80
Sec. 23, NW¼NE¼	40
Sec. 26, SE¼NW¼	40
Sec. 28, NW¼NE¼	40
Sec. 32, SE¼NE¼	40
Sec. 34, SW¼NW¼	40
T. 161 N., R 34 W.,	
Sec. 36, N½SW¼, SW¼SW¼, NW¼SE¼	160
T. 162 N., R 34 W.,	
Sec. 16, NW¼	160
T. 155 N., R 35 W.,	
Sec. 15, SE¼SE¼	40
Sec. 16, N½NE¼, E½NW¼	160
Sec. 22, NE¼	160
Sec. 29, NE¼	160
Sec. 30, Lot 4, SE¼SW¼	78.07
T. 156 N., R 35 W.,	
Sec. 2, Lot 4, SW¼NW¼, N½SW¼, SW¼SW¼, NW¼SE¼	226.76
Sec. 3, Lots 1 and 2, SE¼NE¼, E½SE¼	172.68
Sec. 4, SW¼NE¼	40
Sec. 9, E½SW¼, SW¼SE¼	120
Sec. 10, SE¼	160
Sec. 12, E½SE¼	80
Sec. 14, W½NE¼	80
Sec. 15, N½	320
Sec. 16, SW¼	160
Sec. 19, NE¼	160
Sec. 20, W½NW¼, SE¼NW¼, N½SW¼, SW¼SW¼	240
Sec. 21, SW¼	160
Sec. 34, SW¼	160
T. 157 N., R 35 W.,	
Sec. 4, SE¼NE¼	40
Sec. 6, Lot 7, SE¼SW¼	81.95
Sec. 7, Lot 1, NE¼NW¼	82
Sec. 8, E½SW¼, W½SE¼	160
Sec. 9, NW¼	160
Sec. 34, Lots 1 and 2, N½SW¼	166.05
Sec. 36, Lot 1, NW¼SW¼	80.96
T. 158 N., R 35 W.,	
Sec. 6, Lot 5	42.81
Sec. 18, SW¼NE¼	40
Sec. 27, SE¼NE¼	40
Sec. 31, Lots 3 and 4	70.83
Sec. 36, SW¼NW¼	40
T. 159 N., R 35 W.,	
Sec. 1, Lots 1 and 2, SW¼NE¼, E½SW¼, SW¼SW¼, NW¼SE¼	279.65
Sec. 2, NW¼SE¼	40
Sec. 3, Lot 3, SW¼NE¼, SE¼NW¼, NE¼SW¼	158.44
Sec. 4, Lot 1	38.01
Sec. 5, NW¼SE¼	40
Sec. 9, SE¼NE¼, N½SW¼	120
Sec. 12, NE¼NE¼	40
Sec. 17, SW¼SE¼	40

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 18, SE¼SE¼	40
Sec. 19, SW¼NE¼, SE¼NW¼	80
Sec. 28, SE¼NW¼	40
Sec. 31, S½NE¼, N½SE¼	160
T. 160 N., R 35 W.,	
Sec. 1, S½NW¼, NE¼SW¼, NW¼SE¼	160
Sec. 3, SW¼	160
Sec. 4, Lot 4, S½NW¼	112.61
Sec. 6, Lots 1, 2, 4 and 5, S½NE¼, SE¼NW¼, E½SW¼	307.27
Sec. 7, NE¼SW¼	40
Sec. 8, NW¼	160
Sec. 11, SW¼NW¼, SE¼	200
Sec. 12, E½, SW¼	480
Sec. 14, SE¼	160
Sec. 17, E½NE¼, SW¼NE¼, SE¼NW¼, N½SW¼, SE¼SW¼	280
Sec. 18, Lot 2, E½NE¼, SE¼NW¼, SE¼SE¼	183.84
Sec. 19, Lots 1 thru 4, NE¼, E½NW¼, E½SW¼, SW¼SE¼	459.68
Sec. 20, N½, S½SE¼	400
Sec. 21, S½NE¼, SE¼	240
Sec. 22, SE¼	160
Sec. 23, N½SE¼, SE¼SE¼	120
Sec. 24, N½NW¼, SW¼NW¼, W½SW¼, SE¼SW¼	240
Sec. 25, NW¼NE¼, N½NW¼, W½SE¼, SE¼SE¼	240
Sec. 26, NE¼NE¼	40
Sec. 27, W½NE¼	80
Sec. 28, NE¼, N½NW¼, SW¼SW¼	280
Sec. 29, N½NE¼, E½NW¼, S½	480
Sec. 30, Lots 1 thru 4, NE¼, E½NW¼, E½SW¼, W½SE¼	503.2
Sec. 34, NE¼NE¼	40
Sec. 35, SE¼NW¼, E½SW¼, SW¼SW¼, SE¼	320
T. 161 N., R 35 W.,	
Sec. 36, E½SE¼	80
T. 156 N., R 36 W.,	
Sec. 1, Lots 2 and 3	44.78
T. 158 N., R 36 W.,	
Sec. 3, SW¼NW¼	40
Sec. 5, SE¼SE¼	40
Sec. 8, NE¼NE¼	40
Sec. 10, S½SW¼, SE¼	240
Sec. 11, NW¼NE¼	40
Sec. 12, SW¼SW¼	40
Sec. 15, N½NW¼	80
Sec. 16, NE¼	160
Sec. 19, SW¼	160
Sec. 20, SW¼SE¼	40
Sec. 22, NW¼SE¼	40
Sec. 29, NE¼	160
Sec. 32, NE¼, E½SW¼, W½SE¼	320
Sec. 36, Lot 4, SW¼SE¼	75.92
T. 159 N., R 36 W.,	
Sec. 10, NE¼SW¼, NW¼SE¼	80
Sec. 11, SW¼NE¼, NW¼, E½SW¼, SE¼	440
Sec. 12, W½NE¼, NW¼, N½SW¼, SW¼SW¼	360
Sec. 13, SW¼NW¼, W½SW¼	120
Sec. 14, E½, N½SW¼	400
Sec. 23, N½NW¼	80
Sec. 36, S½NE¼, SE¼NW¼, NE¼SW¼, NW¼SE¼	200
T. 160 N., R 36 W.,	
Sec. 1, S½	320
Sec. 2, Lot 2, S½NE¼	113.86
Sec. 3, Lot 4, SW¼NW¼	72.2
Sec. 9, W½SE¼	80
Sec. 11, SE¼	160
Sec. 12, NE¼, SW¼, SE¼SE¼	360
Sec. 14, SE¼	160
Sec. 16, NW¼	160
Sec. 20, SE¼	160
Sec. 21, NW¼	160
Sec. 23, W½SE¼	80
Sec. 24, SE¼	160

FIFTH PRINCIPAL MERIDIAN, MINNESOTA—Continued

Sec. 25, NE¼, NE¼SW¼, N½SE¼, SE¼SE¼	320
Sec. 26, SE¼NE¼, SE¼NW¼, NE¼SE¼	120
Sec. 29, NE¼	160
Sec. 33, W½, SE¼	480
Sec. 35, NW¼	160
T. 155 N., R 37 W.,	
Sec. 16, S½NE¼	80
T. 157 N., R 37 W.,	
Sec. 20, SW¼	160
T. 158 N., R 37 W.,	
Sec. 2, SE¼SE¼	40
Sec. 4, Lot 1	50.94
Sec. 16, W½NE¼, E½NW¼	160
Sec. 20, SE¼	160
Sec. 21, W½NE¼, E½NW¼, SW¼	320
Sec. 27, NW¼	160
Sec. 28, E½SE¼	80
Sec. 29, NW¼	160
Sec. 30, N½SE¼, SE¼SE¼	120
Sec. 31, NE¼SE¼	40
Sec. 32, W½SW¼	80
Sec. 33, SE¼	160
T. 159 N., R 37 W.,	
Sec. 12, Lot 2, SW¼NE¼	79.99
T. 160 N., R 37 W.,	
Sec. 3, SE¼NW¼	40
Sec. 11, Lot 4	2.95
Sec. 13, SW¼	160
Sec. 15, NW¼	160
Sec. 16, E½NW¼, E½SW¼, SE¼	320
Sec. 18, SE¼NW¼, E½SE¼	120
Sec. 19, NE¼SW¼	40
Sec. 20, NE¼NE¼, W½SE¼	120
Sec. 21, N½NW¼, N½SW¼, SE¼SW¼, W½SE¼	280
Sec. 22, W½	320
Sec. 24, W½NW¼	80
Sec. 26, W½, SE¼	480
Sec. 27, NE¼	160
Sec. 29, N½NE¼, SW¼NE¼	120
Sec. 34, SE¼NW¼, NE¼SW¼	80
Sec. 35, NE¼	160
T. 157 N., R 38 W.,	
Sec. 14, NW¼	160
Sec. 16, SE¼NE¼, NE¼SE¼	80
T. 158 N., R 38 W.,	
Sec. 11, NE¼	160
Sec. 19, Lot 3, NE¼SW¼	77.78
Sec. 21, SE¼	160
Sec. 23, N½SW¼, SW¼SW¼	120
Sec. 31, E½SW¼	80
T. 159 N., R 38 W.,	
Sec. 7, NE¼NW¼, SE¼SW¼	80
Sec. 9, SE¼NE¼, NW¼SE¼	80
T. 159 N., R 39 W.,	
Sec. 10, W½NE¼, N½NW¼	160
Sec. 31, E½SE¼	80
T. 159 N., R 40 W.,	
Sec. 22, Lot 1	5.38
Sec. 27, S½SE¼	80
Sec. 36, NW¼NW¼	40
T. 155 N., R 41 W.,	
Sec. 16, NE¼SW¼, NW¼SE¼	80

The area described aggregates 59,625.01 acres, more or less.

Authority: 25 U.S.C. 461 *et seq.;* Notice of Order of Restoration, Red Lake Reservation, Minnesota, 10 FR 2448 (Mar. 2, 1945).

Janice M. Schneider,

Assistant Secretary, Land and Minerals Management.

Lawrence S. Roberts,

Principal Deputy Assistant Secretary, Indian Affairs.

[FR Doc. 2017–00556 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS09000 L16100000.DR0000 17X]

Notice of Availability of the Record of Decision for the Dominguez-Escalante National Conservation Area Resource Management Plan and Final Environmental Impact Statement, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) and Final Environmental Impact Statement for the Dominguez-Escalante National Conservation Area (NCA) located in Mesa, Delta and Montrose counties, Colorado. The Colorado State Director signed the ROD on January 9, 2017, 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 National Conservation Area Manager, Dominguez-Escalante National Conservation Area, Bureau of Land Management, 2815 H Road, Grand Junction, CO 81506; or online at *http://1.usa.gov/1qKkMVi.* Copies of the ROD/Approved RMP are also available for public inspection at the Grand Junction Field Office (see address above); Uncompahgre Field Office, 2465 South Townsend Avenue, Montrose, CO 81401; Mesa County Public Library Central Branch; Delta County Library Delta Branch; and Montrose Regional Library.

FOR FURTHER INFORMATION CONTACT: Collin Ewing, National Conservation Area Manager; telephone 970–244–3049; see Grand Junction address above; email *cewing@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual during normal business hours. The Service 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 Dominguez-Escalante NCA has worked cooperatively with the public, interest groups, stakeholders, cooperating agencies, tribes, the Dominguez-Escalante NCA Resource Advisory Council, the Environmental Protection

Agency, U.S. Forest Service, U.S. Fish and Wildlife Service, and neighboring BLM offices to develop the Approved RMP. The Approved RMP seeks to provide for the long-term conservation and protection of the ''unique and important values'' of the Dominguez-Escalante NCA identified in the area's enabling legislation: The Omnibus Public Land Management Act of 2009, Public Law 111–11 (Omnibus Act). These values include the ''geological, cultural, archaeological, paleontological, natural, scientific, recreational, wilderness, wildlife, riparian, historical, educational, and scenic resources of the public lands, as well as the water resources of area streams, based on seasonally available flows, that are necessary to support aquatic, riparian, and terrestrial species and communities.'' The Omnibus Act specified that these values be conserved and protected ''for the benefit and enjoyment of present and future generations.'' Furthermore, in recognition of the historic and current traditional use of the NCA for livestock grazing, the Omnibus Act specifically stated that the BLM ''shall issue and administer any grazing leases or permits in the Conservation Area in accordance with the laws (including regulations) applicable to the issuance and administration of such leases and permits on other land under the jurisdiction of the Bureau of Land Management.'' This RMP continues livestock grazing to meet land health standards in consideration of the other purposes of the NCA.

Management decisions outlined in the Approved RMP apply only to BLM-managed lands in the Dominguez-Escalante NCA (approximately 210,172 acres). The Approved RMP will replace management direction contained in the 1987 Grand Junction Resource Area RMP and 1989 Uncompahgre Basin RMP. The Approved RMP establishes goals, objectives, management actions and allowable uses for resources and land uses including, but not limited to: Air, soil, water, Wild and Scenic Rivers, upland and riparian vegetation, fish and wildlife, cultural and paleontological resources, visual resources, National Historic Trails, recreation, lands with wilderness characteristics, livestock grazing, forestry and realty.

The BLM initiated scoping for the RMP revision in 2010 and collected information and public input via public meetings in order to develop the Draft RMP/Environmental Impact Statement (EIS) released in May 2013. The BLM developed the Proposed Plan Alternative based upon the Draft Preferred Alternative and public comments on the Draft RMP/EIS.

The BLM published the Proposed RMP/Final EIS on July 1, 2016, and made it available for a 30-day public protest period. During the protest period for the Proposed RMP/Final EIS, the BLM received seven protests on a variety of issues. All protests were dismissed; however, the BLM made minor editorial modifications to the Approved RMP to provide further clarification of some of the decisions.

The BLM regulations also require a 60-day Governor's Consistency Review period for the Proposed RMP/Final EIS to ensure consistency with State government plans or policies. The Governor did not identify any inconsistencies with State government plans or policies.

The Approved RMP includes decisions that implement components of the land use plan. These implementation decisions are displayed and numbered in the Approved RMP. Implementation decisions are generally appealable to the Interior Board of Land Appeals under 43 CFR 4.410.

For example, the decisions identifying designated routes of travel are implementation decisions and are appealable under 43 CFR part 4. The route decisions are displayed as an attachment to Appendix N of the Approved RMP. Any party adversely affected by the proposed route identifications may appeal within 30 days of publication of this Notice of Availability pursuant to 43 CFR, part 4, subpart E. The appeal should state the specific route(s), as identified in Appendix N of the Approved RMP, on which the decision is being appealed. The appeal must be filed with the NCA Manager at the above listed address. Please consult the appropriate regulations (43 CFR, part 4, subpart E) for further appeal requirements.

Authority: 40 CFR 1506.6.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2017–00772 Filed 1–12–17; 8:45 am]

BILLING CODE 4130–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[17X.LLAZC03000.L12200000.EA0000; AZ–SRP–030–15–01]

Notice of Temporary Closures and Restrictions of Public Lands in La Paz County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that closures and restrictions will be in effect on public lands administered by the Bureau of Land Management (BLM), Lake Havasu Field Office. This action is being taken to protect public safety and resources within and adjacent to the permitted operations of the Best in the Desert (BITD) Racing Association ''GMZ Utility Terrain Vehicle Winter Nationals Parker 250'' and ''BlueWater Resort Parker 425'' off-highway vehicle (OHV) events.

DATES: The closures and restrictions will be in effect from 2 p.m., January 6, 2017, through 6 p.m., January 8, 2016, and 2 p.m., February 3, 2017, through 2 a.m., February 5, 2017, Mountain Standard Time.

FOR FURTHER INFORMATION CONTACT: Jonathan Azar, Colorado River District Chief Ranger, or Amanda Deeds, Assistant Field Manager, at BLM Lake Havasu Field Office, 2610 Sweetwater Avenue, Lake Havasu City, Arizona 86406, telephone 928–505–1200. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. This Service is available 24 hours a day, 7 days a week, to leave a message or question for the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The closures and restrictions are issued under the authority of 43 CFR 8364.1 which allows the BLM to establish closures for the protection of persons, property, and public lands and resources. Violation of any of the terms, conditions, or restrictions contained within this closure order may subject the violator to citation or arrest with a penalty or fine or imprisonment or both as specified by law.

Description of Race Course Closed Area: With the exception of access to designated spectator areas, areas subject to this closure include all public lands situated within the interior of the race course, as well as county-maintained roads and highways located within 2 miles of the designated course's perimeter. Beginning at the eastern boundary of the Colorado River Indian Tribe (CRIT) Reservation, the closed area runs east along Shea Road, then east into Osborne Wash on the Parker-Swansea Road to the Central Arizona Project (CAP) Canal. The closed area runs north on the west side of the CAP Canal, crossing the canal on the county-maintained road, running northeast into

Mineral Wash Canyon, then southeast on the county-maintained road, through the four-corners intersection to the Midway (Pit) intersection. From there, the course runs east on Transmission Pass Road, through State Trust Land located in Butler Valley, turning north into Cunningham Wash to North Tank then continues south to Transmission Pass Road and east (reentering public land) within 2 miles of Alamo Dam Road. The course turns south and west onto the wooden power line road, onto State Trust Land in Butler Valley, then turns southwest into Cunningham Wash to the Graham Well and intersects Butler Valley Road before heading north and west on the county-maintained road to the ''Bouse Y'' intersection, 2 miles north of Bouse, Arizona. The course proceeds north, paralleling the Bouse-Swansea Road to the Midway (Pit) intersection, then west along the north boundary (power line) road of the East Cactus Plain Wilderness Area to Parker-Swansea Road. The course turns west into Osborne Wash crossing the CAP Canal, along the north boundary of the Cactus Plain Wilderness Study Area; it continues west staying in Osborne Wash and crossing Shea Road along the southern boundary of Gibraltar Wilderness, rejoining Osborne Wash at the CRIT Reservation boundary.

Closure Restrictions: The following acts are prohibited during the closures:

1. Being present on or driving on the designated race course or the adjacent lands described above. The spectator areas are located on the south side of Shea Road and also at the Bouse ''Y'', at the intersection of Butler Valley Ranch Road and Swansea Road. All spectators must stay within the designated spectator areas as they have protective fencing and barriers. Emergency medical response shall only be conducted by personnel and vehicles operating under the guidance of the La Paz County Emergency Medical Services and Fire, the Arizona Department of Public Safety, or the BLM.

2. Vehicle parking or stopping in areas affected by the closures, except where such is specifically allowed (designated spectator areas).

3. Camping in the closed area described above, except in the designated spectator areas.

4. Discharge of firearms.

5. Possession or use of any fireworks.

6. Cutting or collecting firewood of any kind, including dead and down wood or other vegetative material.

7. Operating any vehicle, including all-terrain vehicles, motorcycles, utility terrain vehicles, golf carts, rhinos, side by sides, and any OHVs which are not legally registered for street and highway operations.

8. Operating any vehicle in the area of the closure or on roads within the event area at a speed of more than 35 mph. This does not apply to registered race vehicles during the race, while on the designated race course.

9. Failure to obey any official sign posted by the BLM, La Paz County, or the race promoter.

10. Parking any vehicle in violation of posted restrictions, or in such a manner as to obstruct or impede normal or emergency traffic movement or the parking of other vehicles, create a safety hazard, or endanger any person, property, or feature. Vehicles parked in violation are subject to citation, removal, and/or impoundment at the owner's expense.

11. Failure to obey any person authorized to direct traffic or control access to event area including law enforcement officers, BLM officials, and designated race officials.

12. Failure to observe spectator area quiet hours of 10 p.m. to 6 a.m.

13. Failure to keep campsite or race viewing site free of trash and litter.

14. Allowing any pet or other animal to be unrestrained. All pets must be restrained by a leash of not more than 6 feet in length.

15. Reserving sites within the spectator area. Spectators are prohibited from denying other visitors or parties the use of unoccupied portions of the spectator area.

Exceptions to Closure: The restrictions do not apply to emergency or law enforcement vehicles owned by the United States, the State of Arizona, or La Paz County; or designated race officials, participants and pit crews. All BITD registered media personnel are permitted access to existing routes 50 feet from the race course per BITD standards.

Penalties: Any person who violates these closures may be tried before a United States magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and 43 CFR 8360.0–7, or both. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Arizona law.

Effect of Closure: The entire area encompassed by the designated course and all areas outside the course as described above and in the time period as described above are closed to all vehicles. The authorized applicant or their representatives are required to post warning signs, control access to, and clearly mark the event route and areas, common access roads, and road crossings during the closure period. Support vehicles under permit for operation by event participants must follow the race permit stipulations.

Authority: 43 CFR 8364.1.

Jason West,

Field Manager.

[FR Doc. 2017–00771 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[17XL1109AF LLUT03000 L16100000.PH0000 241A]

Notice of Grand Staircase-Escalante National Monument Advisory Committee Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the Department of the Interior, Bureau of Land Management (BLM), Grand Staircase-Escalante National Monument Advisory Committee (GSENMAC) will meet as indicated below.

DATES: The GSENM–MAC will meet Thursday, February 2 (10 a.m.–6 p.m.) and Friday, February 3, 2017, (8:00 a.m.–1:00 p.m.) in Kanab, Utah.

ADDRESSES: The Committee will meet at the Bureau of Land Management Administrative Headquarters, located at 669 S. Highway 89A, Kanab, Utah.

FOR FURTHER INFORMATION CONTACT: Larry Crutchfield, Public Affairs Officer, Grand Staircase-Escalante National Monument, Bureau of Land Management, 669 South Highway 89A, Kanab, Utah, 84741; phone (435) 644–1209.

SUPPLEMENTARY INFORMATION: The 15-member GSENM–MAC was appointed by the Secretary of Interior on January 23, 2016, pursuant to the Monument Management Plan, the Federal Land Policy and Management Act of 1976 (FLPMA), and the Federal Advisory Committee Act of 1972 (FACA). As specified the Committee charter, the GSENM–MAC may be requested to: (1) Gather and analyze information, conduct studies and field examinations, seek public input or ascertain facts to develop recommendations concerning the use and management of the Monument; (2) review programmatic documents including the annual Monument Manager's Reports, and

Monument Science Plans to provide recommendations on the achievement of the Management Plan objectives; (3) Compile monitoring data and assess and advise the DFO of the extent to which the Plan objectives are being met; (4) Make recommendations on Monument protocols and applicable planning projects to achieve the overall objectives are being met; (5) Review appropriate research proposals and make recommendations on project necessity and validity; (6) Make recommendations regarding allocation of research funds through review of research and project proposals as well as needs identified through the evaluation process; (7) Consult and make recommendations on issues such as protocols for specific projects, *e.g.,* vegetation restoration methods or standards for excavation and curation of artifacts and objects; and/or (8) Prepare an annual report summarizing the Committee's activities and accomplishments of the past year, and make recommendations for future needs and activities.

Topics to be discussed by the GSENM–MAC during this meeting include the ongoing Livestock Grazing Management Plan Amendment and Associated Environmental Impact Statement (LGMPA/AEIS); the Skutumpah Terrace Greater Sage-Grouse Habitat Restoration Project; GSENM division briefs, a tour of the GSENM Paleontology Lab and off-site tour of dinosaur track site; future meeting dates and other matters as may reasonably come before the GSENMAC.

The entire meeting is open to the public. Members of the public are welcome to address the Committee at 5:00 p.m., local time, on Feb. 2, 2017; and at 12:00 p.m., local time, on Feb. 3, 2017. Depending on the number of persons wishing to speak, a time limit could be established. Interested persons may make oral statements to the GSENM–MAC during this time or written statements may be submitted for the GSENM–MAC's consideration. Written statements can be sent to: Grand Staircase-Escalante National Monument, Attn.: Larry Crutchfield, 669 South Highway 89A, Kanab, Utah, 84741. Information to be distributed to the GSENM–MAC is requested 10 days prior to the start of the GSENM–MAC meeting.

All meetings are open to the public; however, transportation, lodging, and meals are the responsibility of the participating public.

Gary Torres,

Acting State Director.

[FR Doc. 2017–00657 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORV00000. L10200000. DF0000. LXSSH1040000. 17XL1109AF. HAG 17–0057]

Notice of Public Meetings for the John Day-Snake Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the John Day-Snake Resource Advisory Council (RAC) will meet as indicated below.

DATES: The John Day-Snake RAC will hold a meeting Thursday and Friday, January 26 and 27, 2017. The meeting will be held at the TownePlace Suites in Bend, Oregon. The meeting will run from noon to 5 p.m. on January 26, and from 8 a.m. to noon on January 27.

FOR FURTHER INFORMATION CONTACT: Lisa Clark, Public Affairs Specialist, BLM Prineville District Office, 3050 NE. 3rd Street, Prineville, OR 97754, phone 541–473–6218, or email *lmclark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1(800) 877–8339 to contact the above individual during normal business hours. The service 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 John Day-Snake RAC consists of 15 members, chartered and appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, conservation, and general interests. They provide advice to BLM and Forest Service resource managers regarding management plans and proposed resource actions on public land in central and eastern Oregon. Agenda items for the meeting include a discussion on fees associated with the Deschutes River, recruitment of a grazing representative, and discussion about forming a Snake River collaborative group.

All meetings are open to the public. Information to be distributed to the John Day-Snake RAC is requested prior to the start of each meeting. A public comment period will be offered on January 27, 2017, from 10:30 a.m. to 11 a.m. Unless otherwise approved by the John Day-Snake RAC Chairs, the public comment period will last no longer than 30 minutes. Each speaker may address the John Day-Snake RAC for a maximum of five minutes. The public may call in at 866–650–5651 and listen to the meeting and participate during public comment by using participant code: 3696961.

Meeting times and the duration scheduled for public comment periods may be extended or altered when the authorized representative considers it necessary to accommodate business and all who seek to be heard regarding matters before the John Day-Snake RAC.

Shane DeForest,

Acting Vale District Manager.

[FR Doc. 2017–00661 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORV00000.L10200000.DF0000. LXSSH1050000.17XL1109AF.HAG 17–0058]

Notice of Public Meeting For the Southeast Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, and the U.S. Department of the Interior, Bureau of Land Management (BLM), the Southeast Oregon Resource Advisory Council (RAC) will meet as indicated below:

DATES: The RAC will hold a public meeting Monday and Tuesday, January 30 and 31, 2017. The meeting on January 30th will begin at 12:00 p.m. and end at 5:00 p.m. The meeting on January 31st will begin at 8:00 a.m. and end at 12:00 p.m. The agenda will be released online at *http://www.blm.gov/or/rac/seorrac.php* prior to the meeting. Tentative agenda items for the meeting include updates on the Tri-State Fuels Project, Lands with Wilderness Characteristics. Any other matters that may reasonably come before the RAC may also be addressed. A public comment period will be available during the meeting at a time to be determined. Unless otherwise approved by the RAC Chair, the public comment period will last no longer than 30 minutes, and each speaker may address the RAC for a maximum of 5 minutes. Meeting times and the duration scheduled for public comment periods may be extended or altered when the authorized representative considers it

necessary to accommodate necessary business and all who seek to be heard regarding matters before the RAC.

ADDRESSES: The meeting will be held at the Burns BLM offices, 28910 Highway 20, West Hines, OR 97738. The telephone conference line number for the meeting is 1–866–524–6456, Participant Code: 608605.

FOR FURTHER INFORMATION CONTACT: Larisa Bogardus, Public Affairs Specialist, BLM Lakeview District Office, 1301 S G Street, Lakeview, Oregon 97630, (541) 947–6237 or *lbogardus@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1(800) 877–8339 to contact the above individual during normal business hours. The service is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This RAC consists of 15 members chartered and appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, conservation, and general interests. They provide advice to BLM and Forest Service resource managers regarding management plans and proposed resource actions on public land in southeast Oregon. This meeting is open to the public in its entirety. Information to be distributed to the RAC is requested prior to the start of each meeting.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Shane DeForest,

Acting Vale District Manager.

[FR Doc. 2017–00659 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK930000.L13100000.PP0000]

Renewal of Approved Information Collection; OMB Control No. 1004–0196

AGENCY: Bureau of Land Management, Interior.

ACTION: 60-Day notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act, the Bureau of Land Management (BLM) invites public comments on, and plans to request approval to continue, the collection of information from participants in the oil and gas leasing program within the National Petroleum Reserve—Alaska (NPRA). The Office of Management and Budget (OMB) has assigned control number 1004–0196 to this information collection.

DATES: Please submit comments on the proposed information collection by March 14, 2017.

ADDRESSES: Comments may be submitted by mail, fax, or electronic mail.

Mail: U.S. Department of the Interior, Bureau of Land Management, 1849 C Street, NW., Room 2134LM, Attention: Jean Sonneman, Washington, DC 20240.

Fax: to Jean Sonneman at 202–245–0050.

Electronic mail: Jean_Sonneman@blm.gov.

Please indicate ''Attn: 1004–0196'' regardless of the form of your comments.

FOR FURTHER INFORMATION CONTACT: Wayne Svejnoha at 907–271–4407. Persons who use a telecommunication device for the deaf may call the Federal Relay Service at 1–800–877–8339 to leave a message for Mr. Svejnoha.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act, 44 U.S.C. 3501–3521, require that interested members of the public and affected agencies be given an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8 (d) and 1320.12(a)). This notice identifies an information collection that the BLM plans to submit to OMB for approval. The Paperwork Reduction Act 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.

The BLM will request a 3-year term of approval for this information collection activity. Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany our submission of the information collection requests to OMB.

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.

The following information is provided for the information collection:

Title: Oil and Gas Leasing: National Petroleum Reserve—Alaska.

OMB Control Number: 1004–0196.

Summary: This control number applies to the National Petroleum Reserve—Alaska (NPRA). In accordance with the Naval Petroleum Reserve Production Act (42 U.S.C. 6501–6508) and regulations at 43 CFR part 3130, the BLM may authorize participation in an NPRA unit agreement. Participants in such an agreement are required to comply with routine data submissions that are used to document drilling and production and ensure compliance with the unit agreement, lease terms, regulations, Onshore Oil and Gas Orders, Notices to Lessees, lease stipulations, or conditions of approval. In addition, participants in such an agreement may apply for reduction of royalty, suspension of operations or production, or a subsurface storage agreement.

Frequency of Collection: On occasion.

Forms: None.

Description of Respondents: Participants in the oil and gas leasing program within the NPRA.

Estimated Annual Responses: 21.

Estimated Annual Burden Hours: 218 hours.

Estimated Annual Non-Hour Costs: None.

The estimated burdens are itemized in the following table:

Type of response A.	Number of responses B.	Time per response C.	Total time (Column B × Column C) D.
Royalty reduction (43 CFR 3133.4)	1	16 hours	16 hours.
Suspension of operations (43 CFR 3135.3)	1	4 hours	4 hours.
Notification of operations (43 CFR 3135.6)	2	15 minutes	30 minutes.
Unit designation (43 CFR 3137.21 and 3137.23)	1	80 hours	80 hours.
Notification of unit approval (43 CFR 3137.25)	1	1 hour	1 hour.
Certification for modification (43 CFR 3137.52)	1	4 hours	4 hours.
Acceptable bonding (43 CFR 3137.60)	1	30 minutes	30 minutes.
Change of unit operator (43 CFR 3137.61)	1	1 hour	1 hour.
Certification of unit obligation (43 CFR 3137.70)	1	2 hours	2 hours.
Certification of continuing development (43 CFR 3137.71)	1	2 hours	2 hours.
Productivity for a participating area (43 CFR 3137.84)	1	12 hours	12 hours.
Unleased tracts (43 CFR 3137.87)	1	3 hours	3 hours.
Notification of productivity (43 CFR 3137.88)	1	30 minutes	30 minutes.
Notification of productivity for non-unit well (43 CFR 3137.91)	1	30 minutes	30 minutes.
Production information (43 CFR 3137.92)	1	1 hour	1 hour.
Lease extension (43 CFR 3137.111)	1	3 hours	3 hours.
Inability to conduct operations activities (43 CFR 3137.112)	1	2 hours	2 hours.
Unit termination (43 CFR 3137.130)	1	1 hour	1 hour.
Impact mitigation (43 CFR 3137.135)	1	4 hours	4 hours.
Storage agreement (43 CFR 3138.11)	1	80 hours	80 hours.
Totals	21		218 hours.

Mark Purdy,

Bureau of Land Management, Management Analyst.

[FR Doc. 2017–00759 Filed 1–12–17; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR936000.L14400000.ET0000. 16XL1109AF; OR68370]

Public Land Order No. 7859; Withdrawal of National Forest System and Bureau of Land Management Public Lands in Southwestern Oregon; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws, subject to valid existing rights, approximately 5,216.18 acres of public domain and Revested Oregon and California Railroad lands and 95,805.53 acres of National Forest System lands from settlement, sale, location, and entry under the public land laws; location and entry under the United States mining laws; and operation of the mineral and geothermal leasing laws for a period of 20 years while Congress considers legislation to permanently withdraw those areas and to protect the Southwestern Oregon watershed from possible adverse effects of mineral development.

DATES: This Public Land Order is effective on December 30, 2016.

FOR FURTHER INFORMATION CONTACT: Jacob Childers, Land Law Examiner, at 503–808–6225, Bureau of Land Management, Oregon/Washington State Office, P.O. Box 2965, Portland, Oregon 97208–2965. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FIRS) at 1–800–877–8339 to reach the above individual. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The purpose of this order is to protect the lands while Congress considers legislation to permanently withdraw those areas and to protect the Southwestern Oregon watershed from possible adverse effects of mineral development.

Order

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714, it is ordered as follows:

1. Subject to valid existing rights, the following described public domain, Revested Oregon and California Railroad lands, and National Forest System lands, are hereby withdrawn from settlement, sale, location, and entry under the public land laws, location and entry under the United States mining laws, and operation of the mineral and geothermal leasing laws while Congress considers legislation to permanently withdraw those areas and to protect the Southwestern Oregon watershed from possible adverse effects of mineral development.

Willamette Meridian

Public Lands

T. 36 S., R. 14 W.,
Sec. 24, E½SE¼;
Sec. 25, SE¼SE¼.
T. 37 S., R. 14 W.,
Sec. 1, lots 1 thru 4, inclusive, S½N½, N½SW¼, SE¼SW¼, and SE¼;
Sec. 2, lots 1 and 2, S½NE¼, and E½SE¼;
Sec. 11, E½;
Sec. 12, E½, E½NW¼, NE¼SW¼, and S½SW¼;
Sec. 13, N½N½ and SE¼;
Sec. 14, NE¼NE¼ and SE¼NW¼;
Sec. 23, SE¼NE¼;
Sec. 24, NE¼NE¼, S½NE¼, NW¼NW¼, S½NW¼, and S½.
T. 40 S., R. 8 W.,
Sec. 18, SW¼NE¼NE¼, W½NE¼, SE¼NE¼, W½, and W½SE¼;
Sec. 19, NW¼NE¼;
Sec. 20, NW¼NW¼.
T. 41 S., R. 9 W.,
Sec. 3, lots 2, 3, and 4, and S½NW¼;
Sec. 9.

The areas described aggregate 4,235.61 acres in Josephine and Curry Counties.

Revested Oregon and California Railroad Lands

T. 39 S., R. 8 W.,
Sec. 31, un-numbered lots in the W½NW¼ and W½SW¼, E½NW¼, and NE¼SW¼.
T. 40 S., R. 8 W.,
Sec. 7, lots 1 and 2, E½SW¼, SW¼SW¼, and SW¼SE¼;
Sec. 17, W½NE¼, SE¼NE¼, W½, and NW¼SE¼.

The areas described aggregate 980.57 acres in Josephine and Curry Counties.

National Forest System Lands

Siskiyou National Forest

T. 36 S., R. 13 W.,
Sec. 19, lots 2 thru 6, lots 12, 13, 15, and 16;
Sec. 20, SW¼NE¼, NW¼, and SW¼SE¼;
Sec. 21, E½ and SE¼SW¼;
Sec. 29, NW¼;
Secs. 30 and 31;
Protraction Blocks 43 thru 46.
T. 37 S., R. 13 W.,
Secs. 8, 9, 10, 16, 17, 20, 21, 28, and 29;
Protraction Blocks 39 thru 51.
T. 38 S., R. 13 W.,
Sec. 5, SW¼;
Sec. 6, lots 1 thru 7, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 7, lots 1, 2, 3, and 5, NE¼, E½NW¼, NE¼SW¼, NE¼SW¼SW¼, NE¼SE¼SW¼, and SE¼SE¼SW¼;
Sec. 8, N½.
T. 39 S., R. 9 W.,
Sec. 19;
Sec. 20, SW¼NE¼, NW¼, SW¼, and W½SE¼;
Secs. 29 thru 32;
Sec. 35, NE¼NE¼, S½NE¼, SW¼, and SE¼.
T. 39 S., R. 10 W.,
Protraction Block 46.
T. 40 S., R. 9 W.,
Sec. 1, un-numbered lots in the N½NE¼ and N½NW¼, SW¼NE¼, S½NW¼, SW¼, and W½SE¼;
Sec. 2, lots 1 thru 7, SW¼NE¼, S½NW¼, SW¼, and W½SE¼;
Sec. 3, lots 1 and 2, S½NE¼, S½NW¼, and S½;
Sec. 4, S½NE¼, S½NW¼, and S½;
Sec. 5, lots 2, 3, and 4, S½NE¼, S½NW¼, and S½;
Secs. 6 thru 11;
Sec. 13, NE¼, S½NE¼NW¼, S½NW¼, and S½;
Sec. 14, NE¼, N½NW¼, N½SW¼NW¼, SE¼SW¼NW¼, SE¼NW¼, N½NE¼SW¼, SW¼NW¼SW¼, SW¼SW¼, N½SE¼, and SE¼SE¼;
Secs. 15 thru 22;
Sec. 23, W½NE¼NW¼, W½NW¼, NW¼SE¼NW¼, and W½SW¼;
Secs. 27 thru 33;
Sec. 34, lots 1 thru 8, N½NE¼, SW¼NE¼, and NW¼SE¼.
T. 40 S., R. 10 W.,
Sec. 2, lot 1, SW¼NE¼, SE¼SW¼, E½SE¼, and SW¼SE¼;
Sec. 3, SW¼SW¼;
Sec. 4, SE¼SE¼;
Sec 8, SE¼;
Sec. 9, NE¼, S½NW¼, and S½;
Sec. 10;
Sec. 11, NE¼, E½NW¼, S½NW¼NW¼, S½NW¼, SW¼, and SE¼;
Secs. 14, 15, and 16;
Sec. 17, E½NE¼, SW¼NE¼, E½SW¼, SW¼SW¼, and SE¼;
Sec. 19, S½NE¼NE¼, S½NE¼, E½SW¼, and SE¼;
Secs. 20 thru 23, and 26 thru 30;
Protraction Blocks 37 thru 47.
T. 40 S., R. 11 W.,
Sec. 4, lots 3 and 4, and SW¼NW¼;
Secs. 5 and 8;
Sec. 9, SW¼NW¼, W½SW¼, SE¼SW¼ and SW¼SE¼;
Sec. 16;
Sec. 17, E½NE¼, NE¼SE¼, SE¼SW¼, and S½SE¼;
Sec. 20, E½, E½NW¼, and SW¼;
Sec. 21;
Sec. 27, W½;
Sec. 28;
Sec. 29, NE¼, NE¼NW¼, N½SE¼, and SE¼SE¼;
Protraction Blocks 39, 40, 41, and 43.
T. 41 S., R. 9 W.,
Secs, 4 thru 8;
Secs 17 and 18.
T. 41 S, R. 10 W.,
Secs. 1 thru 18.
T. 41 S., R. 11 W.,
Sec. 1;
Sec. 2, E½NE¼, SW¼NE¼, W½SW¼NW¼, W½NW¼SW¼, and SE¼;
Secs. 3 and 4;
Sec. 5, NE¼, E½SW¼, E½SW¼SW¼, and SE¼;
Sec. 8, E½, E½NW¼, E½NW¼NW¼, E½SW¼NW¼, E½NE¼SW¼, and E½SE¼SW¼;
Secs. 9 thru 15;
Sec. 17, lots 1 thru 4, NE¼, and N½S½;
Sec. 18, lots, 9, 10, 11, NE¼SW¼, and N½SE¼.
The areas described aggregate 95,805.53 acres in Josephine and Curry Counties.

2. The following described non-Federal lands are within the exterior boundaries of the Southwestern Oregon watershed. If title to these non-Federal lands is subsequently acquired by the United States, the lands will be subject to the terms and conditions of the withdrawal.

Willamette Meridian

T. 37 S., R. 14 W.,
Sec. 1, SW¼SW¼;
Sec. 12, W½NW¼ and NW¼SW¼;
Sec. 13, S½N½;
Sec. 24, NW¼NE¼ and NE¼NW¼.
T. 39 S., R. 9 W.,
Sec. 36.
T. 41 S., R. 11 W.,
Sec. 16.
The areas described aggregate 1,680 acres in Josephine and Curry Counties.

3. This withdrawal will expire 20 years from the effective date of this order, unless as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f), the Secretary determines that the withdrawal shall be extended.

Dated: December 30, 2016.

Janice M. Schneider,

Assistant Secretary—Land and Minerals Management.

[FR Doc. 2017–00770 Filed 1–12–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

National Park Service

[NPS–WASO–ANRSS–22067; PPWONRADE2, PMP00EI05.YP0000]

Draft Environmental Impact Statement/ Grizzly Bear Restoration Plan, North Cascades Ecosystem, Washington

AGENCY: Fish and Wildlife Service and National Park Service, Interior.

ACTION: Notice of availability for public comment.

SUMMARY: The Fish and Wildlife Service (FWS) and the National Park Service (NPS) announce the availability of the Grizzly Bear Restoration Plan (plan)/ Draft Environmental Impact Statement (DEIS) in the North Cascades Ecosystem (NCE), Washington. The plan/DEIS evaluates the impacts of a range of alternatives for restoring the grizzly bear to the United States (U.S.) portion of the NCE, a portion of its historical range.

DATES: All written comments on the plan/DEIS must be postmarked or submitted no later than March 14, 2017.

FOR FURTHER INFORMATION CONTACT: Please contact Denise Shultz, Public Information Officer, North Cascades National Park Service Complex at 360–854–7302, or Ann Froschauer, Public Affairs Supervisor, FWS Washington Fish and Wildlife Office at 360–753–4370. Information will be available for public review online at *http://parkplanning.nps.gov/grizzlydeis;* in the Office of the Superintendent, 810 State Route 20, Sedro-Woolley, WA 98284 (360–854–7200, telephone); and in the Washington Fish and Wildlife Office, 510 Desmond Dr. SE., Suite 102, Lacey, WA 98503 (360–753–9440).

SUPPLEMENTARY INFORMATION: The purpose of this plan/DEIS is to determine how to restore the grizzly bear to the NCE, a portion of its historical range. Action is needed at this time to:

- Avoid the permanent loss of grizzly bears in the NCE;
- Contribute to the restoration of biodiversity of the ecosystem for the benefit and enjoyment of present and future generations of people;
- Enhance the probability of long-term survival of grizzly bears in the NCE and thereby contribute to overall grizzly bear recovery; and
- Support the recovery of the grizzly bear to the point where it can be removed from the Federal List of Endangered and Threatened Wildlife.

This plan/DEIS evaluates the impacts of the no-action alternative (Alternative

A) and three action alternatives (Alternatives B, C, and D).

Alternative A would continue existing management practices and assume no new management actions would be implemented beyond those available at the outset of the grizzly bear restoration planning process. Under Alternative A, grizzly bears would not be translocated into the NCE.

The action alternatives include capturing grizzly bears from outside the NCE and releasing them into the NCE for a period of time that is dependent on the particular alternative. The lead agencies would focus on translocating grizzly bears from areas that are ecologically similar to potential release sites. This may include grizzly bears from British Columbia, Canada, or the Northern Continental Divide ecosystem. All of the action alternatives include the replacement of translocated bears in the NCE which are lost from the population due to mortality or emigration during the period of initial releases.

The option to designate the NCE grizzly bear population as an experimental population under section 10(j) of the Endangered Species Act could be applied to any of the action alternatives. The DEIS will assess the potential impacts associated with designating, or not designating, an experimental population under each action alternative; therefore, the DEIS will serve as our National Environmental Policy Act analysis for the proposed restoration effort and any 10(j) experimental population rule.

Alternative B would involve an initial release of up to 10 grizzly bears followed by a period of monitoring in which additional releases would not occur. The alternative would then either repeat the initial release or default to alternative C as described below. At the conclusion of the initial release, there would be a period of adaptive management where additional bears could be released based on a number of factors including human-caused sources of mortality, genetic limitations, population trends, and the adjustment of the sex ratio.

Alternative C would involve the yearly release of up to 5 grizzly bears for a 5 to 10-year period to achieve an initial population of 25 grizzly bears. At the conclusion of these releases, there would be an adaptive management period where additional grizzly bears could be released based on a number of factors including human-caused sources of mortality, genetic limitations, population trends, and the adjustment of the sex ratio.

Alternative D would involve the yearly release of the maximum number of grizzly bears available for capture (anticipated to be 5 to 7 bears) until the minimum population estimate in the NCE reaches 200 grizzly bears.

The U.S. Forest Service and the Washington Department of Fish and Wildlife are cooperating agencies on this plan/DEIS.

Public Participation: After the Environmental Protection Agency Notice of Availability is published, the FWS and NPS will schedule public meetings to be held during the comment period throughout the NCE. Dates, times, and locations of these meetings will be announced in press releases and on the NPS Planning, Environment, and Public Comment Web site for the plan/DEIS at *http://parkplanning.nps.gov/grizzlydeis.*

How to Comment: You are encouraged to comment on the plan/DEIS online at *http://parkplanning.nps.gov/grizzlydeis.* You may also mail or hand-deliver your comments to the Superintendent, North Cascades National Park Service Complex, 810 State Route 20, Sedro-Woolley, WA 98284. Written comments will also be accepted during scheduled public meetings discussed above. Comments will not be accepted by fax, email, or by any method other than those specified above. Bulk comments in any format (hard copy or electronic) submitted on behalf of others will not be accepted. 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: December 13, 2016.

Jon Raby,

Acting Regional Director, Pacific Region, Fish and Wildlife Service.

Dated: December 19, 2016.

Laura E. Joss,

Regional Director, Pacific West Region, National Park Service.

[FR Doc. 2017–00616 Filed 1–12–17; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–340–E and 340–H (Fourth Review)]

Solid Urea From Russia and Ukraine; Termination of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission instituted the subject five-year reviews in November 2016 to determine whether revocation of the antidumping duty orders on solid urea from Russia and Ukraine would be likely to lead to continuation or recurrence of material injury. On December 30, 2016, the Department of Commerce published notice that it was revoking the orders effective December 20, 2016, because the domestic interested parties did not participate in its sunset reviews (81 FR 96434). Accordingly, the subject reviews are terminated.

DATES: *Effective Date:* January 9, 2017.

FOR FURTHER INFORMATION CONTACT: Drew Dushkes (202–205–3229), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. 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 (*https://www.usitc.gov*).

Authority: These reviews are being terminated under authority of title VII of the Tariff Act of 1930 and pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). This notice is published pursuant to section 207.69 of the Commission's rules (19 CFR 207.69).

By order of the Commission.

Issued: January 9, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–00638 Filed 1–12–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1035]

Certain Liquid Crystal Ewriters and Components Thereof; 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 December 8, 2016, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Kent Displays, Inc. of Kent, Ohio. 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 liquid crystal eWriters and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 7,351,506 (''the '506 patent'') and 8,947,604 (''the '604 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests 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 *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of the Secretary, Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

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 (2016).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on January 9, 2017, *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 liquid crystal eWriters and components thereof by reason of infringement of one or more of claims 1–5, 10, 11, 13–16, 18–23, 26, and 27 of the '506 patent and claims 1, 2, 9–11, 15–17, 21, and 22 of the '604 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) 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 complainant is: Kent Displays, Inc., 343 Portage Boulevard, Kent, OH 44240.

(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:

Shenzhen Howshow Technology Co., Ltd., d/b/a Shenzhen Howshare Technology Co., Ltd., d/b/a Howshare, Building 8, 2nd Floor, Fuyuan Industrial Zone, No. 28 Qiaotang Road, Fuyong Street, Baoan District, Shenzhen, China.

Shenzhen SUNstone Technology Co., Ltd., d/b/a iQbe, 3/F, Bldg. F, No. 1 Industry Park, Guanlong Village, Xili, Shenzhen, China.

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge. OUII will not participate as a party in this investigation.

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: January 9, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–00640 Filed 1–12–17; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–566 and 731–TA–1342 (Preliminary)]

Softwood Lumber Products From Canada; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of softwood lumber products from Canada, provided for in subheadings 4407.10.01, 4409.10.05, 4409.10.10, 4409.10.20, 4409.10.90, 4418.90.25, and may also be classified in subheadings 4415.20.40, 4415.20.80, 4418.90.46, 4421.90.70, 4421.90.94, and 4421.90.97 of the Harmonized Tariff Schedule of the United States, that are allegedly subsidized and sold in the United States at less than fair value (''LTFV'').[2]

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner Pinkert not participating.

published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On November 25, 2016, the Committee Overseeing Action for Lumber International Trade Investigations or Negotiations (the ''Coalition'') [3] filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV and subsidized imports of softwood lumber products from Canada and LTFV imports of softwood lumber products from Canada. Accordingly, effective November 25, 2016, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–566 and antidumping duty investigation No. 731–TA–1342 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of December 2, 2016 (81 FR 87069). The conference was held in Washington, DC, on December 16, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on January 9, 2017. The views of the Commission are contained in USITC Publication 4663 (January 2017), entitled *Softwood Lumber Products from Canada: Investigation Nos. 701–TA–566 and 731–TA–1342 (Preliminary).*

By order of the Commission.

Issued: January 9, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–00639 Filed 1–12–17; 8:45 am]

BILLING CODE 7020–02–P

[3] The Coalition is an ad hoc association whose members are: U.S. Lumber Coalition, Inc., Collum's Lumber Products, L.L.C., Hankins, Inc., Potlach Corp., Rex Lumber Company, Seneca Sawmill Company, Sierra Pacific Industries, Stimson Lumber Company, Swanson Group, Weyerhaeuser Company, Carpenters Industrial Council, Giustina Land and Timber Company, Sullivan Forestry Consultants, Inc.. The Coalition is ''an association, a majority of whose members is composed of interested parties'' described in Section 771(9)(C) of the Act, 19 U.S.C. 1677(9)(C).

DEPARTMENT OF JUSTICE

[OMB Number 1140–0012]

Agency Information Collection Activities; Proposed eCollection eComments Requested; [Notice of Firearms Manufactured or Imported (ATF Form 2 (5320.2)]

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-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. The proposed information collection was previously published in the **Federal Register** 81 FR 73140, on October 24, 2016, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until February 13, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Gary Schaible, Office of Enforcement Programs and Services, National Firearms Act Division, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) either by mail at 99 New York Ave. NE., Washington, DC 20226, by email at *nfaombcomments@atf.gov,* or by telephone 202 648–7165. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.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

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *The Title of the Form/Collection:* Notice of Firearms Manufactured or Imported.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 2 (5320.2).

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 ATF Form 2 (5320.2) is required of (1) a person who is qualified to manufacture National Firearms Act

(NFA) firearms, or (2) a person who is qualified to import NFA firearms to register manufactured or imported NFA firearm(s).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 4,552 respondents will utilize the form, and it will take each respondent 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 7,773 hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–00642 Filed 1–12–17; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On January 9, 2017, the Department of Justice lodged a proposed consent decree with the United States District Court for the Central District of California in the lawsuit entitled *United States* v. *Estate of Dorothy Medore,* Civil Action No. 5:17–cv–00029.

The consent decree would resolve claims against the Estate of Dorothy Medore under CERCLA § 107(a), 42 U.S.C. 9607(a), for recovery of response costs in connection with the Banaire Enterprises and Banaire Radium Trailers Superfund Sites in Cabazon, California (''Sites''). The Banaire Enterprises Site consists of two parcels located at 49800 Bonita Avenue and 14993 South Broadway. EPA found radioactive contamination at both parcels. The Banaire Radium Trailers Site is located at 4972 Main Street. Trailers on the property contained radioactive airplane parts and waste solvents. From September 2013 to April 2014, EPA performed a cleanup at both Sites. EPA's response costs through September 30, 2015, are $2,983,852.79. The United States alleges that the Medore Estate is liable for these costs because it is an owner of Site property.

The proposed Consent Decree with the Estate of Dorothy Medore would resolve the liability of the Estate by requiring the Estate to deposit an initial amount of $150,000 in an interest-bearing escrow account. Once the decree is entered, the amounts in escrow will be paid to the United States. The Estate also commits under the decree to inventory and appraise all remaining Estate property and to use best efforts to liquidate it. For real property, the Estate must provide EPA with notice of offers and EPA must approve the sale. If the Estate is not able to sell real property after using best efforts, the real property will be auctioned.

When all Estate property has been liquidated, and the proceeds placed in the Estate's bank account, the Estate will petition the California probate court for permission to distribute Net Proceeds to the United States in satisfaction of Past Response Costs. At least 30 days before filing the petition, the Estate will provide the United States with an accounting of the Estate's assets and its administration costs, including attorney's fees.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Estate of Dorothy Medore,* D.J. Ref. No. 90–11–3–10880. 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 proposed consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed 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 $4.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–00712 Filed 1–12–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On January 10, 2017, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Western District of Wisconsin in the lawsuit entitled *United States and the State of Wisconsin* v. *Northern States Power Co.,* Civil Action No. 17–cv–16.

In this action, the United States and the State of Wisconsin brought claims against Northern States Power Co. (''Defendant'') for response costs and injunctive relief associated with the release and threatened release of hazardous substances from facilities at and near the Ashland/Northern States Power Lakefront Superfund Site in northwestern Wisconsin (hereinafter the ''Site''), pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 *et seq.* (''CERCLA''). The proposed Consent Decree requires Defendant to perform the Chequamegon Bay portion of the Site cleanup at a cost of approximately $42 million. The Consent Decree also requires Defendant to pay $1 million of EPA's past response costs incurred at the Site and all EPA's future response costs. In addition, Defendant will be eligible for reimbursements totaling up to $4.5 million as it performs the work, drawing from a Site-specific special account funded by a prior settlement with other responsible parties. In return, the United States and the State agree not to sue Defendant under sections 106 and 107 of CERCLA or under section 7003 of the Resource Conservation and Recovery Act (''RCRA''). Pursuant to a prior consent decree, Defendant is also performing the on-land portion of the Site work. That consent decree was approved by the Court in the case named *United States and the State of Wisconsin* v. *Northern States Power Co.,* Civ. Action No. 12–cv–00565–bbc. If successfully completed, work under the two consent decrees will complete the cleanup at the Site.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Wisconsin* v. *Northern States Power Co.,* D.J. Ref. No. 90–11–2–08879/5. 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.

Under section 7003(d) of RCRA, a commenter may request an opportunity for a public meeting in the affected area. The United States and the State of Wisconsin have scheduled a public meeting for January 26 at 6:30 p.m. at the Northern Great Lakes Visitor Center, 29270 County Highway G, Ashland, WI 54806.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://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 $27.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–00718 Filed 1–12–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Comprehensive Environmental Response, Compensation, and Liability Act

On January 9, 2017, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Eastern District of Virginia in the lawsuit entitled *United States and Commonwealth of Virginia* v. *Persimmon Lane, LLC, a Virginia limited liability company,* Civil Action No. 1:17–cv–00017–CMH–IDD.

The Consent Decree resolves claims against Persimmon Lane, LLC (''Persimmon Lane'') arising under the Comprehensive Environmental Response, Compensation, and Liability Act relating to the Hidden Lane Landfill Superfund Site, located near the community of Sterling in Loudoun County, Virginia. Under the Consent Decree, Defendant will endeavor to sell the Site property and distribute the proceeds of any sale(s) according to a tiered breakdown between the United States, the Commonwealth of Virginia, and Persimmon Lane, LLC. The proposed Consent Decree will resolve all CERCLA claims alleged in this action by the United States against Defendant. Defendant has an inability to pay the United States' full demand.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and Commonwealth of Virginia* v. *Persimmon Lane, LLC, a Virginia limited liability company,* D.J. Ref. No. 90–11–3–10986. All comments must be submitted no later than 45 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: *https://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 $40.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $10.50.

Jeffrey Sands,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–00618 Filed 1–12–17; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Alan T. Waterman Award Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name: Alan T. Waterman Award Committee (#1172).

Date and Time: January 31, 2017; 9:30 a.m. to 2:30 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Room 1235, Arlington, Virginia 22230.

Type of Meeting: Closed.

Contact Person: Sherrie B. Green, Program Manager, Room 1270, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230; (703) 292–5053.

Purpose of Meeting: To provide advice and recommendations in the selection of the Alan T. Waterman Award recipient.

Agenda: To review and evaluate nominations as part of the selection process for awards.

Reason for Closing: The nominations being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries, and personal information concerning individuals associated with the nominations. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 10, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–00634 Filed 1–12–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name: Committee on Equal Opportunities in Science and

Engineering (CEOSE) Advisory Committee Meeting (# 1173).

Dates/Time: February 9, 2017, 1:00 p.m.–5:30 p.m.; February 10, 2017, 8:30 a.m.–3:30 p.m.

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

To help facilitate your entry into the building, please contact Vickie Fung (*vfung@nsf.gov*) on or prior to February 7, 2017.

Type of Meeting: Open.

Contact Person: Dr. Bernice Anderson, Senior Advisor and CEOSE Executive Secretary, Office of Integrative Activities (OIA), National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Contact Information: 703–292–8040/ *banderso@nsf.gov.*

Minutes: Meeting minutes and other information may be obtained from the CEOSE Executive Secretary at the above address or the Web site at: *http://www.nsf.gov/od/oia/activities/ceose/index.jsp.*

Purpose of Meeting: To study data, programs, policies, and other information pertinent to the National Science Foundation and to provide advice and recommendations concerning broadening participation in science and engineering.

Agenda:

- Opening Statement by the CEOSE Chair
- NSF Executive Liaison Report
- Presentation: NSF Big Idea—INCLUDES (Inclusion across the Nation of Communities of Learners of Underrepresented Discoverers in Engineering and Science)
- Presentation: NSF Big Idea—Navigating the New Arctic
- Working Sessions: Accountability Workshop/Workshop Report/2015–2016 CEOSE Biennial Report
- Discussion: Future Plans for CEOSE
- Discussion: CEOSE Liaisons and Federal Liaisons Reports
- Meeting with NSF Director

Dated: January 10, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–00705 Filed 1–12–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name: Advisory Committee for Mathematical and Physical Sciences (#66) (Virtual).

Date/Time: January 25, 2017; 1:00 p.m. to 2:00 p.m. EST.

Place: National Science Foundation 4201 Wilson Blvd., Arlington, VA 22230 (Virtual).

Information to join this virtual meeting to be posted on the committee's Web site at *https://www.nsf.gov/mps/advisory.jsp* .

Type of Meeting: Open.

Contact Person: John Gillaspy, National Science Foundation, 4201 Wilson Boulevard, Suite 1005, Arlington, Virginia 22230; Telephone: 703/292–8300.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to mathematical and physical sciences programs and activities.

Agenda

January 25, 2017; 1:00 p.m.–2:00 p.m. EST

1:00 p.m.–1:05 p.m. Meeting opening, FACA briefing

1:05 p.m.–2:00 p.m. Division of Mathematical Sciences (DMS) Committee of Visitor (COV)'s report

2:00 p.m. Adjourn

Dated: January 10, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–00633 Filed 1–12–17; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Cyberinfrastructure; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Cyberinfrastructure (25150)

Date and Time:

April 19, 2017; 1:00 p.m.–5:00 p.m.

April 20, 2017; 8:30 a.m.–5:00 p.m.

Place: National Science Foundation, 4201 Wilson Blvd., Stafford I—Room 1235, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Amy Friedlander, CISE, Division of Advanced Cyberinfrastructure, National Science Foundation, 4201 Wilson Blvd., Suite 1145, Arlington, VA 22230; Telephone: 703–292–8970.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To advise NSF on the impact of its policies, programs and activities in the ACI community. To provide advice to the Director/NSF on issues related to long-range planning.

Agenda: Updates on NSF wide ACI activities.

Dated: January 10, 2017.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2017–00635 Filed 1–12–17; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0001]

Sunshine Act Meeting Notice

DATE: January 16, 23, 30, February 6, 13, 20, 2017.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of January 16, 2017—Tentative

There are no meetings scheduled for the week of January 16, 2017.

Week of January 23, 2017—Tentative

Monday, January 23, 2017

10:00 a.m. Discussion of Management and Personnel Issues (Closed Ex. 2 & 6)

Week of January 30, 2017—Tentative

There are no meetings scheduled for the week of January 30, 2017.

Week of February 6, 2017—Tentative

There are no meetings scheduled for the week of February 6, 2017.

February 13, 2017—Tentative

Thursday, February 16, 2017

9:00 a.m. Briefing on Lessons Learned From the Fukushima Dai-ichi Accident (Public Meeting) (Contact: Andrew Proffitt: 301–415–1418)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Friday, February 17, 2017

9:30 a.m. Briefing on Project Aim (Public Meeting) (Contact: Tammy Bloomer: 301–415–1785)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of February 20, 2017—Tentative

There are no meetings scheduled for the week of February 20, 2017.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0981 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: January 11, 2017.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2017–00875 Filed 1–11–17; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–022 and 52–023; NRC–2013–0261]

Duke Energy Progress; Combined License Applications for Shearon Harris Nuclear Plant Units 2 and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to an October 13, 2016, letter from Duke Energy Progress (DEP). On May 2, 2013, DEP requested that the NRC suspend review of its combined license (COL) application until further notice. On October 13, 2016, DEP requested an exemption from certain regulatory requirements which, if granted, would allow them to revise their COL application for Shearon Harris Nuclear Plant (Harris) Units 2 and 3 in order to address enhancements to the Emergency Preparedness (EP) rules by December 31, 2019, rather than by December 31, 2016, as the regulations currently require. The NRC staff reviewed this request and determined that it is appropriate to grant the exemption to the EP update requirements until December 31, 2019, but stipulated that the updates to the Final Safety Analysis Report must be submitted prior to requesting the NRC resume its review of the COL application, or by December 31, 2019, whichever comes first.

DATES: The exemption is effective on January 13, 2017.

ADDRESSES: Please refer to Docket ID NRC–2013–0261 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0261. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced.
- *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.

FOR FURTHER INFORMATION CONTACT: Brian Hughes, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6582; email: *Brian.Hughes@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On February 18, 2008, DEP submitted to the NRC a COL application for two units of Westinghouse Electric Company's AP1000 advanced pressurized water reactors to be constructed and operated at the existing Shearon Harris Nuclear Plant (Harris) site (ADAMS Accession No. ML080580078). The NRC docketed the Harris Units 2 and 3 COL application (Docket Nos. 52–022 and 52–023) on April 23, 2008. On May 2, 2013 (ADAMS Accession No. ML13123A344), DEP requested that the NRC suspend review of the Harris Units 2 and 3 COL application. The NRC granted DEP's request for suspension and all review activities related to the Harris Units 2 and 3 COL application were suspended while the application remained docketed.

On July 29, 2013 (ADAMS Accession No. ML13212A361), DEP requested an exemption from the requirements in part 50, appendix E, Section I.5 of title 10 of the *Code of Federal Regulations* (10 CFR), as referenced by 10 CFR 52.79(a)(21), to submit an update to the COL application, addressing the enhancements to the EP rules by December 31, 2013, which the NRC granted through December 31, 2014. On August 1, 2014 (ADAMS Accession No. ML14216A432), DEP requested another exemption from the requirements of 10 CFR part 50, appendix E, Section I.5, as referenced by 10 CFR 52.79(a)(21), to submit an update to the COL application, addressing the enhancements to the EP rules by December 31, 2014, which the NRC granted through December 31, 2015. On August 12, 2015 (ADAMS Accession No. ML15226A352), DEP requested another exemption from the requirements of 10 CFR part 50, appendix E, Section I.5, as referenced by 10 CFR 52.79(a)(21), to submit an update to the COL application, addressing the enhancements to the EP rules by December 31, 2016. On October 13, 2016 (ADAMS Accession No. ML16288A816) DEP requested another exemption from the requirements of 10 CFR part 50, appendix E, Section I.5, as referenced by 10 CFR 52.79(a)(21), to submit annual updates to the COL application during the years 2016, 2017, and 2018, addressing the enhancements to the EP rules by December 31, 2019.

II. Request/Action

Part 50, appendix E, Section 1.5, requires that an applicant for a COL under Subpart C of 10 CFR part 52 whose application was docketed prior to December 23, 2011, must revise their

COL application to comply with the EP rules published in the **Federal Register** (76 FR 72560) on November 23, 2011. An applicant that does not receive a COL before December 31, 2013, shall revise its COL application to comply with these changes no later than December 31, 2013.

Since DEP will not hold a COL prior to December 31, 2013, it is therefore required to revise its application to be compliant with the new EP rules. Similar to an earlier exemption request it submitted, as described above, by letter dated October 13, 2016 (ADAMS Accession No. ML16288A815), DEP requested another exemption from the requirements of 10 CFR part 50, appendix E, Section I.5, to submit the required COL application revision to comply with the new EP rules. The requested exemption would allow DEP to revise its COL application, and comply with the new EP rules on or before December 31, 2019, rather than the initial December 31, 2013, date required by 10 CFR part 50, appendix E, Section I.5. The current requirement to comply with the new EP rule could not be changed, absent the exemption.

III. Discussion

Pursuant to 10 CFR 50.12(a), the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50, including 10 CFR part 50, appendix E, Section I.5, when: (1) The exemption(s) are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) special circumstances are present. As relevant to the requested exemption, special circumstances exist if: Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule (10 CFR 50.12(a)(2)(ii)).

Authorized by Law

The exemption is a one-time schedule exemption from the requirements of 10 CFR part 50, appendix E, Section I.5. The exemption would allow DEP to revise its COL application, and comply with the new EP rules on or before December 31, 2019, in lieu of the initial December 31, 2013, the date required by 10 CFR part 50, appendix E, Section I.5. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50 . The NRC staff has determined that granting DEP the requested one-time exemption from the requirements of 10 CFR part 50, appendix E, Section I.5 will not result in a violation of the Atomic Energy Act of 1954, as amended, or NRC's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of the enhancements to EP found in 10 CFR part 50, appendix E, is to amend certain EP requirements to enhance protective measures in the event of a radiological emergency; address, in part, enhancements identified after the terrorist events of September 11, 2001; clarify regulations to effect consistent Emergency Plan implementation among licensees; and modify certain requirements to be more effective and efficient. Since plant construction cannot proceed until the NRC review of the application is completed, a mandatory hearing is completed and a license is issued, the exemption does not increase the probability of postulated accidents. Additionally, based on the nature of the requested exemption as described above, no new accident precursors are created by the exemption; thus neither the probability, nor the consequences of postulated accidents are increased. Therefore, there is no undue risk to public health and safety.

Consistent With Common Defense and Security

The requested exemption would allow DEP to submit the revised COL application prior to requesting the NRC to resume the review and, in any event, on or before December 31, 2019. This schedule change has no relation to security issues. Therefore, the common defense and security is not impacted.

Special Circumstances

Special Circumstances, in accordance with 10 CFR 50.12(a)(2(ii) are present whenever: (1) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule (10 CFR 50.12(a)(ii); or (2) The exemption would only provide temporary relief from the applicable regulation or the applicant has made good faith efforts to comply with the regulation (10 CFR 50.12(a)(2)(v)).

The purpose of 10 CFR part 50, appendix E, Section I.5 is to ensure that applicants and new COL holders updated their COL applications or COLs to allow the NRC to review them efficiently and effectively, and to bring the applicants or licensees into compliance prior to receiving a license, or, for licensees, prior to operating the plant. If the NRC were to grant this exemption, and DEP were then required to update its application to comply with the EP rule enhancements by December 31, 2019, or prior to any request to restart their review, the purpose of the rule would still be achieved because the applicant will be required to make required updates to the emergency plan to facilitate NRC review of the application at the appropriate time. For this reason, the application of 10 CFR part 50, appendix E, Section I.5, for the suspended Harris 2 and 3 COL application is deemed unnecessary and, therefore, special circumstances are present.

Eligibility for Categorical Exclusion From Environmental Review

With respect to the exemption's impact on the quality of the human environment, the NRC has determined that this specific exemption request is eligible for categorical exclusion as identified in 10 CFR 51.22(c)(25) and justified by the NRC staff as follows:

The following categories of actions are categorical exclusions provided that:

(i) There is no significant hazards consideration;

The criteria for determining whether there is no significant hazards consideration are found in 10 CFR 50.92. The proposed action involves only a schedule change regarding the submission of an update to the application for which the licensing review has been suspended. Therefore, there are no significant hazards considerations because granting the proposed exemption would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;

The proposed action involves only a schedule change which is administrative in nature, and does not involve any changes to be made in the types or significant increase in the amounts of effluents that may be released offsite.

(iii) There is no significant increase in individual or cumulative public or occupational radiation exposure;

Since the proposed action involves only a schedule change which is administrative in nature, it does not

contribute to any significant increase in occupational or public radiation exposure.

(iv) There is no significant construction impact;

The proposed action involves only a schedule change which is administrative in nature; the application review is suspended until further notice, and there is no consideration of any construction at this time, and hence the proposed action does not involve any construction impact.

(v) There is no significant increase in the potential for or consequences from radiological accidents;

The proposed action involves only a schedule change which is administrative in nature, and does not impact the probability or consequences of accidents.

(vi) The requirements from which an exemption is sought involve:

(B) Reporting requirements;

The exemption request involves submitting an updated COL application by DEP

and

(G) Scheduling requirements;

The proposed exemption relates to the schedule for submitting a COL application update to the NRC.

IV. Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also special circumstances are present. Therefore, the Commission hereby grants DEP a one-time exemption from the requirements of 10 CFR part 50 Appendix E, Section I.5 pertaining to the Harris Units 2 and 3 COL application to allow submittal of the revised COL application that complies with the enhancements to the EP rules prior to any request to the NRC to resume the review, and in any event, no later than December 31, 2019.

Pursuant to 10 CFR 51.22, the Commission has determined that the exemption request meets the applicable categorical exclusion criteria set forth in 10 CFR 51.22(c)(25), and the granting of this exemption will not have a significant effect on the quality of the human environment.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 4th day of January 2017.

For The Nuclear Regulatory Commission.

Francis M. Akstulewicz,

Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–00685 Filed 1–12–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Southern Nuclear Operating Company, Inc., Vogtle Electric Generating Plant, Units 3 and 4; Debris Screen Related Dimensions

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment No. 63 to Combined Licenses (COL), NPF–91 and NPF–92. The COLs were issued to Southern Nuclear Operating Company, Inc., and Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC, MEAG Power SPVJ, LLC, MEAG Power SPVP, LLC, Authority of Georgia, and the City of Dalton, Georgia (the licensee); for construction and operation of the Vogtle Electric Generating Plant (VEGP) Units 3 and 4, located in Burke County, Georgia.

The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and amendment were issued on December 29, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0252. 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.
- *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. The request for the amendment and exemption was submitted by letter dated August 11, 2016 (ADAMS Accession No. ML16224B122).
- *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.

FOR FURTHER INFORMATION CONTACT: Ruth Reyes, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3249; email: *Ruth.Reyes@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from Paragraph B of Section III, ''Scope and Contents,'' of appendix D, ''Design Certification Rule for the AP1000,'' to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment No. 63 to COLs, NP–91 and NPF–92, to the licensee. The exemption is required by Paragraph A.4 of Section VIII, ''Processes for Changes and Departures,'' appendix D, to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes that would revise the Updated Final Safety Analysis Report in the form of departures from the incorporated plant-specific DCD Tier 2 information. The proposed amendment also involves related changes to plant-specific Tier 1 information, with corresponding changes to the associated COL Appendix C information. The proposed changes are to information identifying the frontal face area and screen surface area for the In-Containment Refueling Water Storage Tank (IRWST) screens, the location and dimensions of the protective plate located above the containment recirculation (CR) screens, and increasing the maximum Normal

Residual Heat Removal System flowrate through the IRWST and CR screens.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and Section VIII.A.4 of appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML16307A355.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to the licensee for VEGP Units 3 and 4 (COLs NPF–91 and NPF–92). The exemption documents for VEGP Units 3 and 4 can be found in ADAMS under Accession Nos. ML16307A281 and ML16307A302, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–91 and NPF–92 are available in ADAMS under Accession Nos. ML16307A274 and ML16307A276, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to Vogtle Unit 3 and Unit 4. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated August 11, 2016, the licensee requested from the Commission an exemption to allow departures from Tier 1 information in the certified DCD incorporated by reference in 10 CFR part 52, appendix D, as part of License Amendment Request 16–013, ''Debris Screen Related Dimensions.''

For the reasons set forth in Section 3.1 of the NRC staff's Safety Evaluation, which can be found at ADAMS Accession No. ML16307A355, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1 information, with corresponding changes to Appendix C of the Facility COLs as described in the licensee's request dated August 11, 2016. This exemption is related to, and necessary for, the granting of License Amendment No. 63, which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's Safety Evaluation this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated August 11, 2016, the licensee requested that the NRC amend the COLs for VEGP, Units 3 and 4, COLs NPF–91 and NPF–92. The proposed amendment is described in Section I of this **Federal Register** notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on September 27, 2016 (81 FR 66308). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on August 11, 2016.

The exemption and amendment were issued on December 29, 2016, as part of a combined package to the licensee (ADAMS Accession No. ML16307A260).

Dated at Rockville, Maryland, this 3rd day of January 2017.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–00683 Filed 1–12–17; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79763; File No. SR–DTC–2016–802]

Self-Regulatory Organizations; The Depository Trust Company; Notice of No Objection To Advance Notice Filing Relating To Processing of Transactions in Money Market Instruments

January 9, 2017.

The Depository Trust Company (''DTC'') filed with the Securities and Exchange Commission (''Commission'') on September 23, 2016 advance notice SR–DTC–2016–802 (''Advance Notice'') pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Payment, Clearing and Settlement Supervision Act'') [1] and Rule 19b–4(n)(1)(i) [2] under the Securities Exchange Act of 1934 (''Exchange Act'') to establish a change in the processing of transactions in money market instruments (''MMI'').[3]

[1] 12 U.S.C. 5465(e)(1). The Financial Stability Oversight Council designated DTC a systemically important financial market utility on July 18, 2012. *See* Financial Stability Oversight Council 2012 Annual Report, Appendix A, *http://www.treasury.gov/initiatives/fsoc/Documents/2012%20Annual%20Report.pdf.* Therefore, DTC is required to comply with the Payment, Clearing and Settlement Supervision Act and file advance notices with the Commission. *See* 12 U.S.C. 5465(e).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] MMI are short-term debt securities issued by financial institutions, large corporations, or state and local governments that generally mature 1 to 270 days from their original issuance date, and include, but are not limited to, commercial paper, banker's acceptances, and short-term bank notes. Most MMI trade in large denominations (typically, $250,000 to $50 million) and are purchased by institutional investors.

The Advance Notice was published for comment in the **Federal Register** on November 9, 2016.[4] The Commission did not receive any comments on the Advance Notice. This publication serves as notice of no objection to the Advance Notice.

I. Description of the Advance Notice

The Advance Notice is a proposal by DTC to modify (i) the DTC Rules, By-laws and Organization Certificate (''Rules''),[5] (ii) the DTC Settlement Service Guide (''Settlement Guide''),[6] and (iii) the DTC Distributions Service Guide (''Distributions Guide''),[7] to change the way in which DTC processes transactions in money market instruments (''MMI''). The proposal would affect DTC's processing of issuances of MMI securities as well as maturity presentments, income presentments, principal presentments, and reorganization presentments (collectively, ''presentments'' and with issuances of MMI securities, ''MMI Obligations'').

Specifically, DTC proposes to: (i) With respect to delivery of MMI securities, require purchasers of the securities (or their custodian, if applicable) to acknowledge that they agree to receive the securities via DTC's Receiver Authorized Delivery (''RAD'') system before DTC processes the transaction; (ii) with respect to cash, require an issuing and paying agent (''IPA'') of an MMI issuer to acknowledge its funding obligations for MMI presentments before DTC processes the transaction, except in limited circumstances where there are no funding obligations;[8] (iii) implement an enhanced process to check certain MMI transactions against DTC's risk management controls (referred to as ''MMI Optimization''); (iv) eliminate the largest provisional net credit risk management control; and (v) eliminate DTC's receive versus payment net additions control, as described below. In addition, the proposal would amend DTC's Distributions Guide to conform to the proposed changes.

A. Background

Today, according to DTC, when an issuer issues MMI securities at DTC, the IPA for that issuer sends issuance instructions to DTC electronically, which results in crediting the applicable MMI securities to the DTC account of the IPA. The MMI securities are then delivered by DTC to the accounts of the applicable DTC participants (''Participants'') that are purchasing the issuance, typically as custodians for individual investors, in accordance with their purchase amounts. The IPA's delivery instructions may be free of payment or, most often, for payment (*i.e.,* delivery versus payment or ''DVP''). Unlike deliveries free of payment, DVP transactions are subject to DTC's risk management controls for both the IPA and the receiving Participants, which means they are monitored for Net Debit Cap and Collateral Monitor sufficiency.[9]

When MMI securities of a particular acronym[10] mature, the current presentment process involves DTC automatically sweeping the matured positions from the applicable Participant accounts and debiting the settlement account of the applicable IPA for the amount of the matured position, with corresponding credits made to the settlement accounts of the deliverers. Because presentments are currently processed automatically at DTC, IPAs have the option to refuse to pay (''RTP'') for maturing MMI Obligations to protect against the possibility that an IPA may not be able to fund settlement because it has not received funds from the relevant issuer. An IPA that refuses payment for a presentment (*i.e.,* refuses to make payment for the delivery of matured MMI securities for which it is the designated IPA and/or pay interest or dividend income on MMI securities for which it is the designated IPA) must notify DTC of its RTP. An IPA may notify DTC of an RTP until 3:00 p.m. ET on the date of the affected presentment.

Under the current Rules, the effect of an RTP is for DTC to reverse all processed MMI security deliveries of that MMI acronym, including issuances, related funds credits and debits, and presentments, which means that the securities would fail to settle. This reversal of processed (but not yet settled) transactions could override DTC's risk management controls (*i.e.,* Collateral Monitor and Net Debit Cap) and could result in a Participant's account having, unexpectedly, a net debit balance that exceeds its Net Debit Cap and/or having insufficient collateral to secure its settlement obligations throughout the day. Thus, RTPs can create uncertainty and pose systemic risk with respect to a Participant's and, ultimately, DTC's ability to complete end-of-day net funds settlement.

Currently, to mitigate the risks associated with an RTP, the Rules and the Settlement Guide provide for the Largest Provisional Net Credit control (''LPNC Control''). Under the LPNC Control, DTC withholds from each Participant's Net Debit Cap the two largest intraday net MMI credits owed to that Participant. The MMI credits withheld are not included in the calculation of the Participant's Collateral Monitor or its net debit balance. This provides protection in the event that processed (but not yet settled) MMI transactions are reversed by DTC as a result of an RTP.[11]

According to DTC, its Rules and procedures relating to settlement

[4] Securities Exchange Act Release No. 79224 (November 3, 2016), 81 FR 78884 (November 9, 2016) (SR–DTC–2016–802). DTC also filed a related proposed rule change with the Commission pursuant to Section 19(b)(1) of the Exchange Act and Rule 19b–4 thereunder, seeking approval of changes to its rules necessary to implement the Advance Notice. 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively. Notice of the proposed rule change was published in the **Federal Register** on October 11, 2016. *See* Securities Exchange Act Release No. 34–79046 (October 5, 2016), 81 FR 70200 (October 11, 2016) (SR–DTC–2016–008). On, November 18, 2016, the Commission extended to January 9, 2017 the date by which it shall either approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule change. *See* Securities Exchange Act Release No. 34–79351 (November 18, 2016), 81 FR 85295 (November 25, 2016) (SR–DTC–2016–008). The Commission did not receive any comments on the proposal.

[5] *Available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

[6] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Settlement.pdf.*

[7] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Distributions%20Service%20Guide%20FINAL%20November%202014.pdf.*

[8] An affirmative MMI funding acknowledgement by the IPA would not be required where the aggregate amount of an issuer's delivery of MMI securities that have been approved in RAD exceeds the aggregate amount of presentments because payment for those securities would fully fund the presentments. In such a case, the IPA would be deemed to have provided a funding acknowledgement and DTC would process the transactions, subject to risk management controls.

[9] DVP transfers at DTC are structured so that the completion of delivery of securities to a Participant in end-of-day settlement is contingent on the receiving Participant satisfying its end-of-day net settlement obligation, if any. The risk of Participant failure to settle is managed through risk management controls that would enable DTC to complete settlement despite the failure to settle of the Participant, or affiliated family of Participants, with the largest net settlement obligation. The two principal controls are the Net Debit Cap and Collateral Monitor. The largest net settlement obligation of a Participant or affiliated family of Participants cannot exceed DTC liquidity resources, based on the Net Debit Cap, and must be fully collateralized, based on the Collateral Monitor.

[10] MMI of an issuer are designated by DTC using unique four-character identifiers referred to as acronyms. An MMI issuer can have multiple acronyms representing its securities. MMI transactions and other functions relating to MMI are done on an ''acronym-by-acronym'' basis.

[11] *See* Securities Exchange Act Release No. 71888 (April 7, 2014), 79 FR 20285 (April 11, 2014) (SR–DTC–2014–02) (clarifying the LPNC procedures in the Settlement Guide) and Securities Exchange Act Release No. 68983 (February 25, 2013), 78 FR 13924 (March 1, 2013) (SR–DTC–2012–10) (updating the Rules related to LPNC).

processing for the MMI program [12] were designed to limit credit, liquidity, and operational risk for DTC and Participants. In connection with ongoing efforts by DTC to evaluate the risk associated with the processing of MMI Obligations, DTC has determined that the risks presented by intra-day reversals of processed MMI Obligations should be eliminated to prevent the possibility that a reversal could override DTC's risk controls and heighten liquidity and settlement risk. DTC also states that eliminating intra-day reversals of processed MMI Obligations would enhance intra-day finality and allow for the elimination of the LPNC Control, which creates intra-day blockage and affects liquidity through the withholding of settlement credits.

B. Proposed Changes

The proposal would eliminate provisions for intra-day reversals of processed MMI Obligations based on an IPA's RTP or issuer insolvency of which DTC becomes aware, as described below.

Pursuant to the proposal, DTC would no longer automatically process MMI Obligations. DTC's processing of MMI Obligations involves the delivery of cash and/or securities. With respect to securities, DTC would require purchasers of MMI issuances (or their custodian, if applicable) to acknowledge in RAD that they agree to receive the MMI securities before DTC processes the transaction. With respect to cash, an IPA would make an MMI funding acknowledgment using a new DTC platform designed to accept such acknowledgments. When an MMI funding acknowledgement is received, DTC would attempt to process transactions in the acronym(s) for which the MMI funding acknowledgment pertains.

If the IPA has provided an MMI funding acknowledgment for the full amount of presentments, then all transactions in that acronym would be sent to the normal DTC processing system and tested against DTC's risk management controls. If the IPA provides an MMI funding acknowledgement for only partial funding of the presentments, then DTC would undertake the proposed ''MMI Optimization'' process to determine whether risk management controls would be satisfied by all deliverers and purchasers of the acronym and determine whether all parties would maintain adequate positions to complete the applicable transactions. However, as long as the issuances that could satisfy deliverer and purchaser risk controls for that MMI acronym are equal to or greater than the maturing presentments of that acronym, the applicable transactions (*i.e.,* those that pass risk controls) could be processed without an IPA's funding acknowledgement.

If DTC does not receive the necessary acknowledgments from both the IPA and purchasers for an acronym for which maturing MMI Obligations are due on that day and/or DTC is aware, through ordinary business channels, that the issuer of an acronym is insolvent (''Acronym Payment Failure''), then DTC would not process transactions in the acronym.[13]

In the event of an Acronym Payment Failure, DTC would: (i) Prevent further issuance and maturity activity for the acronym in DTC's system; (ii) prevent deliveries of MMI securities of the acronym and halt all activity in that acronym; (iii) set the collateral value of the MMI securities in the acronym to zero for purposes of calculating the Collateral Monitor of any affected Participant; and (iv) notify Participants of the Acronym Payment Failure via DTC's current notification process. Notwithstanding the occurrence of an Acronym Payment Failure, the IPA would remain liable for funding pursuant to any MMI funding acknowledgment previously provided for that business day.

A ''Temporary Acronym Payment Failure'' would occur when an IPA notifies DTC that it temporarily refuses to pay income presentments, and only income presentments, for an acronym, which typically would be due to an issuer's inability to fund income presentments on that day. A Temporary Acronym Payment Failure would only be initiated if there are no maturity presentments, principal presentments, and/or reorganization presentments on that business day. DTC would require the issuer and/or IPA to resolve such a situation by the next business day.

In the event of a Temporary Acronym Payment Failure, DTC would: (i) Temporarily devalue to zero all of the issuer's MMI securities for purposes of calculating the Collateral Monitor, unless and until the IPA acknowledges funding with respect to the income payments on the following business day; (ii) notify Participants of the delayed payment; and (iii) block from DTC's systems all further issuances and maturities by that issuer for the remainder of the business day on which notification of the Temporary Payment Failure was received by DTC. An IPA would not be able to avail itself of a Temporary Acronym Payment Failure for the same acronym on consecutive business days.

The Commission understands that the proposal would not: (i) Decrease the total number and value of transactions that would pass DTC's risk controls throughout the processing day; or (ii) increase the volume of transactions that would fail to settle. The Commission also understands that the proposal would reduce blockage caused by DTC. Non-MMI transactions and fully funded MMI transactions would likely have a reduction in blockage as a result of the elimination of the LPNC Control. The elimination of the LPNC Control would no longer withhold billions of dollars of settlement credits as it does today, thus permitting MMI transactions subject to the LPNC Control to process earlier in the day. Moreover, it is expected that the value and volume of MMI transactions recycling due to failure to meet DTC's risk management controls during the late morning and afternoon periods would be reduced, as a result of such transactions being held outside of DTC's processing system while they await the necessary acknowledgments.

Similar to the LPNC Control, the RVPNA Control is used to prevent a Participant from delivering free of value or undervalued any MMI securities that were received for payment on the same day.[14] For example, under DTC's current rules, if Participant A delivers MMI securities to Participant B for payment, and then Participant B delivers the same MMI securities to Participant C free of payment (subject to risk management controls), the delivery to Participant C is final when the securities are credited to Participant C. DTC would, therefore, be unable to reverse the delivery to Participant C and, thus, DTC could not reverse the delivery from Participant B to Participant A. The RVPNA Control protects DTC against being unable to reverse such transactions of MMI Securities in the event of an RTP by the IPA. Because DTC would no longer permit the reversal of processed MMI transactions, DTC would no longer need the RVPNA Control.

[12] The procedures applicable to MMI settlement processing are set forth in the Settlement Guide. *Supra* note 6.

[13] DTC would automatically consider an Acronym Payment Failure that occurred due to an IPA's failure to provide timely MMI funding acknowledgement (*i.e.,* provide the acknowledgment by 3:00 p.m. ET) as an RTP.

[14] For purposes of RVPNA, MMI securities are considered undervalued if they are delivered for less than 10 percent below market value.

II. Discussion and Commission Findings

Although the Act does not specify a standard of review for an advance notice, its stated purpose is instructive: To mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[15] Section 805(a)(2) of the Act authorizes the Commission to prescribe risk management standards for the payment, clearing, and settlement activities of designated clearing entities and financial institutions engaged in designated activities for which it is the Supervisory Agency or the appropriate financial regulator.[16] Section 805(b) of the Act states that the objectives and principles for the risk management standards prescribed under Section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.[17]

The Commission has adopted risk management standards under Section 805(a)(2) of the Act [18] and Section 17A of the Exchange Act [19] (''Clearing Agency Standards'').[20] The Clearing Agency Standards require registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[21] Therefore, it is appropriate for the Commission to review proposed changes in advance notices against the objectives and principles of these risk management standards as described in Section 805(b) of the Act and in the Clearing Agency Standards.

A. Consistency With Section 805(b) of the Act

The Commission believes that the proposed changes in the Advance Notice are consistent with the objectives and principles described in Section 805(b) of the Act.[22]

First, the Commission believes that the changes proposed in the Advance Notice promote robust risk management. Under the proposal, DTC would no longer automatically process MMI presentments. Instead, before it processes a presentment, DTC would require purchasers of MMI issuances (or their custodian, if applicable) to acknowledge in RAD that the purchasers agree to receive the MMI securities before DTC processes the transaction. The proposal would also require the applicable IPA to provide an MMI funding acknowledgment, as applicable. The MMI funding acknowledgement would be a commitment by the IPA to make the applicable funds available to DTC. Although the proposed changes would establish new requirements before DTC would process such MMI transactions, the Commission believes that the benefits of eliminating the risk of a potential override of DTC's risk management controls from an RTP supports such requirements.

DTC also would employ the proposed MMI Optimization, which would, for MMI transactions that await funding, continually test the net effect of transactions, across multiple MMI issuers, on receiving and delivering Participants' risk controls and then process the transactions once the controls are met. MMI Optimization would help maximize processing and facilitate more timely settlement of transactions, thus reducing risks that transactions may not settle.

Second, the Commission believes that the changes proposed in the Advance Notice promote safety and soundness. Currently, as described above, if DTC were to reverse MMI transactions because of an RTP, the reversal could override DTC's risk management controls. The Advance Notice would eliminate RTPs and resulting reversals of MMI transactions, and thus eliminates this opportunity to override DTC's risk management controls.

Third, the Commission believes that the Advance Notice helps reduce systemic risk. As described above, DTC would no longer automatically process MMI presentments. Rather, DTC would require purchasers to authorize delivery via RAD and IPAs to provide a funding acknowledgment before processing MMI presentments, as applicable. Because these changes would eliminate the risk of reversals due to an RTP, the changes would mitigate the risk of a potential override of DTC's risk management controls. In turn, this would reduce DTC's exposure to potential failures, promote DTC's safety and soundness, as discussed above, and thereby reduce the systemic risk to the financial system.

Fourth, the Commission believes that the Advance Notice promotes the stability of the broader financial system. As described above, the LPNC Control currently withholds from each Participant the two largest intraday net MMI credits out of all of the MMI credits owed to that Participant in order to protect DTC from a Participant breaching its Net Debit Cap or having insufficient collateral in the event of a reversed because of an RTP. However, withholding the credits makes them unavailable to the Participant, which can cause blockage (*i.e.,* the failure of a transaction to process because of insufficient liquidity) for the Participant. Meanwhile, the RVPNA Control limits a Participant's ability to deliver MMI that the Participant is also due to receive that day. By preventing Participants from delivering certain MMI securities, the RVPNA Control creates blockage.

Because DTC would no longer process MMI transactions without a purchaser's RAD acknowledgement and an IPA's MMI funding acknowledgement, as applicable, RTPs and resulting intraday reversals no longer present the risk that the LPNC and RVPNA Controls are meant to address. As such, DTC would eliminate these controls. This change would make available to Participants the intraday credits that were previously withheld, which would decrease intraday liquidity blockage for the Participant and enable DTC to process MMI transactions earlier. Thus, Participants would have less exposure to intraday reversals that increase liquidity and settlement risk and a more complete view of their actual intraday net debit and credit balances.

For the above reasons, the Commission believes that the changes proposed in the Advance Notice promote robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system consistent with Section 805(b) of the Act.[23]

B. Consistency With Rule 17Ad–22(d) of the Exchange Act

The Commission also believes that the Advance Notice is consistent with the Clearing Agency Standards, in particular Rule 17Ad–22(d)(12) under the Exchange Act.[24] Rule 17Ad–22(d)(12) requires DTC to establish, implement, maintain and enforce written policies and procedures

[15] *See* 12 U.S.C. 5461(b).

[16] 12 U.S.C. 5464(a)(2).

[17] 12 U.S.C. 5464(b).

[18] 12 U.S.C. 5464(a)(2).

[19] 15 U.S.C. 78q–1.

[20] *See* 17 CFR 240.17Ad–22. Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11).

[21] *Id.*

[22] *Id.*

[23] 12 U.S.C. 5464(b).

[24] 17 CFR 240.17Ad–22(d)(12).

reasonably designed to ensure that final settlement occurs no later than the end of the settlement day; and require that intraday or real-time finality be provided where necessary to reduce risks.[25] Through this proposal, DTC would no longer process MMI transactions automatically but, rather, would first require an IPA's funding acknowledgment and a purchaser's RAD acknowledgment, as applicable. Where a funding acknowledgement is provided, DTC would no longer permit an RTP, thus eliminating the risk of an intraday reversal of a processed MMI transaction. Additionally, the proposal would eliminate the LPNC and RVPNA Controls, which would help eliminate the blockage caused by the LPNC Control's withholding of Participants' two largest net credits for MMI transactions and the RVPNA Control's restriction on delivering certain MMI securities. Each of these proposed changes, both individually and collectively, would help ensure that final settlement occurs at the end of the day. As such, the Commission believes that the changes proposed in the Advance Notice are consistent with Rule 17Ad–22(d)(12) under the Exchange Act.[26]

III. Conclusion

It is therefore noticed, pursuant to Section 806(e)(1)(I) of the Payment, Clearing and Settlement Supervision Act,[27] that the Commission *does not object* to the Advance Notice (SR–DTC–2016–802) and that DTC is *authorized* to implement the proposed change as of the date of this notice or the date of an order by the Commission authorizing DTC to implement DTC's proposed rule change SR–DTC–2016–008 that is consistent with this Advance Notice, whichever is later.

By the Commission.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00625 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

[25] *Id.*

[26] *Id.*

[27] 12 U.S.C. 5465(e)(1)(I).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79759; File No. SR–NYSEArca–2016–149]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To Amend NYSE Arca Rule 6.91

January 9, 2017.

On November 14, 2016, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Arca Rule 6.91 to clarify and provide greater transparency to its rules governing the trading of Electronic Complex Orders. The proposed rule change was published for comment in the **Federal Register** on December 2, 2016.[3] On December 23, 2016, NYSE Arca filed Amendment No. 1, which supersedes the original proposal in its entirety. The Commission has received no comments regarding the proposed rule change.

Section 19(b)(2) of the Act [4] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 16, 2017.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the proposed rule change.

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act,[5] the Commission designates March 2, 2017, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File Number SR–NYSEArca–2016–149).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00608 Filed 1–12–17; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 79404 (November 28, 2016), 81 FR 87094.

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79758; File No. SR–BatsBZX–2016–89]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Fees for Connectivity and Its Communication and Routing Service Known as Bats Connect

January 9, 2017.

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 December 27, 2016, Bats BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to BZX Rules 15.1(a)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

and (c) to modify its fees for physical ports, logical ports, and for the use of a communication and routing service known as Bats Connect.

The text of the proposed rule change is available at the Exchange's Web site at *www.bats.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify its fees for physical ports, logical ports, and for the use of a communication and routing service known as Bats Connect. Each of these proposed changes are described below.

Physical Ports

A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,000 per physical port that connects to the System [6] via 1 gigabyte circuit; and $4,000 per physical port that connects to the System via 10 gigabyte circuit. The Exchange proposes to increase the fee per physical port that connects to the System via a 10 gigabyte circuit from $4,000 per month to $6,000 per month in order cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems and enable it to continue to maintain and improve its market technology and services. The Exchange does not propose to amend the fee for a 1 gigabyte circuit, which will remain $2,000 per month.

Logical Ports

The Exchange currently charges for logical ports (including Multicast PITCH Spin Server and GRP ports) $500 per port per month. A logical port represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-Member and grants that Member or non-Member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. Logical port fees are limited to logical ports in the Exchange's primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees to all Members' and non-Members' logical ports. The Exchange now proposes to increase charges for logical ports (including Multicast PITCH Spin Server and GRP ports) from $500 per port per month to $550 per month. Like as for the proposed fee increase for physical ports described above, the proposed increase in logical port fees is intended to cover increased infrastructure costs associated with establishing ports to connect to the Exchange's Systems and to enable the Exchange to continue to maintain and improve its market technology and services.

Bats Connect

The Exchange proposes to increase select fees related to the use of Bats Connect. Bats Connect is offered by the Exchange on a voluntary basis in a capacity similar to a vendor.[7] In sum, Bats Connect is a communication service that provides subscribers an additional means to receive market data from and route orders to any destination connected to the Exchange's network. Bats Connect does not provide any advantage to subscribers for connecting to the Exchange's affiliates [8] as compared to other methods of connectivity. The servers of the subscriber need not be located in the same facilities as the Exchange in order to subscribe to Bats Connect. Subscribers may also seek to utilize Bats Connect in the event of a market disruption where other alternative connection methods become unavailable.

The Exchange charges a monthly connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and broker-dealers that are connected to the Exchange's network via unicast access. The amount of the connectivity fee varies based solely on the bandwidth selected by the subscriber. Specifically, as set forth under the Unicast Access—Order Entry section of the fee schedule, the Exchange charges $350 for 1 Mb, $700 for 5 Mb, $950 for 10 Mb, $1,500 for 25 Mb, $2,500 for 50 Mb, and $3,500 for 100 Mb. The Exchange proposes to increase those fees as follows: $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The proposed increases are designed to cover increased costs related to hardware, installation, and testing, as well as increased expenses involved in maintaining and managing the service. The Exchange does not propose to increase the fees for the 25 Mb, 50 Mb and 100 Mb connections as those fees will remain $1,500, $2,500, and $3,500, respectively.

Bats Connect also allows subscribers to receive market data feeds from the exchanges connected to the Exchange's network. In such case, the subscriber pays the Exchange a connectivity fee, which are set forth under the Market Data Connectivity section of the fee schedule and vary based solely on the amount of bandwidth required to transmit the selected data product to the subscriber.[9] The proposed connectivity fees currently range from no charge to $11,500 based on the market data product the subscriber selects. The Exchange proposes to increase select connectivity fees for market data as follows:

Data feed	Current fee	Proposed fee
UQDF/UTDF/OMDF	$650	$1,200

[6] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' *See* Exchange Rule 1.5(aa).

[7] *See* Exchange Rule 13.8.

[8] The Exchange's affiliated exchanges are Bats EDGX Exchange, Inc. (''EDGX''), Bats EDGA Exchange, Inc. (''EDGA''), and Bats BYX Exchange, Inc. (''BYX'').

[9] Subscribers pays any fees charged by the exchange providing the market data feed directly to that exchange.

Data feed	Current fee	Proposed fee
CQS/CTS	1,000	1,400
OPRA	3,500	4,500
Nasdaq TotalView	1,300	1,500
Nasdaq BX TotalView	650	1,000
Nasdaq PSX TotalView	350	750
NYSE Integrated	11,500	14,500
NYSE ArcaBook	1,000	1,250
NYSE MKT OpenBook Ultra	150	500
NYSE Alerts	250	500
NYSE Imbalances	100	500
NYSE Arca Trades	250	500
BBDS/TDDS	100	500

The proposed increases are designed to allow the Exchange to cover the increased costs related to the amount of bandwidth required to provide connectivity to receive market data as well as the costs of maintaining that infrastructure.

The Exchange also charges a discounted fee of $4,160 per month for subscribers who purchase connectivity to a bundle of select market data products, known as the U.S. Equities Select + SIP Bundle. The following market data products are included in the bundle: UQDF/UTDF/OMDF, CQS/CTS, Nasdaq TotalView, Nasdaq BX TotalView, Nasdaq PSX TotalView, NYSE ArcaBook, NYSE MKT OpenBook Ultra, and BBDS/TTDS.[10] Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would currently pay a total monthly fee of $5,200. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $4,160, which represents a 20% discount. The Exchange proposes to add NYSE OpenBook Ultra to the bundle. Also, in light of the proposed changes outlined above, the Exchange proposes to increase the discounted rate of the bundle to $5,910 per month, which would now represent a 40% discount from the rate of $9,850 a subscriber purchasing connectivity through Bats Connect for each of these market data products would be charged under the proposed rule change.

Lastly, the Exchange proposes to charge a discounted fee of $6,390 per month for subscribers who purchase connectivity to the OPRA, UQDF/UTDF/OMDF, and CQS/CTS data feeds, to be known as the OPRA + SIP Bundle. Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would pay a total monthly fee of $7,100. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $6,390, which represents a 10% discount.

Implementation Date

The Exchange proposes to implement this amendment to its fee schedule on January 3, 2017.[11]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[12] in general, and furthers the objectives of Section 6(b)(4),[13] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

The Exchange believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services.

Physical Ports

The Exchange believes that the proposed fees for a 10 gigabyte circuit of $6,000 per month is reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq'') and NYSE Arca, Inc. (''Arca''), which range from $10,000–$15,000 per month for 10 gigabyte circuits.[14] The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and

[10] The Exchange also proposes to correct a typographical error in referencing BBDS/TDDS in its description of the U.S. Equity Select + SIP bundle.

[11] The Exchange notes that the date of its fee schedule was previously updated to January 3, 2017 in SR–BatsBZX–2016–87 (December 6 [sic], 2017). *See* Securities Exchange Act Release No. 79636 (December 21, 2016).

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4).

[14] *See* Nasdaq Rule 7034(b) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

Logical Ports

The Exchange believes that the increase of fees for logical ports represents an equitable allocation of reasonable dues, fees and other charges. The Exchange believes that its proposed changes to logical port fees are reasonable in light of the benefits to Exchange participants of direct market access and receipt of data. The Exchange believes its proposed fees are reasonable because Nasdaq and NYSE Arca charge comparable rates for logical ports to access such markets.[15]

Bats Connect

The Exchange also believes that its proposed fees for Bats Connect provide for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. First, the Exchange charges a connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and market centers that are connected to the Exchange's network, which varies based solely on the amount of bandwidth selected by the subscriber. The proposed increased connectivity fees remain reasonable and competitive as compared to similar fees charged by other exchanges. For purposes of order routing, the Exchange proposes to now charge $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The New York Stock Exchange, Inc. (''NYSE'') currently charges $300 for 1 Mb, $700 for 5 Mb, and $900 for 10 Mb.[16] In addition, the proposed rates continue to be less than what a subscriber would pay to connect directly to another exchange.[17] The Exchange notes that, overall, the connectivity fee for routing of orders to other market centers proposed by the Exchange is similar to that charged by the NYSE.

Second, with regard to utilizing Bats Connect to receive market data products from other exchanges, the Exchange only charges subscribers a connectivity fee, the amount of which is based solely on the amount of bandwidth required to transmit that specific data product to the subscribers. The Exchange believes it is necessary to increase the rates for select market data feeds as described herein to address changes in bandwidth necessary to receive such feeds. The increased fees will also enable the Exchange to continue to cover the increased infrastructure costs while also enabling it to continue to maintain and improve the service.

The amounts of the connectivity fees continue to be reasonable as compared to similar fees charged by other exchanges. For example, for market data connectivity, Nasdaq charges $1,412 per month for CQS/CTS data feed, and the Exchange proposes to charge $1,400 per month connectivity for CQS/CTS data feed.[18]

The Exchange believes it is reasonable to offer such discounted pricing to subscribers who purchase connectivity to a bundle of market data products as it would enable them to reduce their overall connectivity costs for the receipt of market data. The Exchange is not required by any rule or regulation to make Bats Connect available; nor are subscribers required by any rule or regulation to utilize Bats Connect. Accordingly, subscribers can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Moreover, the Exchange believes the proposed fees are reasonable and equitable because they continue to be based on the Exchange's costs to cover the amount of bandwidth required to provide connectivity to the select bundle of data feeds. The proposed fees will continue to allow the Exchange to recoup this cost, while providing subscribers with an alternative means to connect to the select bundle of data feeds at a discounted rate.

Lastly, the Exchange believes the proposed fees are reasonable and equitable because they are based on the Exchange's costs to cover hardware, installation, testing and connection, as well as expenses involved in maintaining and managing the service. The proposed fees allow the Exchange to recoup these costs, while providing subscribers with an alternative means to connect to other exchange and market centers. The Exchange believes that the proposed fees are reasonable and equitable in that they reflect the costs and the benefit of providing alternative connectivity.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Further, excessive fees for connectivity would serve to impair an exchange's ability to compete for order flow rather than burdening competition.

Lastly, the Exchange does not believe the proposed fees for Bats Connect will result in any burden on competition. The proposed rule change is designed to provide subscribers with an alternative means to access other market centers on the Exchange's network if they choose or in the event of a market disruption where other alternative connection methods become unavailable. Bats Connect is not the exclusive method to connect to these market centers and subscribers may utilize alternative methods to connect to the product if they believe the Exchange's proposed pricing is unreasonable or otherwise. Therefore, the Exchange does not believe the proposed rule change will have any effect on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)

[15] *See* Nasdaq Rule 7015(b) (charging a fee of $575 per month for FIX Trading Ports) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016) (charging a fee of $550 per month for ports for order/quote entry).

[16] *See* Section 3.6.1 of NYSE's SFTI Americas Product and Service List *available at http://www.nyxdata.com/docs/connectivity.*

[17] *See e.g.,* Nasdaq Rule 7034(b) *and* the Co-Location section of the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[18] *See* Nasdaq Rule 7034 (setting forth Nasdaq's connectivity fees for receipt of third party market data products).

of the Act [19] and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBZX–2016–89 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–BatsBZX–2016–89. 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–BatsBZX–2016–89 and should be submitted on or before February 3, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00607 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79764; File No. SR–DTC–2016–008]

Self-Regulatory Organizations; The Depository Trust Company; Order Granting Approval of Proposed Rule Change Relating To Processing of Transactions in Money Market Instruments

January 9, 2017.

The Depository Trust Company (''DTC'') filed on September 23, 2016 with the Securities and Exchange Commission (''Commission'') proposed rule change SR–DTC–2016–008 (''Proposed Rule Change'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder.[2] The Proposed Rule Change was published for comment in the **Federal Register** on October 11, 2016.[3] On, November 18, 2016, the Commission extended to January 9, 2017 the date by which it shall either approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.[4] The Commission did not receive any comments on the Proposed Rule Change. For the reasons discussed below, the Commission is granting approval of the Proposed Rule Change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–79046 (October 5, 2016), 81 FR 70200 (October 11, 2016) (SR–DTC–2016–008) (''Notice''). DTC also filed the Proposed Rule Change as an advance notice with the Commission, pursuant to Section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 and Rule 19b–4(n)(1) under the Act. 12 U.S.C. 5465(e) and 17 CFR 240.19b–4(n)(1), respectively. The advance notice was published in the **Federal Register** on November 9, 2016. Securities Exchange Act Release No. 79224 (November 3, 2016), 81 FR 78884 (November 9, 2016) (SR–DTC–2016–802). The Commission did not receive any comments on the advance notice.

[4] Securities Exchange Act Release No. 34–79351 (November 18, 2016), 81 FR 85295 (November 25, 2016) (SR–DTC–2016–008)

I. Description of the Proposed Rule Change

The Proposed Rule Change is a proposal by DTC to modify (i) the DTC Rules, By-laws and Organization Certificate (''Rules''),[5] (ii) the DTC Settlement Service Guide (''Settlement Guide''),[6] and (iii) the DTC Distributions Service Guide (''Distributions Guide''),[7] in order to change the way in which DTC processes transactions in money market instruments (''MMI''). The proposal would affect DTC's processing of issuances of MMI securities as well as maturity presentments, income presentments, principal presentments, and reorganization presentments (collectively, ''presentments'' and with issuances of MMI securities, ''MMI Obligations'').

Specifically, DTC proposes to: (i) With respect to delivery of MMI securities, require purchasers of the securities (or their custodian, if applicable) to acknowledge that they agree to receive the securities via DTC's Receiver Authorized Delivery (''RAD'') system before DTC processes the transaction; (ii) with respect to cash, require an issuing and paying agent (''IPA'') of an MMI issuer to acknowledge its funding obligations for MMI presentments before DTC processes the transaction, except in limited circumstances where there are no funding obligations; [8] (iii) implement an enhanced process to check certain MMI transactions against DTC's risk management controls (referred to as ''MMI Optimization''); (iv) eliminate the largest provisional net credit risk management control; and (v) eliminate DTC's receive versus payment net additions control, as described below. In addition, the proposal would amend DTC's Distributions Guide to conform to the proposed changes.

A. Background

Today, according to DTC, when an issuer issues MMI securities at DTC, the IPA for that issuer sends issuance

[5] *Available at http://www.dtcc.com/legal/rules-and-procedures.aspx.*

[6] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Settlement.pdf.*

[7] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Distributions%20Service%20Guide%20FINAL%20November%202014.pdf.*

[8] An affirmative MMI funding acknowledgement by the IPA would not be required where the aggregate amount of an issuer's delivery of MMI securities that have been approved in RAD exceeds the aggregate amount of presentments because payment for those securities would fully fund the presentments. In such a case, the IPA would be deemed to have provided a funding acknowledgement and DTC would process the transactions, subject to risk management controls.

instructions to DTC electronically, which results in crediting the applicable MMI securities to the DTC account of the IPA. The MMI securities are then delivered by DTC to the accounts of the applicable DTC participants (''Participants'') that are purchasing the issuance, typically as custodians for individual investors, in accordance with their purchase amounts. The IPA's delivery instructions may be free of payment or, most often, for payment (*i.e.,* delivery versus payment or ''DVP''). Unlike deliveries free of payment, DVP transactions are subject to DTC's risk management controls for both the IPA and the receiving Participants, which means they are monitored for Net Debit Cap and Collateral Monitor sufficiency.[9]

When MMI securities of a particular acronym [10] mature, the current presentment process involves DTC automatically sweeping the matured positions from the applicable Participant accounts and debiting the settlement account of the applicable IPA for the amount of the matured position, with corresponding credits made to the settlement accounts of the deliverers. Because presentments are currently processed automatically at DTC, IPAs have the option to refuse to pay (''RTP'') for maturing MMI Obligations to protect against the possibility that an IPA may not be able to fund settlement because it has not received funds from the relevant issuer. An IPA that refuses payment for a presentment (*i.e.,* refuses to make payment for the delivery of matured MMI securities for which it is the designated IPA and/or pay interest or dividend income on MMI securities for which it is the designated IPA) must notify DTC of its RTP. An IPA may notify DTC of an RTP until 3:00 p.m. ET on the date of the affected presentment.

Under the current Rules, the effect of an RTP is for DTC to reverse all processed MMI security deliveries of that MMI acronym, including issuances, related funds credits and debits, and presentments, which means that the securities would fail to settle. This reversal of processed (but not yet settled) transactions could override DTC's risk management controls (*i.e.,* Collateral Monitor and Net Debit Cap) and could result in a Participant's account having, unexpectedly, a net debit balance that exceeds its Net Debit Cap and/or having insufficient collateral to secure its settlement obligations throughout the day. Thus, RTPs can create uncertainty and pose systemic risk with respect to a Participant's and, ultimately, DTC's ability to complete end-of-day net funds settlement.

Currently, to mitigate the risks associated with an RTP, the Rules and the Settlement Guide provide for the Largest Provisional Net Credit control (''LPNC Control''). Under the LPNC Control, DTC withholds from each Participant's Net Debit Cap the two largest intraday net MMI credits owed to that Participant. The MMI credits withheld are not included in the calculation of the Participant's Collateral Monitor or its net debit balance. This provides protection in the event that processed (but not yet settled) MMI transactions are reversed by DTC as a result of an RTP.[11]

According to DTC, its Rules and procedures relating to settlement processing for the MMI program [12] were designed to limit credit, liquidity, and operational risk for DTC and Participants. In connection with ongoing efforts by DTC to evaluate the risk associated with the processing of MMI Obligations, DTC has determined that the risks presented by intra-day reversals of processed MMI Obligations should be eliminated to prevent the possibility that a reversal could override DTC's risk controls and heighten liquidity and settlement risk. DTC also states that eliminating intra-day reversals of processed MMI Obligations would enhance intra-day finality and allow for the elimination of the LPNC Control, which creates intra-day blockage and affects liquidity through the withholding of settlement credits.

B. Proposed Changes

The proposal would eliminate provisions for intra-day reversals of processed MMI Obligations based on an IPA's RTP or issuer insolvency of which DTC becomes aware, as described below.

Pursuant to the proposal, DTC would no longer automatically process MMI Obligations. DTC's processing of MMI Obligations involves the delivery of cash and/or securities. With respect to securities, DTC would require purchasers of MMI issuances (or their custodian, if applicable) to acknowledge in RAD that they agree to receive the MMI securities before DTC processes the transaction. With respect to cash, an IPA would make an MMI funding acknowledgment using a new DTC platform designed to accept such acknowledgments. When an MMI funding acknowledgement is received, DTC would attempt to process transactions in the acronym(s) for which the MMI funding acknowledgment pertains.

If the IPA has provided an MMI funding acknowledgment for the full amount of presentments, then all transactions in that acronym would be sent to the normal DTC processing system and tested against DTC's risk management controls. If the IPA provides an MMI funding acknowledgement for only partial funding of the presentments, then DTC would undertake the proposed ''MMI Optimization'' process to determine whether risk management controls would be satisfied by all deliverers and purchasers of the acronym and determine whether all parties would maintain adequate positions to complete the applicable transactions. However, as long as the issuances that could satisfy deliverer and purchaser risk controls for that MMI acronym are equal to or greater than the maturing presentments of that acronym, the applicable transactions (*i.e.,* those that pass risk controls) could be processed without an IPA's funding acknowledgement.

If DTC does not receive the necessary acknowledgments from both the IPA and purchasers for an acronym for which maturing MMI Obligations are due on that day and/or DTC is aware, through ordinary business channels, that the issuer of an acronym is insolvent (''Acronym Payment Failure''), then DTC would not process transactions in the acronym.[13]

In the event of an Acronym Payment Failure, DTC would: (i) Prevent further issuance and maturity activity for the acronym in DTC's system; (ii) prevent

[9] DVP transfers at DTC are structured so that the completion of delivery of securities to a Participant in end-of-day settlement is contingent on the receiving Participant satisfying its end-of-day net settlement obligation, if any. The risk of Participant failure to settle is managed through risk management controls that would enable DTC to complete settlement despite the failure to settle of the Participant, or affiliated family of Participants, with the largest net settlement obligation. The two principal controls are the Net Debit Cap and Collateral Monitor. The largest net settlement obligation of a Participant or affiliated family of Participants cannot exceed DTC liquidity resources, based on the Net Debit Cap, and must be fully collateralized, based on the Collateral Monitor.

[10] MMI of an issuer are designated by DTC using unique four-character identifiers referred to as acronyms. An MMI issuer can have multiple acronyms representing its securities. MMI transactions and other functions relating to MMI are done on an ''acronym-by-acronym'' basis.

[11] *See* Securities Exchange Act Release No. 71888 (April 7, 2014), 79 FR 20285 (April 11, 2014) (SR–DTC–2014–02) (clarifying the LPNC procedures in the Settlement Guide) and Securities Exchange Act Release No. 68983 (February 25, 2013), 78 FR 13924 (March 1, 2013) (SR–DTC–2012–10) (updating the Rules related to LPNC).

[12] The procedures applicable to MMI settlement processing are set forth in the Settlement Guide. *Supra* note 6.

[13] DTC would automatically consider an Acronym Payment Failure that occurred due to an IPA's failure to provide timely MMI funding acknowledgement (*i.e.,* provide the acknowledgment by 3:00 p.m. ET) as an RTP.

deliveries of MMI securities of the acronym and halt all activity in that acronym; (iii) set the collateral value of the MMI securities in the acronym to zero for purposes of calculating the Collateral Monitor of any affected Participant; and (iv) notify Participants of the Acronym Payment Failure via DTC's current notification process. Notwithstanding the occurrence of an Acronym Payment Failure, the IPA would remain liable for funding pursuant to any MMI funding acknowledgment previously provided for that business day.

A ''Temporary Acronym Payment Failure'' would occur when an IPA notifies DTC that it temporarily refuses to pay income presentments, and only income presentments, for an acronym, which typically would be due to an issuer's inability to fund income presentments on that day. A Temporary Acronym Payment Failure would only be initiated if there are no maturity presentments, principal presentments, and/or reorganization presentments on that business day. DTC would require the issuer and/or IPA to resolve such a situation by the next business day.

In the event of a Temporary Acronym Payment Failure, DTC would: (i) Temporarily devalue to zero all of the issuer's MMI securities for purposes of calculating the Collateral Monitor, unless and until the IPA acknowledges funding with respect to the income payments on the following business day; (ii) notify Participants of the delayed payment; and (iii) block from DTC's systems all further issuances and maturities by that issuer for the remainder of the business day on which notification of the Temporary Payment Failure was received by DTC. An IPA would not be able to avail itself of a Temporary Acronym Payment Failure for the same acronym on consecutive business days.

The Commission understands that the proposal would not: (i) Decrease the total number and value of transactions that would pass DTC's risk controls throughout the processing day; or (ii) increase the volume of transactions that would fail to settle. The Commission also understands that the proposal would reduce blockage caused by DTC. Non-MMI transactions and fully funded MMI transactions would likely have a reduction in blockage because of the elimination of the LPNC Control. The elimination of the LPNC Control would no longer withhold billions of dollars of settlement credits as it does today, thus permitting MMI transactions subject to the LPNC Control to process earlier in the day. Moreover, it is expected that the value and volume of MMI transactions recycling due to failure to meet DTC's risk management controls during the late morning and afternoon periods would be reduced, because of such transactions being held outside of DTC's processing system while they await the necessary acknowledgments.

Similar to the LPNC Control, the RVPNA Control is used to prevent a Participant from delivering free of value or undervalued any MMI securities that were received for payment on the same day.[14] For example, under DTC's current rules, if Participant A delivers MMI securities to Participant B for payment, and then Participant B delivers the same MMI securities to Participant C free of payment (subject to risk management controls), the delivery to Participant C is final when the securities are credited to Participant C. DTC would, therefore, be unable to reverse the delivery to Participant C and, thus, DTC could not reverse the delivery from Participant B to Participant A. The RVPNA Control protects DTC against being unable to reverse such transactions of MMI Securities in the event of an RTP by the IPA. Because DTC would no longer permit the reversal of processed MMI transactions, DTC would no longer need the RVPNA Control.

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act[15] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. The Commission believes the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act and Rule 17Ad–22(d)(12) under the Act,[16] as described in detail below.

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to protect investors and the public interest.[17]

The Commission believes that the Proposed Rule Change is consistent with promoting prompt and accurate clearance and settlement. First, as described above, DTC automatically processes MMI transactions today but permits RTPs in order to enable IPAs to protect against the possibility that the IPA does not receive the necessary funds from the relevant issuer. However, if DTC reverses processed (but not yet settled) MMI transactions because of an RTP, the transactions would fail to settle and the reversal could override DTC's risk management controls.

The Proposed Rule Change would eliminate such reversals, failures, and possible overrides because the proposal would require, before DTC would process an MMI transaction, that (i) purchasers of MMI issuances (or their custodian, if applicable) authorize delivery of the MMI securities, and (ii) IPAs provide an MMI funding acknowledgement that commits the IPA to the acknowledge funds. If DTC does not receive a RAD authorization or MMI funding acknowledgement, as applicable, it would not process the MMI transaction. However, if a RAD authorization or an MMI funding acknowledgment is receive, DTC would no longer permit an RTP for what was authorized or acknowledge, thus eliminating the risk that the applicable MMI transaction would fail to settle or override DTC's risk management controls due to an RTP. Although theses proposed changes would establish new requirements before DTC would process such MMI transactions, the Commission believes that the benefits of eliminating the risk of a potential override of DTC's risk management controls from an RTP supports such requirements.

Second, the Proposed Rule Change would help ensure prompt and accurate clearance and settlement securities by employing the proposed MMI Optimization. MMI Optimization would, for MMI transactions that await funding, continually test the net effect of transactions, across multiple MMI issuers, on receiving and delivering Participants' risk controls, and then process the transactions once the controls are met. As such, MMI Optimization would help maximize processing and facilitate more timely settlement of MMI transactions, thus reducing risks that transactions may not settle.

Third, the proposed removal of the LPNC and RVPNA Controls also would further promote prompt clearance and settlement. As described above, the LPNC Control currently withholds from each Participant the two largest intraday net MMI credits out of all of the MMI credits owed to that Participant in order to protect DTC from a Participant

[14] For purposes of RVPNA, MMI securities are considered undervalued if they are delivered for less than 10 percent below market value.

[15] 15 U.S.C. 78s(b)(2)(C).

[16] 15 U.S.C. 78q–1(b)(3)(F); 17 CFR 240.17Ad–22(d)(12).

[17] 15 U.S.C. 78q–1(b)(3)(F).

breaching its Net Debit Cap or having insufficient collateral in the event of a reversal caused by an RTP. However, withholding the credits makes them unavailable to the Participant, which can cause blockage (*i.e.,* the failure of a transaction to process because of insufficient liquidity) for the Participant. Meanwhile, the RVPNA Control limits a Participant's ability to deliver MMI that the Participant is due to receive that day. By preventing Participants from delivering certain MMI securities, the RVPNA Control also can create blockage.

Because DTC would no longer process MMI transactions without a purchaser's RAD authorization and an IPA's MMI funding acknowledgement, as applicable, RTPs and resulting intraday reversals no longer present the risk that the LPNC and RVPNA Controls are meant to address. As such, DTC would eliminate these controls. This change would make available to Participants the intraday credits that were previously withheld by those controls, which would decrease intraday liquidity blockage for the Participant and enable DTC to process MMI transactions earlier. Thus, Participants would have less exposure to intraday reversals that increase liquidity and settlement risk and a more complete view of their actual intraday net debit and credit balances.

The Commission also believes that the Proposed Rule Change is consistent with protecting investors and the public interest. As described above, DTC would no longer automatically process MMI presentments. Rather, DTC would require purchasers to authorize delivery via RAD and IPAs to provide a funding acknowledgment before processing MMI presentments, as applicable. Because these changes would eliminate the risk of reversals due to an RTP, the changes would mitigate the risk of a potential override of DTC's risk management controls. Thus, the Proposed Rule Change would help protect investors and the public interest by reducing DTC's exposure to potential failures, promoting DTC's safety and soundness, and providing greater assurance that transactions will settle despite a Participant default.

Therefore, for the above reasons, the Commission believes that the Proposed Rule Change will help promote the prompt and accurate clearance and settlement of securities transactions and help protect investors and the public interest, consistent with Section 17A(b)(3)(F) of the Act, cited above.

B. Consistency With Rule 17Ad–22(d)(12)

Rule 17Ad–22(d)(12) under the Act requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure that final settlement occurs no later than the end of the settlement day; and require that intraday or real-time finality be provided where necessary to reduce risks.[18] Through this proposal, DTC would no longer process MMI transactions automatically but, rather, would first require an IPA's funding acknowledgment and a purchaser's RAD authorization, as applicable. Where such acknowledgements and authorizations are provided, DTC would no longer permit an RTP, thus eliminating the risk of an intraday reversal of a processed MMI transaction. Additionally, the proposal would eliminate the LPNC and RVPNA Controls, which would help eliminate blockage caused by the LPNC Control's withholding of Participants' two largest net credits for MMI transactions and the RVPNA Control's restriction on delivering certain MMI securities. Each of these proposed changes, both individually and collectively, would help ensure that final settlement occurs at the end of the day. Therefore, the Commission believes that the changes proposed in the Advance Notice are consistent with Rule 17Ad–22(d)(12) under the Act.[19]

III. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[20] and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that proposed rule change SR–DTC–2016–008 be, and hereby is, *Approved* as of the date of this order or the date of a notice by the Commission authorizing DTC to implement DTC's advance notice proposal (SR–DTC–2016–802) that is consistent with this Proposed Rule Change, whichever is later.[21]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00626 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 240.17Ad–22(d)(12).

[19] *Id.*

[20] 15 U.S.C. 78q–1.

[21] In approving the proposed rule change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79762; File No. SR–BatsBZX–2016–90]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Fees for Connectivity and Its Communication and Routing Service Known as Bats Connect

January 9, 2017.

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 December 27, 2016, Bats BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BZX Rules 15.1(a) and (c) to modify its fees for its equity options platform (''BZX Options'') for physical ports and for the use of a communication and routing service known as Bats Connect.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

The text of the proposed rule change is available at the Exchange's Web site at *www.bats.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the fee schedule for BZX Options to modify its fees for physical ports and for the use of a communication and routing service known as Bats Connect. Each of these proposed changes are described below.

Physical Ports

A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: 2,000 per physical port that connects to the System [6] via 1 gigabyte circuit; and 4,000 per physical port that connects to the System via 10 gigabyte circuit. The Exchange proposes to increase the fee per physical port that connects to the System via a 10 gigabyte circuit from 4,000 per month to 6,000 per month in order cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems and enable it to continue to maintain and improve its market technology and services. The Exchange does not propose to amend the fee for a 1 gigabyte circuit, which will remain $2,000 per month.

Bats Connect

The Exchange proposes to increase select fees related to the use of Bats Connect. Bats Connect is offered by the Exchange on a voluntary basis in a capacity similar to a vendor.[7] In sum, Bats Connect is a communication service that provides subscribers an additional means to receive market data from and route orders to any destination connected to the Exchange's network. Bats Connect does not provide any advantage to subscribers for connecting to the Exchange's affiliates [8] as compared to other methods of connectivity. The servers of the subscriber need not be located in the same facilities as the Exchange in order to subscribe to Bats Connect. Subscribers may also seek to utilize Bats Connect in the event of a market disruption where other alternative connection methods become unavailable.

The Exchange charges a monthly connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and broker-dealers that are connected to the Exchange's network via unicast access. The amount of the connectivity fee varies based solely on the bandwidth selected by the subscriber. Specifically, as set forth under the Unicast Access—Order Entry section of the fee schedule, the Exchange charges $350 for 1 Mb, $700 for 5 Mb, $950 for 10 Mb, $1,500 for 25 Mb,$2,500 for 50 Mb, and $3,500 for 100 Mb. The Exchange proposes to increase those fees as follows: $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The proposed increases are designed to cover increased costs related to hardware, installation, and testing, as well as increased expenses involved in maintaining and managing the service. The Exchange does not propose to increase the fees for the 25 Mb, 50 Mb and 100 Mb connections as those fees will remain $1,500, $2,500, and $3,500, respectively.

Bats Connect also allows subscribers to receive market data feeds from the exchanges connected to the Exchange's network. In such case, the subscriber pays the Exchange a connectivity fee, which are set forth under the Market Data Connectivity section of the fee schedule and vary based solely on the amount of bandwidth required to transmit the selected data product to the subscriber.[9] The proposed connectivity fees currently range from no charge to $11,500 based on the market data product the subscriber selects. The Exchange proposes to increase select connectivity fees for market data as follows:

Data feed	Current fee	Proposed fee
UQDF/UTDF/OMDF	$650	$1,200
CQS/CTS	1,000	1,400
OPRA	3,500	4,500
Nasdaq TotalView	1,300	1,500
Nasdaq BX TotalView	650	1,000
Nasdaq PSX TotalView	350	750
NYSE Integrated	11,500	14,500
NYSE ArcaBook	1,000	1,250
NYSE MKT OpenBook Ultra	150	500
NYSE Alerts	250	500
NYSE Imbalances	100	500
NYSE Arca Trades	250	500
BBDS/TDDS	100	500

[6] The term ''System'' is defined as ''the automated trading system used by BZX Options for the trading of options contracts.'' *See* Exchange Rule 16.1(a)(59).

[7] *See* Exchange Rule 13.8.

[8] The Exchange's affiliated exchanges are Bats EDGX Exchange, Inc. (''EDGX''), Bats EDGA Exchange, Inc. (''EDGA''), and Bats BYX Exchange, Inc. (''BYX'').

[9] Subscribers pays any fees charged by the exchange providing the market data feed directly to that exchange.

The proposed increases are designed to allow the Exchange to cover the increased costs related to the amount of bandwidth required to provide connectivity to receive market data as well as the costs of maintaining that infrastructure.

The Exchange also charges a discounted fee of $4,160 per month for subscribers who purchase connectivity to a bundle of select market data products, known as the U.S. Equities Select + SIP Bundle. The following market data products are included in the bundle: UQDF/UTDF/OMDF, CQS/CTS, Nasdaq TotalView, Nasdaq BX TotalView, Nasdaq PSX TotalView, NYSE ArcaBook, NYSE MKT OpenBook Ultra, and BBDS/TTDS.[10] Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would currently pay a total monthly fee of $5,200. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $4,160, which represents a 20% discount. The Exchange proposes to add NYSE OpenBook Ultra to the bundle. Also, in light of the proposed changes outlined above, the Exchange proposes to increase the discounted rate of the bundle to $5,910 per month, which would now represent a 40% discount from the rate of $9,850 a subscriber purchasing connectivity through Bats Connect for each of these market data products would be charged under the proposed rule change.

Lastly, the Exchange proposes to charge a discounted fee of $6,390 per month for subscribers who purchase connectivity to the OPRA, UQDF/UTDF/OMDF, and CQS/CTS data feeds. Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would pay a total monthly fee of $7,100. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $6,390, which represents a 10% discount.

Implementation Date

The Exchange proposes to implement this amendment to its fee schedule on January 3, 2017.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[11] in general, and furthers the objectives of Section 6(b)(4),[12] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

The Exchange believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services.

Physical Ports

The Exchange believes that the proposed fees for a 10 gigabyte circuit of $6,000 per month is reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq'') and NYSE Arca, Inc. (''Arca''), which range from $10,000–$15,000 per month for 10 gigabyte circuits.[13] The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

Bats Connect

The Exchange also believes that its proposed fees for Bats Connect provide for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. First, the Exchange charges a connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and market centers that are connected to the Exchange's network, which varies based solely on the amount of bandwidth selected by the subscriber. The proposed increased connectivity fees remain reasonable and competitive as compared to similar fees charged by other exchanges. For purposes of order routing, the Exchange proposes to now charge $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The New York Stock Exchange, Inc. (''NYSE'') currently charges $300 for 1 Mb, $700 for 5 Mb, and $900 for 10 Mb.[14] In addition, the proposed rates continue to be less than what a subscriber would pay to connect directly to another exchange.[15] The Exchange notes that, overall, the connectivity fee for routing of orders to other market centers proposed by the

[10] The Exchange also proposes to correct a typographical error in referencing BBDS/TDDS in its description of the U.S. Equity Select + SIP bundle.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

[13] *See* Nasdaq Rule 7034(b) *and* the Co-Location section of the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[14] *See* Section 3.6.1 of NYSE's SFTI Americas Product and Service List *available at http://www.nyxdata.com/docs/connectivity.*

[15] *See e.g.,* Nasdaq Rule 7034(b) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

Exchange is similar to that charged by the NYSE.

Second, with regard to utilizing Bats Connect to receive market data products from other exchanges, the Exchange only charges subscribers a connectivity fee, the amount of which is based solely on the amount of bandwidth required to transmit that specific data product to the subscribers. The Exchange believes it is necessary to increase the rates for select market data feeds as described herein to address changes in bandwidth necessary to receive such feeds. The increased fees will also enable the Exchange to continue to cover the increased infrastructure costs while also enabling it to continue to maintain and improve the service.

The amounts of the connectivity fees continue to be reasonable as compared to similar fees charged by other exchanges. For example, for market data connectivity, Nasdaq charges $1,412 per month for CQS/CTS data feed, and the Exchange proposes to charge $1,400 per month connectivity for CQS/CTS data feed.[16]

The Exchange believes it is reasonable to offer such discounted pricing to subscribers who purchase connectivity to a bundle of market data products as it would enable them to reduce their overall connectivity costs for the receipt of market data. The Exchange is not required by any rule or regulation to make Bats Connect available; nor are subscribers required by any rule or regulation to utilize Bats Connect. Accordingly, subscribers can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Moreover, the Exchange believes the proposed fees are reasonable and equitable because they continue to be based on the Exchange's costs to cover the amount of bandwidth required to provide connectivity to the select bundle of data feeds. The proposed fees will continue to allow the Exchange to recoup this cost, while providing subscribers with an alternative means to connect to the select bundle of data feeds at a discounted rate.

Lastly, the Exchange believes the proposed fees are reasonable and equitable because they are based on the Exchange's costs to cover hardware, installation, testing and connection, as well as expenses involved in maintaining and managing the service. The proposed fees allow the Exchange to recoup these costs, while providing subscribers with an alternative means to connect to other exchange and market centers. The Exchange believes that the proposed fees are reasonable and equitable in that they reflect the costs and the benefit of providing alternative connectivity.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Further, excessive fees for connectivity would serve to impair an exchange's ability to compete for order flow rather than burdening competition.

Lastly, the Exchange does not believe the proposed fees for Bats Connect will result in any burden on competition. The proposed rule change is designed to provide subscribers with an alternative means to access other market centers on the Exchange's network if they choose or in the event of a market disruption where other alternative connection methods become unavailable. Bats Connect is not the exclusive method to connect to these market centers and subscribers may utilize alternative methods to connect to the product if they believe the Exchange's proposed pricing is unreasonable or otherwise. Therefore, the Exchange does not believe the proposed rule change will have any effect on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[17] and paragraph (f) of Rule 19b–4 thereunder.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsBZX–2016–90 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–BatsBZX–2016–90. 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

[16] *See* Nasdaq Rule 7034 (setting forth Nasdaq's connectivity fees for receipt of third party market data products).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

available publicly. All submissions should refer to File Number SR–BatsBZX–2016–90 and should be submitted on or before February 3, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00611 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32420; 812–14627]

Guardian Variable Products Trust and Park Avenue Institutional Advisers LLC; Notice of Application

January 9, 2017.

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 in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and Sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements''). The requested exemption would permit an investment adviser to hire and replace certain sub-advisers without shareholder approval and grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

APPLICANTS: Guardian Variable Products Trust (the ''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series (each, a ''Subadvised Series''), and Park Avenue Institutional Advisers LLC, a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Adviser,'' and, together with the Trust, the ''Applicants'').

FILING DATES: The application was filed March 16, 2016, and amended on September 8, 2016.

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 February 3, 2017, 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 under 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: Richard T. Potter, The Guardian Life Insurance Company of America, Law Department, H–23–G, Suite 300, 7 Hanover Square, New York, New York 10004.

FOR FURTHER INFORMATION CONTACT: Kyle R. Ahlgren, Senior Counsel, at (202) 551–6857, or Holly L. Hunter-Ceci, 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.

Summary of the Application

1. The Adviser will serve as the investment adviser to the Subadvised Series pursuant to an investment management agreement with the Trust (the ''Investment Management Agreement'').[1] The Adviser will provide the Subadvised Series with continuous investment management subject to the supervision of the Trust's board of trustees (the ''Board''). The Investment Management Agreement permits the Adviser, subject to the approval of the Board, to delegate to one or more sub-advisers (each, a ''Sub-Adviser'' and collectively, the ''Sub-Advisers'') the responsibility to provide the day-to-day portfolio investment management of each Subadvised Series, subject to the supervision and direction of the Adviser. The primary responsibility for managing the Subadvised Series will remain vested in the Adviser. The Adviser will evaluate, allocate assets to and oversee the Sub-Advisers, and make recommendations about their hiring, termination and replacement to the Board, at all times subject to the authority of the Board.

2. Applicants request an exemption to permit the Adviser, subject to Board approval, to select certain Sub-Advisers[2] pursuant to sub-advisory agreements (each, a ''Sub-Advisory Agreement'' and collectively, the Sub-Advisory Agreements'') and materially amend Sub-Advisory Agreements without obtaining the shareholder approval required under section 15(a) of the Act and rule 18f–2 under the Act. Applicants also seek an exemption from the Disclosure Requirements to permit a Subadvised Series to disclose (as both a dollar amount and a percentage of the Subadvised 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, ''Aggregate Fee Disclosure'').

3. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions provide for, among other safeguards, appropriate disclosure to Subadvised Series' shareholders and notification about sub-advisory changes and enhanced Board oversight to protect the interests of Subadvised Series' shareholders.

4. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such relief is necessary or appropriate in the public interest and consistent with the protection of investors and purposes

[1] Applicants request relief with respect to the Applicants, any existing or future series of the Trust (the ''Series''), and any Subadvised Series. For 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.

[2] The requested relief will extend to certain advisers that meet the definition of ''wholly-owned subsidiary'' in section 2(a)(43) of the Act (''Wholly-Owned Sub-Advisers'') and certain other advisers that are not ''affiliated persons'' (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 sub-adviser to one or more Series (each, a ''Non-Affiliated Sub-Adviser'' and collectively, the ''Non-Affiliated Sub-Advisers''). The requested relief will not extend to any sub-adviser, other than a Wholly-Owned Sub-Adviser, who is an ''affiliated person'' (as such term is defined in section 2(a)(3) of the 1940 Act) of the Subadvised Series or of the Adviser, other than by reason of serving as a sub-adviser to one or more of the Subadvised Series (each, an ''Affiliated Sub-Adviser'' and collectively, the ''Affiliated Sub-Advisers'').

fairly intended by the policy and provisions of the Act. Applicants believe that the requested relief meets this standard because, as further explained in the application, the Investment Management Agreement will remain subject to shareholder approval, while the role of the Sub-Advisers will be substantially equivalent to the role of individual portfolio managers, so that requiring shareholder approval of Sub-Advisory Agreements would impose unnecessary delays and expenses on the Subadvised Series. Applicants believe that the requested relief from the Disclosure Requirements meets this standard because it will improve the Adviser's ability to negotiate fees paid to the Sub-Advisers that are more advantageous for the Subadvised Series.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00628 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79761; File No. SR–BatsEDGX–2016–75]

Self-Regulatory Organizations; Bats EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Fees for Connectivity and Its Communication and Routing Service Known as Bats Connect

January 9, 2017.

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 December 27, 2016, Bats EDGX Exchange, Inc. (''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. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to EDGX Rules 15.1(a) and (c) to modify its fees for its equity options platform (''EDGX Options'') for physical ports and for the use of a communication and routing service known as Bats Connect.

The text of the proposed rule change is available at the Exchange's Web site at *www.bats.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the fee schedule for EDGX Options to modify its fees for physical ports and for the use of a communication and routing service known as Bats Connect. Each of these proposed changes are described below.

Physical Ports

A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,000 per physical port that connects to the System[6] via 1 gigabyte circuit; and $4,000 per physical port that connects to the System via 10 gigabyte circuit. The Exchange proposes to increase the fee per physical port that connects to the System via a 10 gigabyte circuit from $4,000 per month to $6,000 per month in order cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems and enable it to continue to maintain and improve its market technology and services. The Exchange does not propose to amend the fee for a 1 gigabyte circuit, which will remain $2,000 per month.

Bats Connect

The Exchange proposes to increase select fees related to the use of Bats Connect. Bats Connect is offered by the Exchange on a voluntary basis in a capacity similar to a vendor.[7] In sum, Bats Connect is a communication service that provides subscribers an additional means to receive market data from and route orders to any destination connected to the Exchange's network. Bats Connect does not provide any advantage to subscribers for connecting to the Exchange's affiliates[8] as compared to other methods of connectivity. The servers of the subscriber need not be located in the same facilities as the Exchange in order to subscribe to Bats Connect. Subscribers may also seek to utilize Bats Connect in the event of a market disruption where other alternative connection methods become unavailable.

The Exchange charges a monthly connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and broker-dealers that are connected to the Exchange's network via unicast access. The amount of the connectivity fee varies based solely on the bandwidth selected by the subscriber. Specifically, as set forth under the Unicast Access—Order Entry section of the fee schedule, the Exchange charges $350 for 1 Mb, $700 for 5 Mb, $950 for 10 Mb, $1,500 for 25 Mb, $2,500 for 50 Mb, and $3,500 for 100 Mb. The Exchange proposes to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

[6] The term ''System'' is defined as ''the automated trading system used by EDGX Options for the trading of options contracts.'' *See* Exchange Rule 11.16(a)(59) [sic].

[7] *See* Exchange Rule 13.9.

[8] The Exchange's affiliated exchanges are Bats EDGA Exchange, Inc. (''EDGA''), Bats BYX Exchange, Inc. (''BYX''), and Bats BZX Exchange, Inc. (''BZX'').

increase those fees as follows: $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The proposed increases are designed to cover increased costs related to hardware, installation, and testing, as well as increased expenses involved in maintaining and managing the service. The Exchange does not propose to increase the fees for the 25 Mb, 50 Mb and 100 Mb connections as those fees will remain $1,500, $2,500, and $3,500, respectively.

Bats Connect also allows subscribers to receive market data feeds from the exchanges connected to the Exchange's network. In such case, the subscriber pays the Exchange a connectivity fee, which are set forth under the Market Data Connectivity section of the fee schedule and vary based solely on the amount of bandwidth required to transmit the selected data product to the subscriber.[9] The proposed connectivity fees currently range from no charge to $11,500 based on the market data product the subscriber selects. The Exchange proposes to increase select connectivity fees for market data as follows:

Data feed	Current fee	Proposed fee
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CQS/CTS	1,000	1,400
OPRA	3,500	4,500
Nasdaq TotalView	1,300	1,500
Nasdaq BX TotalView	650	1,000
Nasdaq PSX TotalView	350	750
NYSE Integrated	11,500	14,500
NYSE ArcaBook	1,000	1,250
NYSE MKT OpenBook Ultra	150	500
NYSE Alerts	250	500
NYSE Imbalances	100	500
NYSE Arca Trades	250	500
BBDS/TDDS	100	500

The proposed increases are designed to allow the Exchange to cover the increased costs related to the amount of bandwidth required to provide connectivity to receive market data as well as the costs of maintaining that infrastructure.

The Exchange also charges a discounted fee of $4,160 per month for subscribers who purchase connectivity to a bundle of select market data products, known as the U.S. Equities Select + SIP Bundle. The following market data products are included in the bundle: UQDF/UTDF/OMDF, CQS/CTS, Nasdaq TotalView, Nasdaq BX TotalView, Nasdaq PSX TotalView, NYSE ArcaBook, NYSE MKT OpenBook Ultra, and BBDS/TTDS.[10] Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would currently pay a total monthly fee of $5,200. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $4,160, which represents a 20% discount. The Exchange proposes to add NYSE OpenBook Ultra to the bundle. Also, in light of the proposed changes outlined above, the Exchange proposes to increase the discounted rate of the bundle to $5,910 per month, which would now represent a 40% discount from the rate of $9,850 a subscriber purchasing connectivity through Bats Connect for each of these market data products would be charged under the proposed rule change.

Lastly, the Exchange proposes to charge a discounted fee of $6,390 per month for subscribers who purchase connectivity to the OPRA, UQDF/UTDF/OMDF, and CQS/CTS data feeds. Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would pay a total monthly fee of $7,100. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $6,390, which represents a 10% discount.

Implementation Date

The Exchange proposes to implement this amendment to its fee schedule on January 3, 2017.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[11] in general, and furthers the objectives of Section 6(b)(4),[12] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

The Exchange believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any

[9] Subscribers pays any fees charged by the exchange providing the market data feed directly to that exchange.

[10] The Exchange also proposes to correct a typographical error in referencing BBDS/TDDS in its description of the U.S. Equity Select + SIP bundle.

[11] 15 U.S.C. 78f.

[12] 15 U.S.C. 78f(b)(4).

exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services.

Physical Ports

The Exchange believes that the proposed fees for a 10 gigabyte circuit of $6,000 per month is reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq'') and NYSE Arca, Inc. (''Arca''), which range from $10,000—$15,000 per month for 10 gigabyte circuits.[13] The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

Bats Connect

The Exchange also believes that its proposed fees for Bats Connect provide for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. First, the Exchange charges a connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and market centers that are connected to the Exchange's network, which varies based solely on the amount of bandwidth selected by the subscriber. The proposed increased connectivity fees remain reasonable and competitive as compared to similar fees charged by other exchanges. For purposes of order routing, the Exchange proposes to now charge $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The New York Stock Exchange, Inc. (''NYSE'') currently charges $300 for 1 Mb, $700 for 5 Mb, and $900 for 10 Mb.[14] In addition, the proposed rates continue to be less than what a subscriber would pay to connect directly to another exchange.[15] The Exchange notes that, overall, the connectivity fee for routing of orders to other market centers proposed by the Exchange is similar to that charged by the NYSE.

Second, with regard to utilizing Bats Connect to receive market data products from other exchanges, the Exchange only charges subscribers a connectivity fee, the amount of which is based solely on the amount of bandwidth required to transmit that specific data product to the subscribers. The Exchange believes it is necessary to increase the rates for select market data feeds as described herein to address changes in bandwidth necessary to receive such feeds. The increased fees will also enable the Exchange to continue to cover the increased infrastructure costs while also enabling it to continue to maintain and improve the service.

The amounts of the connectivity fees continue to be reasonable as compared to similar fees charged by other exchanges. For example, for market data connectivity, Nasdaq charges $1,412 per month for CQS/CTS data feed, and the Exchange proposes to charge $1,400 per month connectivity for CQS/CTS data feed.[16]

The Exchange believes it is reasonable to offer such discounted pricing to subscribers who purchase connectivity to a bundle of market data products as it would enable them to reduce their overall connectivity costs for the receipt of market data. The Exchange is not required by any rule or regulation to make Bats Connect available; nor are subscribers required by any rule or regulation to utilize Bats Connect. Accordingly, subscribers can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Moreover, the Exchange believes the proposed fees are reasonable and equitable because they continue to be based on the Exchange's costs to cover the amount of bandwidth required to provide connectivity to the select bundle of data feeds. The proposed fees will continue to allow the Exchange to recoup this cost, while providing subscribers with an alternative means to connect to the select bundle of data feeds at a discounted rate.

Lastly, the Exchange believes the proposed fees are reasonable and equitable because they are based on the Exchange's costs to cover hardware, installation, testing and connection, as well as expenses involved in maintaining and managing the service. The proposed fees allow the Exchange to recoup these costs, while providing subscribers with an alternative means to connect to other exchange and market centers. The Exchange believes that the proposed fees are reasonable and equitable in that they reflect the costs and the benefit of providing alternative connectivity.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Further, excessive fees for connectivity would serve to impair an exchange's ability to compete for order flow rather than burdening competition.

Lastly, the Exchange does not believe the proposed fees for Bats Connect will result in any burden on competition. The proposed rule change is designed to provide subscribers with an alternative means to access other market centers on the Exchange's network if they choose or in the event of a market disruption where other alternative connection methods become unavailable. Bats Connect is not the exclusive method to connect to these market centers and subscribers may utilize alternative methods to connect to the product if they believe the Exchange's proposed pricing is unreasonable or otherwise. Therefore, the Exchange does not believe the proposed rule change will have any effect on competition.

[13] *See* Nasdaq Rule 7034(b) *and* the Co-Location section of the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[14] *See* Section 3.6.1 of NYSE's SFTI Americas Product and Service List *available at http://www.nyxdata.com/docs/connectivity.*

[15] *See e.g.,* Nasdaq Rule 7034(b) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[16] *See* Nasdaq Rule 7034 (setting forth Nasdaq's connectivity fees for receipt of third party market data products).

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [17] and paragraph (f) of Rule 19b–4 thereunder.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsEDGX–2016–75 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–BatsEDGX–2016–75. 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–BatsEDGX–2016–75 and should be submitted on or before February 3, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00610 Filed 1–12–17; 8:45 am]

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[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–79760; File No. SR–BatsBYX–2016–40]

Self-Regulatory Organizations; Bats BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify Fees for Connectivity and Its Communication and Routing Service Known as Bats Connect

January 9, 2017.

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 December 27, 2016, Bats BYX Exchange, Inc. (''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. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members [5] and non-members of the Exchange pursuant to BYX Rules 15.1(a) and (c) to modify its fees for physical ports, logical ports, and for the use of a communication and routing service known as Bats Connect.

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

The Exchange proposes to modify its fees for physical ports, logical ports, and for the use of a communication and routing service known as Bats Connect. Each of these proposed changes are described below.

Physical Ports

A physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange's business is primarily conducted on a daily basis, and (ii) a secondary data center, which is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term ''Member'' is defined as ''any registered broker or dealer that has been admitted to membership in the Exchange.'' *See* Exchange Rule 1.5(n).

predominantly maintained for business continuity purposes. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,000 per physical port that connects to the System [6] via 1 gigabyte circuit; and $4,000 per physical port that connects to the System via 10 gigabyte circuit. The Exchange proposes to increase the fee per physical port that connects to the System via a 10 gigabyte circuit from $4,000 per month to $6,000 per month in order cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems and enable it to continue to maintain and improve its market technology and services. The Exchange does not propose to amend the fee for a 1 gigabyte circuit, which will remain $2,000 per month.

Logical Ports

The Exchange currently charges for logical ports (including Multicast PITCH Spin Server and GRP ports) $500 per port per month. A logical port represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-Member and grants that Member or non-Member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. Logical port fees are limited to logical ports in the Exchange's primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees to all Members' and non-Members' logical ports. The Exchange now proposes to increase charges for logical ports (including Multicast PITCH Spin Server and GRP ports) from $500 per port per month to $550 per month. Like as for the proposed fee increase for physical ports described above, the proposed increase in logical port fees is intended to cover increased infrastructure costs associated with establishing ports to connect to the Exchange's Systems and to enable the Exchange to continue to maintain and improve its market technology and services.

Bats Connect

The Exchange proposes to increase select fees related to the use of Bats Connect. Bats Connect is offered by the Exchange on a voluntary basis in a capacity similar to a vendor.[7] In sum, Bats Connect is a communication service that provides subscribers an additional means to receive market data from and route orders to any destination connected to the Exchange's network. Bats Connect does not provide any advantage to subscribers for connecting to the Exchange's affiliates [8] as compared to other methods of connectivity. The servers of the subscriber need not be located in the same facilities as the Exchange in order to subscribe to Bats Connect. Subscribers may also seek to utilize Bats Connect in the event of a market disruption where other alternative connection methods become unavailable.

The Exchange charges a monthly connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and broker-dealers that are connected to the Exchange's network via unicast access. The amount of the connectivity fee varies based solely on the bandwidth selected by the subscriber. Specifically, as set forth under the Unicast Access—Order Entry section of the fee schedule, the Exchange charges $350 for 1 Mb, $700 for 5 Mb, $950 for 10 Mb, $1,500 for 25 Mb, $2,500 for 50 Mb, and $3,500 for 100 Mb. The Exchange proposes to increase those fees as follows: $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The proposed increases are designed to cover increased costs related to hardware, installation, and testing, as well as increased expenses involved in maintaining and managing the service. The Exchange does not propose to increase the fees for the 25 Mb, 50 Mb and 100 Mb connections as those fees will remain $1,500, $2,500, and $3,500, respectively.

Bats Connect also allows subscribers to receive market data feeds from the exchanges connected to the Exchange's network. In such case, the subscriber pays the Exchange a connectivity fee, which are set forth under the Market Data Connectivity section of the fee schedule and vary based solely on the amount of bandwidth required to transmit the selected data product to the subscriber.[9] The proposed connectivity fees currently range from no charge to $11,500 based on the market data product the subscriber selects. The Exchange proposes to increase select connectivity fees for market data as follows:

Data feed	Current fee	Proposed fee
UQDF/UTDF/OMDF	$650	$1,200
CQS/CTS	1,000	1,400
OPRA	3,500	4,500
Nasdaq TotalView	1,300	1,500
Nasdaq BX TotalView	650	1,000
Nasdaq PSX TotalView	350	750
NYSE Integrated	11,500	14,500
NYSE ArcaBook	1,000	1,250
NYSE MKT OpenBook Ultra	150	500
NYSE Alerts	250	500
NYSE Imbalances	100	500
NYSE Arca Trades	250	500
BBDS/TDDS	100	500

The proposed increases are designed to allow the Exchange to cover the increased costs related to the amount of bandwidth required to provide connectivity to receive market data as well as the costs of maintaining that infrastructure.

The Exchange also charges a discounted fee of $4,160 per month for subscribers who purchase connectivity to a bundle of select market data

[6] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' *See* Exchange Rule 1.5(aa).

[7] *See* Exchange Rule 13.8.

[8] The Exchange's affiliated exchanges are Bats EDGX Exchange, Inc. (''EDGX''), Bats EDGA Exchange, Inc. (''EDGA''), and Bats BZX Exchange, Inc. (''BZX'').

[9] Subscribers pays any fees charged by the exchange providing the market data feed directly to that exchange.

products, known as the U.S. Equities Select + SIP Bundle. The following market data products are included in the bundle: UQDF/UTDF/OMDF, CQS/CTS, Nasdaq TotalView, Nasdaq BX TotalView, Nasdaq PSX TotalView, NYSE ArcaBook, NYSE MKT OpenBook Ultra, and BBDS/TTDS.[10] Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would currently pay a total monthly fee of $5,200. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $4,160, which represents a 20% discount. The Exchange proposes to add NYSE OpenBook Ultra to the bundle. Also, in light of the proposed changes outlined above, the Exchange proposes to increase the discounted rate of the bundle to $5,910 per month, which would now represent a 40% discount from the rate of $9,850 a subscriber purchasing connectivity through Bats Connect for each of these market data products would be charged under the proposed rule change.

Lastly, the Exchange proposes to charge a discounted fee of $6,390 per month for subscribers who purchase connectivity to the OPRA, UQDF/UTDF/OMDF, and CQS/CTS data feeds, to be known as the OPRA + SIP Bundle. Absent the discount, a subscriber purchasing connectivity through Bats Connect for each of these market data products would pay a total monthly fee of $7,100. Instead, a subscriber who purchases connectivity to each of the above market data products is charged a monthly fee of $6,390, which represents a 10% discount.

Implementation Date

The Exchange proposes to implement this amendment to its fee schedule on January 3, 2017.[11]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[12] in general, and furthers the objectives of Section 6(b)(4),[13] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The proposed rule change reflects a competitive pricing structure designed to incent market participants to direct their order flow to the Exchange. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the fees and credits remain competitive with those charged by other venues and therefore continue to be reasonable and equitably allocated to Members.

The Exchange believes that the proposal represents an equitable allocation of reasonable dues, fees, and other charges as its fees for physical connectivity are reasonably constrained by competitive alternatives. If a particular exchange charges excessive fees for connectivity, affected Members and non-Members may opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, if the Exchange charges excessive fees, it would stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

Furthermore, the proposed rule change is also an equitable allocation of reasonable dues, fees, and other charges as the Exchange believes that the increased fees obtained will enable it to cover its increased infrastructure costs associated with establishing physical ports to connect to the Exchange's Systems. The additional revenue from the increased fees will also enable the Exchange to continue to maintain and improve its market technology and services.

Physical Ports

The Exchange believes that the proposed fees for a 10 gigabyte circuit of $6,000 per month is reasonable in that they are less than analogous fees charged by the Nasdaq Stock Market LLC (''Nasdaq'') and NYSE Arca, Inc. (''Arca''), which range from $10,000–$15,000 per month for 10 gigabyte circuits.[14] The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all Members and non-Members. Members and non-Members will continue to choose whether they want more than one physical port and choose the method of connectivity based on their specific needs. All Exchange Members that voluntarily select various service options will be charged the same amount for the same services. As is true of all physical connectivity, all Members and non-Members have the option to select any connectivity option, and there is no differentiation with regard to the fees charged for the service.

Logical Ports

The Exchange believes that the increase of fees for logical ports represents an equitable allocation of reasonable dues, fees and other charges. The Exchange believes that its proposed changes to logical port fees are reasonable in light of the benefits to Exchange participants of direct market access and receipt of data. The Exchange believes its proposed fees are reasonable because Nasdaq and NYSE Arca charge comparable rates for logical ports to access such markets.[15]

Bats Connect

The Exchange also believes that its proposed fees for Bats Connect provide for the equitable allocation of reasonable dues, fees and other charges among members and other persons using its facilities. First, the Exchange charges a connectivity fee to subscribers utilizing Bats Connect to route orders to other exchanges and market centers that are connected to the Exchange's network, which varies based solely on the amount of bandwidth selected by the subscriber. The proposed increased connectivity fees remain reasonable and competitive as compared to similar fees charged by other exchanges. For purposes of order routing, the Exchange proposes to now charge $500 for 1 Mb, $1,000 for 5 Mb, and $1,250 for 10 Mb. The New York Stock Exchange, Inc. (''NYSE'') currently charges $300 for 1 Mb, $700 for 5 Mb, and $900 for 10

[10] The Exchange also proposes to correct a typographical error in referencing BBDS/TDDS in its description of the U.S. Equity Select + SIP bundle.

[11] The Exchange notes that the date of its fee schedule was previously updated to January 3, 2017 in SR–BatsBYX–2016–39 (December 6 [sic], 2017). *See* Securities Exchange Act Release No. 79623 (December 20, 2016).

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4).

[14] *See* Nasdaq Rule 7034(b) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[15] *See* Nasdaq Rule 7015(b) (charging a fee of $575 per month for FIX Trading Ports) *and* the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016) (charging a fee of $550 per month for ports for order/quote entry).

Mb.[16] In addition, the proposed rates continue to be less than what a subscriber would pay to connect directly to another exchange.[17] The Exchange notes that, overall, the connectivity fee for routing of orders to other market centers proposed by the Exchange is similar to that charged by the NYSE.

Second, with regard to utilizing Bats Connect to receive market data products from other exchanges, the Exchange only charges subscribers a connectivity fee, the amount of which is based solely on the amount of bandwidth required to transmit that specific data product to the subscribers. The Exchange believes it is necessary to increase the rates for select market data feeds as described herein to address changes in bandwidth necessary to receive such feeds. The increased fees will also enable the Exchange to continue to cover the increased infrastructure costs while also enabling it to continue to maintain and improve the service.

The amounts of the connectivity fees continue to be reasonable as compared to similar fees charged by other exchanges. For example, for market data connectivity, Nasdaq charges $1,412 per month for CQS/CTS data feed, and the Exchange proposes to charge $1,400 per month connectivity for CQS/CTS data feed.[18]

The Exchange believes it is reasonable to offer such discounted pricing to subscribers who purchase connectivity to a bundle of market data products as it would enable them to reduce their overall connectivity costs for the receipt of market data. The Exchange is not required by any rule or regulation to make Bats Connect available; nor are subscribers required by any rule or regulation to utilize Bats Connect. Accordingly, subscribers can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Moreover, the Exchange believes the proposed fees are reasonable and equitable because they continue to be based on the Exchange's costs to cover the amount of bandwidth required to provide connectivity to the select bundle of data feeds. The proposed fees will continue to allow the Exchange to recoup this cost, while providing subscribers with an alternative means to connect to the select bundle of data feeds at a discounted rate.

Lastly, the Exchange believes the proposed fees are reasonable and equitable because they are based on the Exchange's costs to cover hardware, installation, testing and connection, as well as expenses involved in maintaining and managing the service. The proposed fees allow the Exchange to recoup these costs, while providing subscribers with an alternative means to connect to other exchange and market centers. The Exchange believes that the proposed fees are reasonable and equitable in that they reflect the costs and the benefit of providing alternative connectivity.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Further, excessive fees for connectivity would serve to impair an exchange's ability to compete for order flow rather than burdening competition.

Lastly, the Exchange does not believe the proposed fees for Bats Connect will result in any burden on competition. The proposed rule change is designed to provide subscribers with an alternative means to access other market centers on the Exchange's network if they choose or in the event of a market disruption where other alternative connection methods become unavailable. Bats Connect is not the exclusive method to connect to these market centers and subscribers may utilize alternative methods to connect to the product if they believe the Exchange's proposed pricing is unreasonable or otherwise. Therefore, the Exchange does not believe the proposed rule change will have any effect on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBYX–2016–40 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–BatsBYX–2016–40. 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.,

[16] *See* Section 3.6.1 of NYSE's SFTI Americas Product and Service List *available at http://www.nyxdata.com/docs/connectivity.*

[17] *See e.g.,* Nasdaq Rule 7034(b) *and* the Co-Location section of the NYSE Arca fee schedule *available at https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf* (dated December 2, 2016).

[18] *See* Nasdaq Rule 7034 (setting forth Nasdaq's connectivity fees for receipt of third party market data products).

[19] 15 U.S.C. 78s(b)(3)(A).

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–BatsBYX–2016–40 and should be submitted on or before February 3, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–00609 Filed 1–12–17; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14970 and #14971]

North Carolina Disaster Number NC–00086

AGENCY: U.S. Small Business Administration

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA–4285–DR), dated 11/10/2016.

Incident: Hurricane Matthew.

Incident Period: 10/04/2016 through 10/24/2016.

Effective Date: 01/04/2017.

Physical Loan Application Deadline Date: 01/09/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 08/10/2017.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of North Carolina, dated 11/10/2016, is hereby amended to include the following areas as adversely affected by the disaster. Primary Counties: Warren

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–00704 Filed 1–12–17; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 9848]

In the Matter of the Designation of Jamaah Ansharut Daulah also known as Jemaah Anshorut Daulahalso known as Jamaah Ansharut Daulatalso Known as JAD as a Specially Designated Global Terrorist Pursuant to Section 1(b) of E.O. 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of E.O. 13224 of September 23, 2001, as amended by E.O. 13268 of July 2, 2002, and E.O. 13284 of January 23, 2003, I hereby determine that the entity known as Jamaah Ansharut Daulah, aka Jemaah Anshorut Daulah, aka Jamaah Ansharut Daulat, aka JAD committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of E.O. 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: December 8, 2016.

John F. Kerry,

Secretary of State.

[FR Doc. 2017–00708 Filed 1–12–17; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 9792]

30-Day Notice of Proposed Information Collection: Request for Determination of Possible Loss of United States Citizenship

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to February 13, 2017.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, 2201 C. St. NW., Washington, DC 20522, who may be reached at *mailto:RiversDA@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Determination of Possible Loss of United States Citizenship.
- *OMB Control Number:* 1405–0178.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–4079.
- *Respondents:* United States Citizens.
- *Estimated Number of Respondents:* 600.
- *Estimated Number of Responses:* 600.

- *Average Time per Response:* 40 minutes.
- *Total Estimated Burden Time:* 400 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Voluntary, but if not completed, may not obtain or retain benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The purpose of the DS–4079 questionnaire is to determine current citizenship status and the possibility of loss of United States citizenship. The information provided assists consular officers and the Department of State in determining if the U.S. citizen has lost his or her nationality by voluntarily performing an expatriating act with the intention of relinquishing United States nationality. 8 U.S.C. 1501 grants authority to collect this information.

Methodology

The Bureau of Consular Affairs will post this form on Department of State Web sites to give respondents the opportunity to complete the form online, or print the form and fill it out manually and submit the form in person or by fax or mail.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizens Services, Department of State.

[FR Doc. 2017–00665 Filed 1–12–17; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Tenth RTCA SC–229 406 MHz ELT Plenary Joint With WG–98; Correction

AGENCY: Federal Aviation Administration (FAA).

ACTION: Notice; correction.

SUMMARY: The Federal Aviation Administration published a document in the **Federal Register** of January 9, 2017, concerning the Tenth RTCA SC–229 406 MHz ELT Plenary Joint with WG–98. The document contained the incorrect location.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or 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.*

Correction

In **Federal Register**, of January 9, 2017, in FR doc Vol. 82, No. 5, on page 2435 in Column 3 Correct the caption **ADDRESS** to read:

ADDRESSES: The meeting will be held at: E.A.S.A., Konrad-Adenauer-Ufer 3, D–50668 Cologne, Germany.

Dated: January 10, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–00699 Filed 1–12–17; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Action on Proposed Transportation Project in Illinois

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The action relates to a the proposed construction of a new highway between Huntley Road and Illinois Route 62 and a new bridge crossing over the Fox River in Kane County. The Federal action, taken as a result of an Environmental Assessment and Finding of No Significant Impact under the National Environmental Policy Act, 42 U.S.C. 4321–4351 (NEPA) and 23 CFR part 771 determined certain issues relating to the proposed project. This decision will be used by Federal agencies in subsequent proceedings, including decisions whether to grant licenses, permits, and approvals for the proposed highway project. The decision also may be relied upon by State and local agencies in proceedings on the proposed project.

DATES: By this notice, the FHWA is advising the public of the final agency action subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency action of the proposed highway project will be barred unless the claim is filed on or before June 12, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA Ms. Catherine A. Batey, Division Administrator, 3250 Executive Park Drive, Springfield, Illinois 62703; telephone: (217) 492–4600; email address: *Catherine.Batey@dot.gov.* The FHWA Illinois Division Office's normal business hours are 7:30 a.m. to 4:15 p.m. (Central Standard Time). For the Illinois Department of Transportation: Mr. Jose Rios, Engineer of Program Development, 201 West Center Court, Schaumburg, Illinois 60196; telephone: (847) 705–4000. The Illinois Department of Transportation Region One's normal business hours are 8:00 a.m. to 4:30 p.m. (Central Standard Time). For the Kane County Division of Transportation, Mr. Steve Coffinbarger, Assistant Director, 41W011 Burlington Road, St. Charles, IL 60175; telephone: (630) 584–5265. The Kane County Division of Transportation's normal business hours are 8:00 a.m. to 4:30 p.m. (Central Standard Time).

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has issued a Finding of No Significant Impact (FONSI) in connection with the proposed highway project in Illinois: the proposed construction of a new highway between Huntley Road and Illinois Route 62 and a new bridge crossing over the Fox River in Kane County.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the EA approved July 26, 2016, the FONSI approved November 22, 2016, and in other documents in the FHWA project records. The EA, FONSI, and other documents in the FHWA project file are available by contacting the FHWA, the Illinois Department of Transportation,

or the Kane County Division of Transportation at the addresses provided above. The EA and FONSI also are available online at *http://www.co.kane.il.us/dot/foxBridges/longmeadowPkwy.aspx.* Interested parties may consult the EA, the Errata, and the FONSI for further information on each of the decisions described above.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including, but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351] Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].
2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].
3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303 and 23 U.S.C. 138].
4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Migratory Bird Treaty Act [16 U.S.C. 703–712].
5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*].
6. Water Resources: Safe Drinking Water Act [42 U.S.C. 300(f)–300(j)(6)]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287].
7. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898 Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Authority: 23 U.S.C. 139(l)(1)

Issued on: January 5, 2017.

Glenn D. Fulkerson,

Assistant Division Administrator, Springfield, Illinois.

[FR Doc. 2017–00551 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Statute of Limitations on Claims; Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans), pursuant to 23 U.S.C. 327, and United States Fish and Wildlife Service (USFWS), and United States Army Corp of Engineers (USACE).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans, USFWS and USACE, that are final within the meaning of 23 U.S.C. 139(*l*)(1). The actions relate to a proposed highway project, United States (US) 101/State Route (SR) 84 interchange in the City of Redwood City, along 1.9 miles on US 101 and 0.4 mile on SR 84 in the County of San Mateo, State of California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before June 12, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT:

For Caltrans: Stefan Galvez, Chief of Environmental Analysis; Caltrans District #4; 111 Grand Avenue, Oakland CA 94611; 8 a.m.–5 p.m.; (510) 867–6786; *Stefan.galvez@dot.ca.gov*.

For USFWS: Ryan Olah, Coast Bay Division Chief; USFWS; Sacramento Fish and Wildlife Office; 2800 Cottage Way, Suite W–2605, Sacramento, CA 95825; 8 a.m.–5 p.m.; (916) 414–6623; *ryan_olah@fws.gov*.

For USACE: Calvin Fong, Regulatory Chief; USACE; 1455 Market Street, San Francisco, CA 94103; 8 a.m.–5 p.m.; (415) 977–8461; *Calvin.c.fong@usace.army.mil*.

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans, USFWS, and USACE have taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The project proposes to widen and add lanes to SR 84 (hereafter simply Woodside Road), reconstruct all ramp connections to US 101, and construct direct-connect flyover ramps between US 101 and Veterans Boulevard. The project would also construct additional pedestrian and bicycle facilities throughout the project area and improve the intersections of Woodside Road with Veterans Boulevard, Broadway, and Bay Road to the south of US 101, and Seaport Boulevard/East Bayshore Road/Blomquist Road to the north of US 101. The project extends for 1.9 miles along US 101 and 0.4 mile along Woodside Road. The total project length is 2.3 miles. Federal Project Number SM–050027. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA) for the project, approved on December 16, 2016, in the Caltrans' Finding of No Significant Impact (FONSI) issued on December 16, 2016 and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA and FONSI can also be viewed and downloaded from the project Web site at *http://www.dot.ca.gov/d4/envdocs.htm.*

The USFWS, concurred that the proposed Project will not directly affect the following species or their habitat: Ridgeway's rail (*Laterallus jamaicensis coturniculus*), California least tern (*Sternula antillarum browni*), and salt marsh harvest mouse (*Reithrodontomys raviventris*).

The USACE, concurred that the proposed Project would not affect jurisdictional wetlands or waters of the U.S., as defined in Section 404 of the Clean Water Act. As a result, a Section 404 permit from USACE will not be required.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4351 *et seq.)*
2. Council on Environmental Quality Regulations
3. Map-21, the Moving Ahead for Progress in the 21st Century Act
4. Clean Air Act (42 U.S.C. 7401–7671(q))
5. Migratory Bird Treaty Act (16 U.S.C. 703–712)
6. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended, (16 U.S.C. 470(f) *et seq.*)
7. Clean Water Act (Section 401)
8. Federal Endangered Species Act of 1973 (16 U.S.C. 1531–1543)

9. Fish and Wildlife Coordination Act of 1934, as amended
10. Noise Control Act of 1972
11. Safe Drinking Water Act of 1944, as amended
12. Executive Order 11990—Protection of Wetlands
13. Executive Order 11988 Floodplain Management
14. Executive Order 13112, Invasive Species
15. Executive Order 12898, Federal Actions to Address Environmental Justice and Low-Income Populations
16. Title VI of Civil Rights Act 1964, as amended
17. Clean Air Act of 1963, as amended

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: January 3, 2017.

Matt Schmitz,

Director, Project Delivery, Federal Highway Administration, Sacramento, California.

[FR Doc. 2017–00662 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitations on claims for judicial review of actions by FHWA and other federal agencies.

SUMMARY: This notice announces action taken by the FHWA and other federal agencies that is final within the meaning of 23 U.S.C. 139(l)(1). This final agency action relates to a proposed highway project, Bonner Bridge Replacement Project along NC 12, from Rodanthe to Bodie Island in Dare County, North Carolina. The FHWA's Record of Decision (ROD) identifies the Bridge on New Location as the selected alternative for Phase IIb (Rodanthe Breach) of the Bonner Bridge Replacement Project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before June 12, 2017. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Clarence W. Coleman, P.E., Director of Preconstruction and Environment, Federal Highway Administration, North Carolina Division, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina 27601–1418; Telephone: (919) 747–7014; email: *clarence.coleman@dot.gov.* FHWA North Carolina Division Office's normal business hours are 8 a.m. to 5 p.m. (Eastern Time). For the North Carolina Department of Transportation (NCDOT): Rodger Rochelle, Director of Technical Services, North Carolina Department of Transportation (NCDOT), 1548 Mail Service Center, Raleigh, North Carolina 27699–1548; Telephone (919) 707–2900; email: *rdrochelle@ncdot.gov.* NCDOT Technical Services Division Office's normal business hours are 8 a.m. to 5 p.m. (Eastern Time).

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency action by issuing a Record of Decision (ROD) for the following highway project in the State of North Carolina: Rodanthe Breach Long-Term Improvements for Phase IIb of the Bonner Bridge Replacement Project along Highway NC 12 in Dare County, North Carolina. The project is also known as State Transportation Improvement Program (STIP) Project B–2500B, and is part of the second phase (Phase IIb) of the Parallel Bridge Corridor/Transportation Management Plan (PBC/TMP), which was identified as the selected alternative for the Bonner Bridge Replacement Project (STIP No. B–2500) in the Record of Decision (ROD) approved by FHWA on December 20, 2010. The NC 12 PBC/TMP addresses the length of the entire project for STIP No. B–2500, from the Village of Rodanthe to Bodie Island. The TMP is guiding the implementation of future phases of the project through 2060.

Located along the Outer Banks of North Carolina, the selected alternative for Phase IIb is approximately 2.8 miles in length, including a 2.4-mile long bridge on new location. The proposed alignment for NC 12 would leave the existing NC 12 alignment within the Pea Island National Wildlife Refuge at a point approximately 1.8 miles north of the Refuge boundary and enter Pamlico Sound. The bridge would be in Pamlico Sound until a point north of the Rodanthe emergency ferry terminal, where NC 12 would turn east and enter Rodanthe. The bridge extends approximately 1,400 feet west of the Pamlico Sound shoreline at its farthest point. The Rodanthe area was breached as a result of Hurricane Irene in August 2011 and remains susceptible to breaches at the south end of the Refuge and Rodanthe, as well as the Rodanthe 'S' Curves Hot Spot that experiences high erosion rates.

The FHWA's action, related actions by other Federal agencies and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS)/Final Section 4(f) Evaluation for the project, approved on September 17, 2008; the Revised Final Section 4(f) Evaluation, approved on October 9, 2009; the Environmental Assessment, approved on May 7, 2010; the FHWA ROD approved on December 20, 2010 for Phase I and the PBC/TMP for the remainder of the project; the Phase IIb Environmental Assessment, approved December 3, 2013; a Revised Phase IIb Environmental Assessment, approved May 24, 2016, the FHWA ROD for Phase IIb approved on December 15, 2016 and other documents in the project file. The above documents are available for review by contacting the FHWA or the NCDOT at the addresses provided above. In addition, these documents can be viewed and downloaded from the project Web site at *http://www.ncdot.gov/projects/bonnerbridgereplace/.*

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].
2. Air: Clean Air Act [42 U.S.C. 7401–7671(q)].
3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Coastal Barrier Resources Act [16 U.S.C. 3501–3510].
4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544]; Marine Mammal Protection Act [16 U.S.C. 1361–1407]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(g)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act [16 U.S.C. 1801 *et seq.*].
5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966 [16 U.S.C. 470(f)].
6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)].

7. Wetlands and Water Resources: Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251–1377]; Coastal Barrier Resources Act [16 U.S.C. 3501–3510]; Coastal Zone Management Act [16 U.S.C. 1451–1465]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; TEA–21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

8. Hazardous Materials: Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601–9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA; 42 U.S.C. 11011 *et seq.*); Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901–6992(k)].

9. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species; and E.O. 13186—Responsibilities of Federal Agencies to Protect Migratory Birds.

This notice does not apply to those pending environmental permitting decisions. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1).

Issued on: December 22, 2016.

Clarence W. Coleman,

Director of Preconstruction and Environment, Raleigh, North Carolina.

[FR Doc. 2017–00554 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2017–0001]

Establishment of an Emergency Relief Docket for Calendar Year 2017

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of establishment of public docket.

SUMMARY: This Notice announces the establishment of FRA's emergency relief docket (ERD) for calendar year 2017. The designated ERD for calendar year 2017 is Docket Number FRA–2017–0001.

SUPPLEMENTARY INFORMATION: On May 19, 2009, FRA published a direct final rule establishing ERDs and the procedures for handling petitions for emergency waivers of safety rules, regulations, or standards during an emergency situation or event. 74 FR 23329. The direct final rule became effective on July 20, 2009, and made minor modifications to 49 CFR 211.45 in FRA's Rules of Practice in 49 CFR part 211. Section 211.45(b) provides that each calendar year FRA will establish an ERD in the publicly accessible DOT docket system (available at *http://www.regulations.gov*). Section 211.45(b) further provides that FRA will publish a notice in the **Federal Register** identifying by docket number the ERD for that year. FRA established the ERD and emergency waiver procedures to provide an expedited process for FRA to address the needs of the public and the railroad industry during emergency situations or events. This Notice announces the designated ERD for calendar year 2017 is Docket Number FRA–2017–0001.

As detailed in Section 211.45, if the FRA Administrator determines an emergency event as defined in 49 CFR 211.45(a) has occurred, or that an imminent threat of such an emergency occurring exists, and public safety would benefit from providing the railroad industry with operational relief, the emergency waiver procedures of 49 CFR 211.45 will go into effect. In such an event, the FRA Administrator will issue a statement in the ERD indicating the emergency waiver procedures are in effect and FRA will make every effort to post the statement on its Web site at *http://www.fra.dot.gov.* Any party desiring relief from FRA regulatory requirements as a result of the emergency should submit a petition for emergency waiver under 49 CFR 211.45(e) and (f). Specific instructions for filing petitions for emergency waivers under 49 CFR 211.45 are found at 49 CFR 211.45(f). Specific instructions for filing comments in response to petitions for emergency waivers are at 49 CFR 211.45(h).

Anyone can search the electronic form of any written communications and comments received regarding any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2017–00691 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2002–11896]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 of the Code of Federal Regulations (CFR), this document provides the public notice that by a document dated December 5, 2016, Norfolk Southern Corporation (NS) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 231. FRA assigned the petition Docket Number FRA–2002–11896.

In its petition, NS requested that the FRA extend its existing waiver of compliance from certain provisions of 49 CFR part 231 for an additional 5 years, permitting NS's Triple Crown Service to continue to operate RoadRailer® trains.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE., W12–140, Washington, DC 20590. The Docket

Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by February 27, 2017 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov.*

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2017–00692 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0121]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 of the Code of Federal Regulations (CFR), this provides the public notice that by a document dated December 6, 2016, the Long Island Railroad Company (LIRR) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 214.353(a). FRA assigned the petition Docket Number FRA–2016–0121. LIRR submitted this petition for a partial waiver of a new regulation, which will be set forth in 49 CFR 214.353(a) and will go into effect on April 1, 2017, requiring that conductors who act as roadway workers in charge (RWICs) receive annual training as set forth in that section. *See* 81 FR 37840.

LIRR is not requesting a waiver from the portion of the new rule requiring that it provide conductors who act as RWICs the specified training set forth in the rule. LIRR already includes all of those items in its training of assistant conductors prior to their promotion to conductors. In fact, the level of Qualifications/Certifications for LIRR assistant conductors and conductors far exceeds the RWIC requirements, and LIRR conductors are fully qualified on all operating rules and physical characteristics for LIRR's entire system. LIRR also is revising its syllabus to make sure that, as of April 1, 2017, the refresher training given to conductors includes all of the specified topics, as well as any additional topics recommended in FRA Safety Advisory 2016–02 (*See* 81 FR 85676). Nor is it requesting a waiver from the portion of the new rule requiring that these individuals be qualified every 3 years and, in fact, will require that they be qualified every 2 years. Finally, LIRR is not requesting that the annual training requirement be waived for LIRR's roadway workers or any employees (such as non-roadway worker Engineering Department employees) other than conductors who act as RWICs. It is simply requesting that LIRR be permitted to provide the specified training to its conductors who act as RWICs every 2 years.

LIRR is making this request because of the difficulty of training all of its 1,200 conductors each year. LIRR currently conducts bi-annual block training, with half of its conductors (600 out of 1,200) trained in 1 year and the other half trained the following year. LIRR also notes that it provides all of them each spring with a ''Roadway Worker Refresher Guide'' that includes specific RWIC responsibilities. In running its program in this manner, LIRR is able to maintain its 24 hour a day/7 day a week operation of the largest commuter railroad in the United States and carry over 87 million passengers per year. Requiring that all 1,200 conductors receive training each year would force LIRR to hire additional conductors (an expensive and lengthy process) and/or increase overtime (also expensive) to cover the assignments that conductors cannot cover due to the increased training. LIRR also may need to hire additional training personnel and/or limit the amount of time such training personnel can devote to teaching LIRR employees other non-mandated but useful subjects. As a public benefit corporation that receives much of its funding from tax revenues, these added personnel and training costs then would be passed on to the public.

LIRR has spoken with officials from The International Association of Sheet Metal, Air, Rail and Transportation Workers (SMART) Division, the union representing LIRR's conductors. SMART provided a letter in support, and it is available for review in the public docket for this waiver petition.

Permitting LIRR to instruct and qualify its conductors who act as RWICs on the items set forth in 49 CFR 214.353, *Training and qualification of roadway workers who provide on-track safety for roadway work groups,* every 2 years, rather than instruct them every year and qualify them every 3 years, would allow LIRR to maintain the safety of its passengers and employees and also allow it to maintain its operations without the need to: (i) Hire additional conductors and/or training personnel, (ii) increase overtime, or (iii) reduce training in non-mandated areas. As the waiver would be in the public interest and consistent with public safety, LIRR requests that it be granted.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in

connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by February 27, 2017 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2017–00693 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2015–0030]

Award Management Requirements: Availability of Final Circular

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of availability of final circular.

SUMMARY: The Federal Transit Administration (FTA) has placed in the docket and on its Web site guidance in the form of FTA Circular 5010.1E, ''Award Management Requirements,'' to facilitate implementation of FTA's assistance programs. The final Circular updates the ''Grant Management Requirements'' Circular 5010.1D to reflect various changes in the law, as well as FTA's transition to a new electronic award management system.

DATES: The effective date of the Circular is February 13, 2017.

FOR FURTHER INFORMATION, CONTACT: For program matters, contact Pamela A. Brown, FTA Office of Program Management, at (202) 493–2503, or *pamela.brown@dot.gov.* For legal matters, contact Linda W. Sorkin, FTA Attorney Advisor, Office of Chief Counsel, at (202) 366–0959 or *linda.sorkin@dot.gov.*

SUPPLEMENTARY INFORMATION:

Availability of Final Circular

This notice provides a summary of the final changes to the Award Management Requirements Circular and responds to comments received on the proposed Circular. The final Circular itself is not included in this notice; instead, an electronic version may be found on FTA's Web site, at *www.transit.dot.gov,* and in the docket, at *www.regulations.gov.* Paper copies of the final Circular may be obtained by contacting FTA's Administrative Services Help Desk, at (202) 366–4865.

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I. Overview

FTA is updating its Award Management Requirements Circular (formerly ''Grant Management Requirements'' Circular) to incorporate changes to FTA's programs resulting from enactment of FTA's most recent authorizing legislation, the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114–94, Dec. 4, 2015), as well as the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, July 6, 2012). In addition, the final Circular incorporates Department of Transportation (DOT) regulations, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,'' 2 CFR part 1201, and changes in the terms as used in FTA's new electronic award management system, the Transit Award Management System (TrAMS).

This notice provides a summary of changes to FTA Circular 5010.1D, ''Grant Management Requirements,'' and addresses comments received in response to the February 29, 2016, **Federal Register** notice of proposed circular and request for comments (81 FR 10358). The final Circular 5010.1E, ''Award Management Requirements'' becomes effective on February 13, 2017 and supersedes Circular 5010.1D.

On December 26, 2014, U.S. DOT adopted the Office of Management and Budget (OMB) regulatory guidance, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,'' (Uniform Guidance), 2 CFR part 200, now incorporated by reference in U.S. DOT regulations, 2 CFR part 1201. The Uniform Guidance streamlines and adds to the guidance formerly found in eight OMB Circulars that have been superseded by 2 CFR part 200. While 2 CFR part 1201 adopts most of the Uniform Guidance, part 1201 does contain several DOT-specific provisions.

U.S. DOT regulations, 2 CFR part 1201, apply to an FTA award and any amendments thereto signed by an authorized FTA official on or after December 26, 2014. These regulations supersede 49 CFR part 18, ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' and 49 CFR part 19, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,'' except that Grants and Cooperative Agreements executed before December 26, 2014, continue to be subject to 49 CFR parts 18 and 19 as in effect on the date of such Grants or Cooperative Agreements.

In addition to addressing changes to federal law, the final Circular reflects terminology changes for consistency with FTA's new electronic award management system, TrAMS. The Circular also clarifies FTA's requirements and processes, includes FTA policies, and restructures FTA Circular 5010.1D, ''Grant Management Requirements.'' The final Circular applies to Grants and Cooperative Agreements when program-specific requirements are not addressed in an FTA program-specific Circular.

II. Chapter-by-Chapter Analysis

A. General Comments

Approximately 71 commenters provided feedback to the docket in response to the proposed Award Management Requirements Circular, including providers of public transportation, State Departments of Transportation, bus and bus part manufacturers, members of Congress, industry associations, and individuals.

Generally, commenters were supportive of FTA's efforts to update this Circular. Several commenters suggested the award management process should be streamlined, with Activity Line Items (ALIs) as general as possible while still meeting FTA's oversight needs. Commenters suggested that administrative staff time to receive and then manage Awards is significant, given the specificity of information required, and that specific ALIs and scope codes do not ensure better oversight or stronger adherence to federal law. Commenters suggested that Grant Agreements and Cooperative Agreements simply provide a ''general understanding of the project'' in place of the specific detail required currently. FTA did not propose any changes to the ALI and scope codes as the level of information is necessary to define what is being funded and to report on program activities.

Commenters further suggested that, in particular for states, FTA should approach ''Administration of Award'' at the recipient level, giving states more flexibility to define projects for subrecipients over the course of implementing an Award. In response, FTA's practice is to approach Administration of Award at the recipient level. States and designated recipients are required to have a State or Program Management Plan and manage subrecipient programs in compliance with that plan. Further, when FTA last issued the Rural Area Formula Program Circular (C. 9040.1G), FTA made streamlining efforts; for example, commenters were supportive of FTA providing flexibility to states when making minor revisions to the program of projects.

B. Chapter I—Introduction and Background

Chapter I covers general information regarding FTA, FTA's authorizing legislation, *Grants.gov*, and how to contact FTA; this chapter also includes definitions and acronyms used in the Circular. In Chapter I, FTA proposed a new list of acronyms and their meanings, as well as changes to definitions, particularly those needed for consistency with 49 U.S.C. chapter 53 as amended by the FAST Act and MAP–21, the Uniform Guidance, and TrAMS.

In the proposed Circular, FTA added and amended numerous definitions to align with changes in the law and TrAMS. Some commenters noted defined terms and acronyms that were not included in the text of the document; FTA has reviewed all defined terms and acronyms to ensure all are used in the text of the Circular. Similarly, FTA has added terms (such as ''Intelligent Transportation Systems,'' ''Project Budget'') in response to commenters who noted the terms would make the Circular easier to read.

A number of commenters suggested small edits to some of the definitions, and FTA adopted most of those suggestions. For example, FTA has amended the definition of the term ''Rolling Stock Repowering'' to clarify that repowering does not require a propulsion system to be replaced with a different type of propulsion system, and amended the definition of the term ''Overhaul'' to state that it applies to revenue and non-revenue vehicles. Where terms included in the Circular are defined in regulation, FTA has not amended the Circular definition; this includes terms such as ''Subrecipient'' (2 CFR 200.93) and ''Questioned Cost'' (2 CFR 200.84). One commenter sought a definition of ''non-functional landscaping''; in response, FTA has included examples of functional landscaping in the definition of ''Associated Transit Improvement.''

Finally, several commenters expressed concern with the definition of ''Capital Asset,'' both in reference to proposed text indicating an asset with a useful life of at least one year, and to the value of capital assets, suggesting that no individual asset with an initial value below $50,000 should be deemed capital for FTA purposes or tracked as a unit of equipment. FTA has amended the definition from a useful life of ''at least one year'' to a useful life of ''more than one year.'' In addition, FTA has amended the definition for consistency with the Uniform Guidance (2 CFR 200.12) and FTA's Transit Asset Management (TAM) rule (49 CFR 625.5). Notably, the TAM rule requires an inventory of ''all capital assets that a provider owns, except equipment with an acquisition value under $50,000 that is not a service vehicle.''

C. Chapter II—Circular Overview

Chapter II covers general information regarding the requirements and procedures for FTA programs, particularly when a program-specific Circular does not discuss a particular issue.

Chapter II lists descriptions of new or revised programs under 49 U.S.C. chapter 53, as amended by the FAST Act and MAP–21. As in Circular 5010.1D, Chapter II then discusses various federal civil rights requirements, such as those pertaining to the Americans with Disabilities Act (ADA), Title VI of the Civil Rights Act of 1964 (Title VI), Equal Employment Opportunity (EEO), and Disadvantaged Business Enterprise (DBE).

The proposed Circular provided updates to Chapter II consistent with changes in the law and FTA policy. FTA has made some edits to this chapter for clarity and ease of reading. In response to comments, FTA had edited the section on Disadvantaged Business Enterprise (DBE), including Transit Vehicle Manufacturers (TVM), and closely reviewed to ensure the Circular text is consistent with the DOT DBE regulations.

D. Chapter III—Administration of the Award

Chapter III provides more detail about administrative requirements that accompany an Award to ensure compliance with 49 U.S.C. chapter 53 and the Uniform Guidance. While Chapter III of the final Circular covers the same information found in Circular 5010.1D, FTA proposed substantial edits to this chapter.

In response to comments, FTA included the stages of the Award Cycle in a bulleted list, in order to provide clarity for readers. In addition, the Department is now using the term ''notice of funding opportunity'' or NOFO, in place of ''notice of funding availability'' or NOFA, so FTA has used the acronym ''NOFO'' in the final Circular.

In section 3, Reporting Requirements, one commenter read the sentence, ''FTA's policy for reporting requirements may vary depending on the size of the recipient or the type or amount of federal assistance the recipient receives'' as meaning the recipient might be able to negotiate its reporting requirements with FTA. The sentence following the above-quoted sentence is instructive: ''The Award may include special reporting requirements.'' In other words, there are cases where additional reporting may be required depending on the circumstances; however, the basic reporting requirements apply to all recipients, with some variation as necessary and appropriate, as determined by FTA.

A few commenters had questions about the reporting requirements for transit vehicle manufacturers (TVM). The regulation at 49 CFR 26.49 requires recipients to report to FTA the name of the TVM contractor and the total dollar amount of the contract to FTA within 30 days of entering into a contract for a federally-funded vehicle. FTA has amended the language in the Circular for clarity. One commenter questioned the threshold for reporting under the Federal Funding Accountability and Transparency Act of 2006 (FFATA) (Pub. L. 109–282, Sept. 26, 2006). The threshold for reporting is $25,000, not $25 million as suggested by the commenter.

Throughout Chapter III, FTA has made edits as requested by commenters to ensure consistency, add clarity, and improve readability. Specifically, FTA has edited the section on NTD reporting to include additional information on the small systems waiver, tribal reporting, annual and monthly reports, and safety reports. In addition, FTA has made clarifying edits to the section on modifications to the award, including award budget revisions and amendments to awards; as well as to the section on award closeout.

E. Chapter IV—Management of the Award

Chapter IV includes guidance regarding the management, use, and disposition of FTA assisted assets, including real property and the facilities purchased or constructed thereon, equipment consisting of rolling stock and other items of personal property, and supplies, consistent with 2 CFR part 1201 and 2 CFR part 200. It also addresses the design and construction of facilities in light of amendments to 49 U.S.C. chapter 53.

1. Real Property

One commenter sought clarity on the text related to preliminary discussions and preliminary negotiations related to acquisition of real property. The text in the Circular is clear that preliminary discussions and preliminary negotiations are two different activities.

FTA proposed that the paragraph, ''title to real property'' require the recipient to include a covenant in the title of the property acquired that assures non-discrimination during the useful life of the property. One commenter suggested this covenant was neither necessary nor customary for commercial real estate transactions. The U.S. DOT Title VI regulation at 49 CFR 21.7 provides, ''the instrument effecting or recording the transfer shall contain a covenant running with the land assuring nondiscrimination for the period during which the real property is used for a purpose for which the federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.'' There is a similar provision in the Department's Section 504 regulation at 49 CFR 27.9. Therefore, FTA has not amended the language.

Some commenters had questions about real property inventory and reporting, with one commenter recommending the inventory/reporting requirements be removed, as pulling data for property could be time-consuming and expensive. To clarify, the requirement applies only to new federal awards made on or after December 26, 2014. The Excess Real Property and Utilization Plan continues to apply to awards made prior to December 26, 2014. FTA has made clarifying edits to this section.

FTA received several comments related to incidental use of federal assets. The proposed Circular stated that FTA approval would be required for incidental use. One commenter suggested FTA reconsider that proposal; FTA has removed the language and instead the final Circular states the recipient must maintain satisfactory continuing control over the asset, and should consult with FTA before continuing with incidental use. FTA proposed that an incidental use agreement should permit revocation by the recipient. One commenter observed that in its experience, few incidental users would agree to a revocation provision, and suggested FTA strike the language or clarify that a revocation clause may be commercially reasonable under certain circumstances. FTA has accepted the suggestion and added the words, ''if commercially feasible'' to the provision. Two commenters asked about ''no-income incidental use''; in response, FTA has provided examples of no-income use.

One commenter suggested the language on shared use was not clear as to whether a non-transit partner is free to sell or lease the part of the property that the partner is occupying. FTA has added text to this section to be clear that the recipient must maintain satisfactory continuing control of the property.

2. Equipment, Supplies, and Rolling Stock

Section 4 of Chapter IV addresses issues pertaining to the acquisition, use, management, and disposition of equipment and supplies, including rolling stock.

FTA received several comments pertaining to useful life of rolling stock. One commenter suggested the useful life of a trolley should be the same as that of a bus, given they operate in the same environment. The Circular indicates that trolleys with combustion engines do have the same useful life as a bus of similar size. Trolleys that operate on overhead catenaries have a longer useful life as the propulsion system lasts longer than combustion engines. For rebuilt buses, FTA proposed the additional useful life be the remaining useful life at the time of rebuild plus four years. One commenter suggested the extension of useful life be based on the cost of repowering the vehicle, and two commenters suggested that FTA add a mileage option to the useful life, in addition to years. FTA declines to accept the first suggestion, and we have amended the Circular to include ''or miles equivalent to four years.''

FTA specifically sought comment on whether the current useful life requirement for buses discourages the consideration of zero emission technology, and if so, what an appropriate useful life requirement for these vehicles should be and/or whether these requirements should change over time as the technology advances. One commenter suggested that FTA consider reassessing its useful life and spare ratio requirements for zero emission vehicles. One commenter suggested that a rigid useful life requirement prevents transit agencies from adopting new technologies when they are first introduced. The commenter suggested that a graduated useful life policy for new technologies would mean that manufacturers would commit to a certain durability, but recipients would have the option to upgrade prior to the end of the useful life of the vehicles they've acquired, as additional technologies become available. FTA did not receive information sufficient to determine another method of determining whether useful life for zero emission technology would be sufficient or appropriate and has retained the current language.

Several commenters addressed zero emission buses and spare ratio requirements. The proposed Circular added the introduction of zero emission vehicles as a reason that an agency would be permitted to maintain their contingency fleet. One commenter noted that at times, it has experienced up to 45 percent of the zero emission fleet out of commission due to mechanical issues, and a 20 percent spare ratio does not fill that gap. Some commenters suggested removing advanced technology vehicles from the spare ratio calculation. Another commenter suggested that, absent a spare ratio

policy specifically for zero emission buses, FTA's proposal of permitting agencies to include vehicles that have met their useful life in their contingency fleet if the agency is adding zero emission vehicles into its fleet is a reasonable solution. Another commenter suggested that newer technology should not be considered for the spare ratio until the technology is at least five years old and the industry has an understanding of the durability of the technology. In response to these concerns as well as to a comment requesting additional information on contingency fleets, FTA has added language to clarify the use of vehicles held in a contingency fleet. In addition, FTA has retained language from the proposed Circular that permits an agency to seek a spare ratio deviation from FTA for no more than two (2) years.

Similarly, some commenters requested the spare ratio be increased to 25 percent and increased proportionally for fleets with an average vehicle age exceeding 12 years or an average vehicle mileage greater than 500,000. There may be situations in which a recipient may want to seek a spare ratio deviation from FTA, or keep vehicles in a contingency fleet, and the final Circular provides guidance on these issues.

Several small operators had questions about spare ratio requirements for smaller fleets. The proposed Circular stated that the spare ratio requirement of 20 percent applies to recipients operating 50 or more fixed route buses in peak service, but was silent as to the ratio requirement for operators with fewer than 50 fixed route buses in peak service. FTA does not set a specific spare ratio for smaller operators, but expects the number of spare buses to be reasonable taking into account the number of vehicles and variety of vehicle types and sizes. We have added this information to the final Circular for clarity.

3. Remanufactured Vehicles

Almost every commenter to the docket commented on FTA's proposals related to remanufactured vehicles. Generally, commenters objected to FTA including this information in a Circular; asserted that remanufactured vehicles should not be subject to bus testing, useful life, and other requirements that apply to new vehicles; and asserted that remanufactured vehicles have already undergone testing, proven reliable over the years, and have provided value, particularly to smaller transit providers. Commenters asserted that FTA's efforts to define the remanufacturing process limits the manufacturer's ability to control the cost of the remanufacturing process, and that requiring remanufactured vehicles to comply with new bus requirements would diminish the cost and time savings in the remanufacturing process, and likely eliminate remanufactured buses as a viable option.

FTA's previous Grant Management Requirements Circular did not specifically address requirements for the purchase of previously-owned and/or remanufactured vehicles purchased from a third party. As the remanufactured vehicle market has developed, FTA has received questions from recipients on what requirements apply to the acquisition of these vehicles if using FTA funding. As the previous Circular applied Buy America, useful life, and Bus Testing requirements to the acquisition of vehicles in general, unless FTA provided for otherwise, those requirements would have applied to the acquisition of all vehicles whether new or previously owned.

While FTA will continue to study the issue, FTA has modified its requirements in the final Circular to provide guidance for these procurements without proscribing specific performance characteristics. For clarification, FTA has added a definition of previously-owned vehicles and modified its definition of remanufactured vehicles to be a subset of previously-owned vehicles. FTA has added language permitting funds to be used to purchase previously-owned vehicles that had previously met FTA's Bus Testing and Buy America requirements. Recipients are required to identify their intent to purchase previously-owned vehicles and identify the proposed useful life in their procurement. As part of the bid or proposal the recipient is required to obtain from the vendor certification and documentation ascertaining that applicable Bus Testing and Buy America requirements have been met by the original owner.

Additionally, for remanufactured vehicles, the remanufacturer would need to demonstrate compliance with Buy America and DBE TVM requirements. No additional bus testing would be required for the remanufactured vehicles.

Further, FTA has not added any new requirements for bus overhauls or bus rebuilds for work on buses a recipient already owns, whether or not the work is done by the recipient or contracted.

4. Other

FTA proposed a number of changes to the section on capital leases, in accordance with changes to the law pursuant to the FAST Act. One commenter suggested that the organization of the provisions in the proposed Circular was confusing and did not clearly indicate when FTA's capital leasing regulation, 49 CFR part 639, applies and when it doesn't, nor did it adequately explain when section 3019 of the FAST Act applies. Another commenter asked for specificity related to the applicability of 49 CFR part 639. FTA has amended the text of the final Circular to clarify these matters.

Several commenters had questions and suggestions related to disposition of assets. One commenter asked about disposal costs of assets that have become liabilities, as when a bus or railcar is at the end of or past its useful life and there is no buyer for the asset. Disposal of assets is considered an operating cost and thus may be an eligible expense for recipients in small urbanized or rural areas. Often, these assets do have a salvage value that can offset transportation and disposal costs. To the extent there remains a federal interest in the asset disposed of, the final Circular provides that a recipient may subtract $500 or ten percent of the proceeds, whichever is less, for selling and handling expenses, from the amount due to FTA.

For calculating the federal interest in an asset, one commenter requested information on how fair market value is determined. Generally, fair market value is determined by the value an unrelated party is willing to pay for an asset. This may be obtained by advertising the asset for sale, seeking an estimate from dealers, published values for assets (*e.g.,* blue book value), prior experience in valuation of similar assets, selling the asset for scrap, or any reasonable means the recipient has to access to in order to determine the remaining value of the asset.

Section 5 of Chapter IV provides information on design and construction of facilities, sets forth references to major environmental laws and regulations that affect the design and construction of facilities, and clarifies force account requirements.

One commenter objected to language in the proposed Circular stating that recipients agree to comply with FTA ''recommendations and determinations'' pertaining to its review of construction plans and specifications, given the recipient is responsible for managing the Award. The commenter asserted the language suggests FTA would take full control of the Award. Similarly, the commenter suggested that language providing the FTA regional office should be consulted to determine

whether FTA review is necessary to advance the Award to the next level of design could delay Awards. Importantly, the text does not state that FTA will manage or take control of the Award. However, there may be instances in which FTA or its contractors observe a situation that must be addressed, such as a failure to comply with the law. Thus, FTA has not amended the language in the final Circular.

FTA received two comments related to force accounts: one commenter asked whether a force account plan is required for preventive maintenance, and one commenter asked whether the requirement for force account plans was subject to the Paperwork Reduction Act. First, a force account plan is not required for preventive maintenance. Second, FTA has paperwork collection approvals for all of its federal assistance programs. Paperwork submissions and recordkeeping requirements are captured in those approvals.

In addition to the changes described above, FTA made minor edits to the text of Chapter IV for clarity.

F. Chapter V—FTA Oversight

Chapter V includes guidance regarding the various types of reviews that FTA conducts. Reviews are grouped in the following categories: (1) Program Oversight, (2) Safety Oversight, and (3) Project Oversight.

FTA received one comment related to Chapter V. The commenter asked if FTA intended to use the term ''project sponsor'' instead of ''recipient.'' In response, FTA edited the text to state, ''project sponsor or recipient.'' In addition, FTA made minor, clarifying edits to this chapter.

G. Chapter VI—Financial Management

Chapter VI includes guidance regarding internal controls, non-federal share, financial plan, federal principles for determining allowable costs, indirect costs, program income, annual audit, payment procedures, de-obligation of federal assistance, debt service reserve, and the right to terminate.

Farebox Revenues is discussed in the Program Income section of Chapter VI, found at section 7(i). For purposes of operating assistance grants, farebox revenues are deducted from the eligible operating expenses to derive the ''net project cost.'' The question regarding FTA's treatment of farebox revenues for recipients of capital assistance arose in light of the proposed definition of program income in proposed FTA Circular 5010.1E. Although FTA Circular 5010.1D does not discuss the relationship, if any, between program income and farebox revenue, the proposed Circular 5010.1E included explicit language listing farebox revenue as a type of program income. Whereas Circular 5010.1D allowed program income to be spent ''for public transportation purposes,'' the proposed Circular permits program income to be spent only on allowable costs. Under Circular 5010.1D, there are no federal requirements governing the disposition of program income earned after the end of the period of performance (*i.e.,* after the ending date of the final Federal Financial Report), unless the terms of the agreement or the federal agency regulations provide otherwise. In proposed Circular 5010.1E, FTA has included an exception to this general rule for farebox revenue states that farebox revenue retains its status as program income after the close of the Award. FTA has made edits to Chapter VI to withdraw these changes and clarify these points.

FTA received several comments related to indirect costs. One commenter noted that the discussion of indirect costs in section 6 of Chapter VI contained a different definition than that found in the definitions section of Chapter I. Specifically, the text in Chapter VI contains additional language relating to states and local governments and Cost Allocation Plans found in 2 CFR 200.416. We have clarified the language in Chapter VI.

One commenter suggested that FTA clarify that cost allocation plans will not apply to every recipient. The commenter also suggested that FTA clarify that indirect cost proposals and cost allocation plans are separate documents. FTA has made edits to Chapter VI to clarify these points.

One commenter indicated that reporting indirect costs on a cumulative basis in the Federal Financial Report (FFR) would require adding many lines to the FFR. Further, the commenter noted that indirect costs currently are not reported for subrecipients. In response, FTA agrees that cumulative reporting will add lines to the FFR. However, indirect cost rates should be reported for the reporting agency, not for subrecipients. Documentation and reporting on subawards and contractual indirect cost rates should be maintained by the recipient and collected as part of its subrecipient monitoring. We have made edits to Appendix B to provide additional guidance to recipients for this reporting requirement. In addition, a commenter suggested that the requirement to identify the indirect cost rate as a separate budget line item ''would require recipients to provide a level of budget detail that will be impossible to meet.'' The commenter asserted that many Awards contain multiple projects, and many projects are funded by multiple Awards. However, the indirect cost rate should be the same across multiple Awards and multiple projects, as indirect cost rates are not determined on an Award by Award or project by project basis.

H. Appendices

As stated in the summary under Chapter VI, FTA has amended Appendix B, Federal Financial Report, for clarity in reporting indirect costs.

FTA has reversed the order of proposed Appendices F and G, such that now Appendix F is Cost Allocation Plans and Appendix G is Indirect Cost Rate Proposals.

FTA struck proposed Appendix J, ''Award Amendments and Budget Revision Guidelines,'' as the information is otherwise available on FTA's Web site at *https://www.transit.dot.gov/trams.*

In addition to the above, FTA made minor, clarifying edits to the appendices.

Carolyn Flowers,

Acting Administrator.

[FR Doc. 2017–00728 Filed 1–12–17; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Community Development Advisory Board Meeting

ACTION: Notice of open meeting.

SUMMARY: This notice announces the next meeting of the Community Development Advisory Board (the Advisory Board), which provides advice to the Director of the Community Development Financial Institutions Fund (the CDFI Fund). The meeting will be conducted via telephone conference call.

DATES: The meeting will be held from 2:00 p.m. to 3:00 p.m. Eastern Standard Time on Monday, January 30, 2017.

Submission of Written Statements: Participation in the discussions at the meeting will be limited to Advisory Board members, Department of the Treasury staff, and certain invited guests. Anyone who would like to have the Advisory Board consider a written statement must submit it by 5:00 p.m. Eastern Standard Time on Monday, January 23, 2017. Send paper statements to Bill Luecht, Senior Advisor, Office of

Legislative and External Affairs, CDFI Fund, 1500 Pennsylvania Avenue NW., Washington, DC 20220. Send electronic statements to *AdvisoryBoard@cdfi.treas.gov.*

In general, the CDFI Fund will make all statements available in their original format, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers, for public inspection, and photocopying at the CDFI Fund. The CDFI Fund is open on official business days between the hours of 9:00 a.m. and 5:00 p.m. You can make an appointment to inspect statements by emailing *AdvisoryBoard@cdfi.treas.gov.* All statements received, including attachments and other supporting materials, are 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: Bill Luecht, Senior Advisor, Office of Legislative and External Affairs, CDFI Fund, 1500 Pennsylvania Avenue NW., Washington, DC 20220, (202) 653–0322 (this is not a toll free number) or *AdvisoryBoard@cdfi.treas.gov.* Other information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's Web site at *http://www.cdfifund.gov.*

SUPPLEMENTARY INFORMATION: Section 104(d) of the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4703(d)) established the Advisory Board. The charter for the Advisory Board has been filed in accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and with the approval of the Secretary of the Treasury.

The function of the Advisory Board is to advise the Director of the CDFI Fund (who has been delegated the authority to administer the CDFI Fund) on the policies regarding the activities of the CDFI Fund. The Advisory Board shall not advise the CDFI Fund on the approving or declining any particular application for monetary or non-monetary awards. The Advisory Board shall meet at least annually.

It has been determined that this document is not a major rule as defined in Executive Order 12291 and therefore regulatory impact analysis is not required. In addition, this document does not constitute a rule subject to the Regulatory Flexibility Act (5 U.S.C. chapter 6).

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and the regulations thereunder, Bill Luecht, Designated Federal Officer of the Advisory Board, has ordered publication of this notice that the Advisory Board will convene an open meeting which will be conducted via a telephone conference call from 2:00 p.m. to 3:00 p.m. Eastern Standard Time on Monday, January 30, 2017.

Public participation will be limited to 50 individual phone lines. Notification of intent to attend the meeting must be made via email to *AdvisoryBoard@cdfi.treas.gov.* The CDFI Fund will send confirmation of attendance and instructions for accessing the meeting to the first 50 individuals who submit notifications of intent. For more information, please call (202) 653–0322.

The Advisory Board meeting will include (i) a presentation to the full Advisory Board by an Advisory Board subcommittee on a plan to promote the knowledge and utilization of the Access to Capital and Credit in Native Communities report and (ii) deliberation on the recommendations contained therein.

Authority: 12 U.S.C. 4703.

Mary Ann Donovan,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2017–00649 Filed 1–12–17; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to the Sergei Magnitsky Rule of Law Accountability Act of 2012

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing the names of five individuals whose property and interests in property are blocked pursuant to the Sergei Magnitsky Rule of Law Accountability Act of 2012 (the ''Magnitsky Act'').

DATES: OFAC's actions described in this notice were effective on January 9, 2017.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Policy, tel.: 202–622–2746, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*).

Background

On January 9, 2017, OFAC blocked the property and interests in property of the following five individuals pursuant to the Magnitsky Act (Pub. L. 112–208, December 14, 2012):

1. PLAKSIN, Gennady Nikolaevich, Russia; DOB 31 Aug 1961; Gender Male (individual) [MAGNIT].
2. GORDIEVSKY, Stanislav Evgenievich, Russia; DOB 09 Sep 1977; Gender Male (individual) [MAGNIT].
3. LUGOVOI, Andrei Konstantinovich, Russia; DOB 19 Sep 1966; Gender Male (individual) [MAGNIT].
4. KOVTUN, Dmitri, Russia; DOB 1965; Gender Male (individual) [MAGNIT].
5. BASTRYKIN, Alexander Ivanovich, Russia; DOB 27 Aug 1953; Gender Male (individual) [MAGNIT].

Gennady Plaksin and Stanislav Gordievsky are being designated pursuant to Section 404(a) of the Magnitsky Act because they were involved in the criminal conspiracy uncovered by Sergei Magnitsky. Andrei Lugovoi and Dmitri Kovtun are being designated pursuant to Section 404(a) of the Magnitsky Act because they are responsible for the extrajudicial killing of Alexander Litvinenko for his activities seeking to expose illegal activity carried out by officials of the Government of the Russian Federation. Alexander Bastrykin is being designated pursuant to Section 404(a) of the Magnitsky Act for participating in efforts to conceal the legal liability for the detention, abuse, or death of Sergei Magnitsky.

Dated: January 9, 2017.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2017–00603 Filed 1–12–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant To The Cuban Assets Control Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names

of 10 individuals and 14 entities whose names have been removed from the list of Specially Designated Nationals and Blocked Persons (SDN List) pursuant to the Cuban Assets Control Regulations.

DATES: OFAC's actions described in this notice were effective on January 6, 2017.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available from OFAC's Web site at *http://www.treasury.gov/ofac.*

Notice of OFAC Actions

On January 6, 2017, OFAC removed from the SDN List the persons listed below, whose property and interests in property were blocked pursuant to the Cuban Assets Control Regulations.

Individuals

1. ANGELINI, Alejandro Abood, Panama (individual) [CUBA].
2. DOMINGUEZ, Carlos, Vinales Tours, Oaxaca 80, Roma, Mexico, D.F., Mexico (individual) [CUBA].
3. DE FRANCE, Naomi A., Cubanatur, Baja California 255, Edificio B., Oficina 103, Condesa, Mexico, D.F. 06500, Mexico (individual) [CUBA].
4. EGGLETON, Wilfred, Baja California 255, Edificio B., Oficina 103, Condesa, Mexico, D.F. 06500, Mexico; Director General, Cubanatur (individual) [CUBA].
5. GARCIA, Daniel, Avenida Insurgentes Sur No. 421, Bloque B Despacho 404, Mexico, D.F. 06100, Mexico; Manager, Promociones Artisticas (PROARTE) (individual) [CUBA].
6. GONZALEZ, Carlos Alfonso (a.k.a. ALFONSO, Carlos), Panama (individual) [CUBA].
7. ORTIZ, Guadalupe, Cubanatur, Baja California 255, Edificio B, Oficina 103, Condesa, Mexico, D.F. 06500, Mexico (individual) [CUBA].
8. PONCE DE LEON GOMEZ, Lazaro, Medira, Mexico (individual) [CUBA].
9. SANTO, Anabel, Avenida Insurgentes Sur No. 421, Bloque B Despacho 404, Mexico, D.F. 06100, Mexico (individual) [CUBA].
10. YAM, Melvia Isabel Gallegos, Merida, Mexico (individual) [CUBA].

Entities

1. CARIBSUGAR INTERNATIONAL TRADERS, S.A., 125–133 Camden High Street, London NW1 7JR, United Kingdom [CUBA].
2. CUREF METAL PROCESSING BV, Boezembolcht 23, Rotterdam, Netherlands [CUBA].
3. MANZPER CORP., Panama [CUBA].
4. NIPPON–CARIBBEAN CO., LTD., Chuo-Ku, Akasaki-Chuo 1–1 Akasaki Bldg., Tokyo, Japan [CUBA].
5. BELMEX IMPORT EXPORT CO., LTD., 24 Corner Regent and Kings Streets, Belize City, Belize [CUBA].
6. COLONY TRADING, S.A., Panama [CUBA].
7. CORPORACION ARGENTINA DE INGENIERIA Y ARQUITECTURA, S.A. (a.k.a. COPIA, S.A.), San Martin 323, 4th Floor, Buenos Aires, Argentina [CUBA].
8. EXPORTADORA DEL CARIBE, Medira, Mexico [CUBA].
9. KYOEI INTERNATIONAL COMPANY, LIMITED, Tokyo, Japan [CUBA].
10. LEVERYE, S.A., Corrientes 1386, 5th Floor, Buenos Aires, Argentina [CUBA].
11. MARISCO DE FARALLON, S.A. (a.k.a. MARISCOS DE FARALLON, S.A.), Panama [CUBA].
12. PANOAMERICANA, Panama [CUBA].
13. PROMOCIONES ARTISTICAS (a.k.a. PROARTE), Avenida Insurgentes Sur No. 421, Bloque B Despacho 404, C.P. 06100, Mexico, D.F., Mexico [CUBA].
14. SHIPLEY SHIPPING CORP., Panama [CUBA].

Dated: January 6, 2017.

Gregory T. Gatjanis,

Associate Director, Office of Global Targeting, Office of Foreign Assets Control.

[FR Doc. 2017–00647 Filed 1–12–17; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of Citizens Coinage Advisory Committee January 17, 2017, Public Meeting Pursuant to United States Code, Title 31, Section 5135(b)(8)(C), the United States Mint Announces the Citizens Coinage Advisory Committee (CCAC) Public Meeting Scheduled for January 17, 2017

Date: January 17, 2017.

Time: 1:00 p.m. to 2:00 p.m. EST.

Location: This meeting will occur *via teleconference.* Interested members of the public may dial in to listen to the meeting at (866) 564–9287/Access Code: 62956028.

Subject: Consideration of artists' concepts for the 2019 and 2020 Native American $1 Coins.

Interested persons should call the CCAC HOTLINE at (202) 354–7502 for the latest update on meeting time and room location.

In accordance with 31 U.S.C. 5135, the CCAC:

- Advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals.
- Advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Makes recommendations with respect to the mintage level for any commemorative coin recommended.

FOR FURTHER INFORMATION CONTACT: Betty Birdsong, Acting United States Mint Liaison to the CCAC; 801 9th Street NW., Washington, DC 20220; or call 202–354–7200.

Any member of the public interested in submitting matters for the CCAC's consideration is invited to submit them by fax to the following number: 202–756–6525.

Authority: 31 U.S.C. 5135(b)(8)(C).

Dated: January 9, 2017.

David Motl,

Acting Deputy Director, United States Mint.

[FR Doc. 2017–00594 Filed 1–12–17; 8:45 am]

BILLING CODE 4810–37–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0801]

Agency Information Collection Activity: (Non-Degenerative Arthritis (Including Inflammatory, Autoimmune, Crystalline and Infectious Arthritis) and Dysbaric Osteonecrosis Disability Benefits Questionnaire (VA Form 21–0960M–3)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

VA Forms 21–0960M–3 is used to gather necessary information from a claimant's treating physician regarding the results of medical examinations.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 14, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0801'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: (Non-Degenerative Arthritis (including inflammatory, autoimmune, crystalline and infectious arthritis) and Dysbaric Osteonecrosis Disability Benefits Questionnaire (VA Form 21–0960M–3).

OMB Control Number: 2900–0801.

Type of Review: Extension of an approved collection.

Abstract: VA Forms 21–0960M–3 is used to gather necessary information from a claimant's treating physician regarding the results of medical examinations.

Affected Public: Individuals or households.

Estimated Annual Burden: 25,000 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 100,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–00624 Filed 1–12–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Energy

Federal Energy Regulatory Commission

18 CFR Parts 35 and 37

Reform of Generator Interconnection Procedures and Agreements; Proposed Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 35 and 37

[Docket No. RM17–8–000]

Reform of Generator Interconnection Procedures and Agreements

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to revise its regulations and the *pro forma* Large Generator Interconnection Procedures and *pro forma* Large Generator Interconnection Agreement. The Commission proposes reforms designed to improve certainty, promote more informed interconnection, and enhance interconnection processes. The proposed reforms are intended to ensure that the generator interconnection process is just and reasonable and not unduly discriminatory or preferential.

DATES: Comments are due March 14, 2017.

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 and not 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 on submitting comments and additional information on the rulemaking process, see the Comment Procedures section of this document.

FOR FURTHER INFORMATION CONTACT:

Tony Dobbins (Technical Information), Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6630, *Tony.Dobbins@ferc.gov*.

Adam Pan (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE.,Washington, DC 20426, (202) 502–6023, *Adam.Pan@ferc.gov.*

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NOT PUBLISHED IN THE FEDERAL REGISTER

Appendix A: List of Short Names of Commenters on the AWEA Petition (Docket No. RM 15–21–000) and the 2016 Technical Conference (Docket No. RM16–12–000)

Appendix B: Compilation of proposed changes to the pro forma LGIP

Appendix C: Compilation of proposed changes to the pro forma LGIA

I. Introduction

1. In this Notice of Proposed Rulemaking (Proposed Rule), the Commission is proposing to revise its regulations and the *pro forma* Large Generator Interconnection Procedures (LGIP) and *pro forma* Large Generator Interconnection Agreement (LGIA).[1] The Commission proposes reforms designed to improve certainty, promote more informed interconnection, and enhance interconnection processes. The proposed reforms are intended to ensure that the generator interconnection process is just and reasonable and not unduly discriminatory or preferential.[2]

2. The *pro forma* LGIP and LGIA establish the terms and conditions under which public utilities [3] must provide interconnection service to Large Generating Facilities.[4] While Order No. 2003 was a significant step to reduce undue discrimination in the generator interconnection process, interconnection customers have continued to express concerns with systemic inefficiencies and discriminatory practices that affect them.[5] In addition, there have been a number of developments that impact generator interconnection, including the changing resource mix, the emergence of new technologies, and state and federal policies that have impacted the resource mix. At the same time, transmission providers have expressed concern that the interconnection study process can be difficult to manage because some interconnection customers submit requests for interconnection service associated with new generating facilities that have little chance of reaching commercial operation. Upon consideration of these issues, the Commission finds that it is appropriate to propose reforms to the interconnection processes.

3. In 2015, the American Wind Energy Association (AWEA) filed a Petition for Rulemaking (Petition) requesting changes to the Commission's interconnection rules and procedures.[6] The Commission sought and received comments on the Petition. In May 2016, a technical conference was convened to further explore these issues (2016 Technical Conference). Comments were requested and received both prior to the technical conference and after the technical conference.

4. Based, in part, on that input, the Commission has identified proposed reforms that could remedy potential shortcomings in the existing interconnection processes. The Commission believes the proposed reforms will benefit interconnection customers through more timely and cost-effective interconnection and will benefit transmission providers by mitigating the potential for serial re-studies associated with late-stage interconnection request withdrawals. Specifically, the Commission believes that the provision of more timely and accurate information could increase certainty for interconnection customers and assist them in earlier evaluation and quicker development, as well as assist in earlier, less disruptive withdrawals from the interconnection queue. The Commission also believes that more thorough and transparent information presented for the interconnection customer could enable more informed decisions earlier in the interconnection process, which could reduce late-stage interconnection request withdrawals and result in fewer restudies and delays. More timely and accurate information regarding an interconnection request, as well as greater transparency, will also reduce the incentive for interconnection customers to submit multiple interconnection requests when they only intend to see one to commercial operation. The Commission has also identified a set of reforms that enhance the interconnection process by, for example, addressing interconnection issues experienced most acutely by new technologies. The Commission believes there are ways to allow flexibility in the interconnection process to accommodate innovation.

5. Specifically, the Commission preliminarily finds that certain interconnection practices may not be just and reasonable and may be unduly discriminatory or preferential and proposes several potential reforms. The Commission is proposing fourteen reforms that focus on improving aspects of the *pro forma* LGIP and LGIA, the *pro forma* Open Access Transmission Tariff, and the Commission's regulations. The proposed reforms fall into three broad categories and are intended to: (1) Improve certainty in the interconnection process; (2) improve transparency by providing more information to interconnection customers; and (3) enhance interconnection processes.

6. First, the Commission proposes four reforms to improve certainty by affording interconnection customers more predictability in the interconnection process. To accomplish this goal, the Commission proposes to: (1) Revise the *pro forma* LGIP to require transmission providers that conduct cluster studies to move toward a scheduled, periodic restudy process; (2) remove from the *pro forma* LGIA the limitation that interconnection customers may only exercise the option to build transmission provider's interconnection facilities and stand alone network upgrades if the transmission owner cannot meet the dates proposed by the interconnection customer; (3) modify the *pro forma* LGIA to require mutual agreement between the transmission owner and interconnection customer for the transmission owner to opt to initially self-fund the costs of the construction of network upgrades; and (4) require that the Regional Transmission Organizations (RTO) and Independent System Operators (ISO) establish dispute resolution procedures for interconnection disputes. The Commission also seeks comment on the extent to which a cap on the network upgrade costs for which interconnection customers are responsible can mitigate the potential for serial restudies without inappropriately shifting cost responsibility.

7. Second, the Commission proposes five reforms to improve transparency by providing improved information for the benefit of all participants in the interconnection process. These reforms would provide a fuller picture of the considerations involved in interconnecting a new large generating facility. The Commission proposes to: (1) Require transmission providers to outline and make public a method for

[1] *Standardization of Generator Interconnection Agreements and Procedures,* Order No. 2003, FERC Stats. & Regs. ¶ 31,146 (2003) (Order No. 2003), *order on reh'g,* Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 (Order No. 2003–A), *order on reh'g,* Order No. 2003–B, FERC Stats. & Regs. ¶ 31,171 (2004) (Order No. 2003–B), *order on reh'g,* Order No. 2003–C, FERC Stats. & Regs. ¶ 31,190 (2005) (Order No. 2003–C), *aff'd sub nom. Nat'l Ass'n of Regulatory Util. Comm'rs* v. *FERC,* 475 F.3d 1277 (D.C. Cir. 2007), *cert. denied,* 552 U.S. 1230 (2008).

[2] In this proceeding, the Commission refers to comments and filings in Docket Nos. RM15–21–000 and RM16–12–000. A list of commenters in those proceedings and the abbreviated names used in this Proposed Rule appears in Appendix A. Any comments to this Proposed Rule should be filed in this proceeding, Docket No. RM17–8–000.

[3] A public utility is a utility that owns, controls, or operates facilities used for transmitting electric energy in interstate commerce, as defined by the Federal Power Act (FPA). *See* 16 U.S.C. 824(e) (2012). A non-public utility that seeks voluntary compliance with the reciprocity condition of an Open Access Transmission Tariff (OATT) may satisfy that condition by filing an OATT, which includes the *pro forma* LGIP and the *pro forma* LGIA. *See* Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 773.

[4] A large generating facility is ''a Generating Facility having a Generating Facility Capacity of more than 20 MW.'' *Pro forma* LGIA Art. 1.

[5] *See, e.g.,* AWEA June 19, 2015 Petition at 2 (Petition).

[6] American Wind Energy Association, Petition for Rulemaking to Revise Generator Interconnection Rules and Procedures, Docket No. RM15–21–000 (filed June 19, 2015).

determining contingent facilities in their LGIPs and LGIAs based upon guiding principles in the Proposed Rule; (2) require transmission providers to list in their LGIPs and on their Open Access Same-Time Information System (OASIS) sites the specific study processes and assumptions for forming the networking models used for interconnection studies; (3) require congestion and curtailment information to be posted in one location on each transmission provider's OASIS site; (4) revise the definition of ''Generating Facility'' in the *pro forma* LGIP and LGIA to explicitly include electric storage resources; and (5) create a system of reporting requirements for aggregate interconnection study performance. The Commission also seeks comment on proposals or additional steps that the Commission could take to improve the resolution of issues that arise when affected systems are impacted by a proposed interconnection.

8. Third, the Commission proposes five reforms to enhance interconnection processes by making use of underutilized existing interconnections, providing interconnection service earlier, or accommodating changes in the development process. In this area, the Commission proposes to: (1) Allow interconnection customers to limit their requested level of interconnection service below their generating facility capacity; (2) require transmission providers to allow for provisional agreements so that interconnection customers can operate on a limited basis prior to completion of the full interconnection process; (3) require transmission providers to create a process for interconnection customers to utilize surplus interconnection service at existing interconnection points; (4) require transmission providers to set forth a separate procedure to allow transmission providers to assess and, if necessary, study an interconnection customer's technology changes (*e.g.,* incorporation of a newer turbine model) without a change to the interconnection customer's queue position; and (5) require transmission providers to evaluate their methods for modeling electric storage resources for interconnection studies and report to the Commission why and how their existing practices are or are not sufficient.

9. The Commission seeks comments on these proposed reforms and areas for further comment within 60 days after publication of this Proposed Rule in the **Federal Register**.

10. The purpose of these proposals is to ensure that the processing of generator interconnection requests will be just and reasonable and not unduly discriminatory or preferential consistent with Federal Power Act (FPA) sections 205 and 206. These proposed reforms could help improve the efficiency of processing interconnection requests for both transmission providers and interconnection customers, maintain reliability, increase energy supply, balance the needs of interconnection customers and transmission owners and remove barriers to needed resource development.[7]

11. Unless otherwise noted, the proposed reforms described below would result in changes to the *pro forma* LGIP and *pro forma* LGIA and regulations that affect transmission provider LGIPs and LGIAs. The Commission also seeks comment, however, on whether any of these proposed reforms should be applied to small generating facilities and implemented in the *pro forma* Small Generator Interconnection Procedures (SGIP) and Small Generator Interconnection Agreement (SGIA).[8]

II. Background

A. Order No. 2003

12. In 1996, the Commission issued Order No. 888,[9] which ''established the foundation necessary to develop competitive bulk power markets in the United States: Nondiscriminatory open access transmission services by public utilities and stranded cost recovery rules to provide a fair transition to competitive markets.'' [10] In Order No. 888, the Commission did not, however, address generator interconnection issues. In *Tennessee Power Company,* the Commission encouraged, but did not require, transmission providers to revise their OATTs to include interconnection procedures, including a standard interconnection agreement and specific criteria, procedures, milestones, and timelines for evaluating interconnection requests.[11]

13. In Order No. 2003, the Commission recognized a ''pressing need for a single set of procedures for jurisdictional Transmission Providers and a single, uniformly applicable interconnection agreement for Large Generators.'' [12] Prior to the issuance of Order No. 2003, the Commission addressed interconnection issues on a case-by-case basis through, for example, applications under FPA section 205.

14. In Order No. 2003, the Commission asserted that interconnection is a ''critical component of open access transmission service and thus is subject to the requirement that utilities offer comparable service under the OATT.'' [13] The Commission found that a standard set of procedures would ''minimize opportunities for undue discrimination and expedite the development of new generation, while protecting reliability and ensuring that rates are just and reasonable.'' [14]

15. Consequently, in Order No. 2003, the Commission required public utilities that own, control, or operate transmission facilities to file standard generator interconnection procedures and a standard agreement to provide interconnection service to generating facilities with a capacity greater than 20 megawatts (MW). To this end, the Commission adopted the *pro forma* LGIP and LGIA and required all public utilities subject to Order No. 2003 to modify their OATTs to incorporate the *pro forma* LGIP and LGIA.

B. 2008 Order on Interconnection Queueing Practices

16. The Commission held a technical conference on December 17, 2007 and issued a notice inviting further comments in response to concerns raised about the effectiveness of queue management practices.[15] Comments revealed that some transmission providers were not processing their interconnection queues with the timelines envisioned in Order No. 2003. Commenters pointed to surges in the volume of new generation development in some regions, particularly for renewable resources, as taxing interconnection queues. Commenters

[7] 16 U.S.C. 824d and 824e (2012).

[8] The Commission adopted these documents in Order No. 2006. *Standardization of Small Generator Interconnection Agreements and Procedures,* Order No. 2006, FERC Stats. & Regs. ¶ 31,180, *order on reh'g,* Order No. 2006–A, FERC Stats. & Regs. ¶ 31,196 (2005), *order granting clarification,* Order No. 2006–B, FERC Stats. & Regs. ¶ 31,221 (2006).

[9] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

[10] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 8.

[11] *Tenn. Power Co.,* 90 FERC ¶ 61,238 (*Tennessee*).

[12] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 11.

[13] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 9 (citing *Tennessee,* 90 FERC ¶ 61,238).

[14] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 11.

[15] *Interconnection Queuing Practices,* Docket No. AD08–2–000, November 2, 2007 Notice of Technical Conference.

also noted that some regions had developed capacity markets after the issuance of Order No. 2003 and struggled with accommodating these new markets.[16]

17. On March 20, 2008, the Commission issued an order addressing interconnection queue issues (2008 Order). The Commission acknowledged that delays in processing interconnection queues were more pronounced in RTOs/ISOs that were attracting significant new entry.

18. The Commission declined to impose generally applicable solutions, given the regional nature of some interconnection queue issues. However, the Commission provided guidance to assist RTOs/ISOs and their stakeholders in their efforts to improve the processing of interconnection queues.[17] The Commission further stated that, while it ''may need to [impose solutions] if the RTOs and ISOs do not act themselves,'' each region would be provided an opportunity to propose its own solutions through ''consensus proposals.'' [18] Following the 2008 Order, RTOs/ISOs submitted multiple queue reform proposals to the Commission, generally moving their interconnection queuing practices from a ''first-come, first-served'' approach to a ''first-ready, first-served'' approach.

C. 2015 American Wind Energy Association Petition

19. On June 19, 2015, AWEA filed the Petition in Docket No. RM15–21–000 requesting that the Commission revise the *pro forma* LGIP and *pro forma* LGIA. AWEA asserts that the current interconnection process has ''imbedded unjust and unreasonable and unduly discriminatory delays, costs, rates, terms and conditions'' and ''imposes barriers to the development of needed new generation resources.'' [19] AWEA states that while transmission providers have modified their LGIPs in ways that ''occasionally [provide] limited benefits. . . . [they] have not solved, and have even exacerbated, problems encountered by interconnection customers.'' [20] AWEA contends that, consequently, the interconnection process often results in ''complex, time consuming technical disputes about . . . interconnection feasibility, cost, and cost responsibility'' with delays that ''undermine the ability of new generators to compete.'' [21]

20. AWEA proposes multiple reforms to improve: (1) Certainty in the interconnection study/restudy process; (2) transparency in the interconnection process; (3) certainty with respect to network upgrade costs; and (4) accountability.[22]

21. On July 7, 2015, the Commission issued a Notice of Petition for Rulemaking in Docket No. RM15–21–000 to seek public comment on the Petition. The Commission received thirty-five comments and three answers and reply comments.[23]

D. 2016 Technical Conference

22. On May 13, 2016, Commission staff convened the 2016 Technical Conference at Commission headquarters. The 2016 Technical Conference featured five panels on ''The Current State of Generator Interconnection Queues,'' ''Transparency and Timing in the Interconnection Study Process,'' ''Certainty in Cost Estimates and Construction Time,'' ''Other Queue Coordination and Management Issues,'' and ''Interconnection of Electric Storage Resources.'' The panels featured representatives from RTOs/ISOs, non-independent transmission providers, transmission owners within RTOs/ISOs, renewable generation developers, and other stakeholders.

23. On June 3, 2016, the Commission issued a Notice Inviting Post-Technical Conference Comments. The Commission received 24 post-technical conference comments.

III. Need for Reform of the Interconnection Process

24. Since the issuance of Order No. 2003, the electric power industry has undergone numerous changes. For example, the nation's resource mix has undergone significant change. In many regions, the resource mix now includes increasing amounts of generation powered by wind,[24] natural gas, solar, and most recently, electric storage resources.[25] These changes are the result of a multitude of factors, such as the economics of new power generation largely driven by sustained low natural gas prices, technology advances, and federal and state policies, including federal environmental regulations and state-level mandates for renewable capacity. The changing resource mix has impacted the Commission's interconnection policies.

25. The increasing penetration of variables energy resources and emerging technologies has implications for the interconnection process, for both interconnection customers and transmission providers.[26] For example, wind generation is limited geographically because it is concentrated in locations where there are dependable windy conditions that are sufficient to generate electricity. Additionally, a lengthy interconnection process affects all resources attempting to interconnect and can have a disproportionate effect on resources that can be built more quickly than traditional resources. Further, interconnection processes should consider the evolving capabilities of electric storage resources, which may involve different considerations than the interconnection of more traditional generation resources. These factors suggest a need for the Commission to reevaluate its interconnection policies to ensure that they are just and reasonable and not unduly discriminatory or preferential.

26. As described above, beginning with Order No. 2003, the Commission has sought to improve the interconnection process by minimizing opportunities for undue discrimination and expediting the development of new generation while protecting system reliability and ensuring just and reasonable rates. However, at present, many interconnection customers

[16] *Interconnection Queuing Practices,* 122 FERC ¶ 61,252, at P 3 (2008) (2008 Order). With regard to capacity markets, commenters noted that in regions that had established capacity markets, interconnection queue delays could prevent least cost resources from being available in new capacity market auctions. *Id.* P 5.

[17] 2008 Order, 122 FERC ¶ 61,252 at PP 16–18.

[18] 2008 Order, 122 FERC ¶ 61,252 at P 8.

[19] Petition at 2.

[20] Petition at 3.

[21] Petition at 3.

[22] Petition at 4–5.

[23] *See* Appendix A: List of Short Names of Commenters on the AWEA Petition (Docket No. RM15–21–000) and the 2016 Technical Conference (Docket No. RM16–12–000).

[24] In 2015, for example, wind, natural gas, and solar power were the largest classes of new entrants. *See Wind Adds the Most Electric Generation Capacity in 2015, Followed by Natural Gas and Solar* (Mar. 23, 2016) *https://www.eia.gov/todayinenergy/detail.php?id=25492.*

[25] *See* U.S. Energy Information Administration, *Natural Gas Expected to Surpass Coal in Mix of Fuel Used for U.S. Power Generation in 2016* (Mar. 16, 2016), *http://www.eia.gov/todayinenergy/detail.cfm?id=25392; see also* Energy Storage Association, *US Surpasses 100 MW of Storage Deployments through Q3 2015, Already Best Year Ever* (Dec. 3, 2015, 11:13 a.m.), *http://energystorage.org/resources/us-surpasses-100-mw-storage-deployments-through-q3-2015-already-best-year-ever.* The Commission defines an electric storage resource as a facility that can receive electric energy from the grid and store it for later injection of electricity back to the grid. This includes all types of electric storage technologies, regardless of their size or storage medium (*e.g.,* batteries, flywheels, compressed air, pumped-hydro, etc.). *See Midcontinent Indep. Sys. Operator, Inc.,* 155 FERC ¶ 61,211, at n.7 (2016).

[26] *See, e.g.,* Monitoring Analytics, PJM State of the Market at Table 12–17, *http://monitoringanalytics.com/reports/PJM_State_of_the_Market/2016/2016q2-som-pjm-sec12.pdf.*

experience delays, and interconnection queues have significant backlogs and long timelines.[27] According to interconnection customers and transmission providers, a recurring problem is that late-stage interconnection request withdrawals lead to interconnection study restudies and consequent delays for lower-queued interconnection customers.[28] Interconnection request withdrawals can also lead to increased network upgrade cost responsibility for lower-queued interconnection customers, which could, in turn, result in further cascading withdrawals. Further, a lack of cost and timing certainty can hinder interconnection customers from obtaining financing. Cost uncertainty in particular presents a significant obstacle, as some interconnection customers are less able to absorb unexpected and potentially higher costs.

27. Consistent with the 2008 Order, where the Commission allowed RTOs/ISOs to develop and propose their own solutions to interconnection timing issues, most RTOs/ISOs have implemented different procedures to alleviate queue delays. MISO, in particular, has proposed four different queue reforms, each of which have been designed to improve and expedite the interconnection process.[29] SPP has implemented two queue reforms, for similar reasons.[30] CAISO has employed network upgrade cost caps and periodic, scheduled restudies in order to provide certainty to the interconnection customer.[31] Despite these efforts, delays, backlogs, and long queue times continue to affect interconnection customers.[32]

28. The Petition highlighted some of the issues affecting the interconnection process and encouraged the Commission to consider these and other interconnection issues as well as the overall state of interconnection queues. In light of these issues, the Commission in this proceeding reviewed current interconnection processes and proposes reforms to ensure that these processes continue to ''minimize opportunities for undue discrimination and expedite the development of new generation, while protecting reliability and ensuring that rates are just and reasonable.'' [33] The Commission conducted this review and developed proposals based on information provided in the 2016 Technical Conference and comments submitted in that proceeding.

29. The Commission preliminarily finds that aspects of the current interconnection process may hinder the timely development of new generation and, thereby, stifle competition in the wholesale markets, resulting in rates, terms, and conditions that are not just and reasonable or are unduly discriminatory or preferential. The current interconnection process can create uncertainty for interconnection customers regarding both costs and timing. A lack of transparency in the interconnection process can result in interconnection customers submitting interconnection requests to the queue that may be speculative or unlikely to reach commercial operation, which can affect other interconnection customers and create difficulties for transmission providers and owners. Increasing transparency will allow for interconnection customers to better evaluate the viability of an interconnection request prior to entering the queue, which could result in fewer interconnection requests dropping out of the queue. A lack of timely and clear information can also affect an interconnection customer's decisions regarding whether and where to build a generating facility or other resource and can also affect the viability of an interconnection request after it enters the interconnection queue. Finally, the current interconnection process can involve unnecessary obstacles to the interconnection of new technologies and as such, the Commission has proposed reforms to address these issues.

30. The Commission also preliminarily finds that the process for a transmission provider to conduct interconnection studies may result in uncertainty and inaccurate information. The current interconnection study process is meant to allow for refinements in the study estimates of interconnection costs as an interconnection request moves through each of the interconnection study phases.[34] However, uncertainty in study results and a lack of transparency may hamper generation development. Cost uncertainty presents a particularly significant obstacle as some interconnection customers are less able to absorb unexpected and potentially higher costs for interconnection facilities and network upgrades that may occur either in the normal course of refined estimates or as a result of restudy. Moreover, if an interconnection customer does not obtain timely studies or is assessed previously unanticipated network upgrade costs, this could affect a number of development aspects, including the interconnection customer's land lease agreements required to support unanticipated network upgrades, additional project financing required for increased network upgrade costs, and/or ability to obtain a power purchase agreement in the face of a potential delay.

31. Additionally, the Commission preliminarily finds that the potential for discriminatory interconnection processes exists as new technologies enter the power generation sphere. New technologies may be hampered in the study process as study conductors come up to speed on how to evaluate the incorporation of these technologies onto the system. Interconnection customers involving new technologies may be affected more by process and information uncertainty than incumbents experienced with the interconnection process in certain regions.

IV. Proposed Reforms

32. The Commission is proposing to reform certain aspects of the Commission's regulations and the *pro forma* LGIP and *pro forma* LGIA that affect the interconnection process to ensure that they are just and reasonable and not unduly discriminatory or preferential.

33. The provision of more timely and accurate information could increase certainty for interconnection customers and assist them in earlier project evaluation and quicker project development, as well as assist in earlier, less disruptive withdrawals from the interconnection queue. Interconnection customers and transmission providers alike have frequently expressed frustration at the need for repeated restudies and prolonged queue times resulting from the withdrawal of higher-queued interconnection requests.[35]

[27] *See, e.g.,* 2016 Technical Conference Tr. 210: 1–10 (discussion of delays up to a year).

[28] *See, e.g.,* 2016 Technical Conference Tr. 20:15–23 (discussion regarding MISO's experiencing 50 percent withdrawal rates in many parts of the queue).

[29] *See Midwest Indep. Transmission Sys. Operator, Inc.,* 124 FERC ¶ 61,183 (2008), *order on reh'g,* 127 FERC ¶ 61,294 (2009); *Midwest Indep. Transmission Sys. Operator, Inc.,* 129 FERC ¶ 61,301 (2009); *Midwest Indep. Transmission Sys. Operator, Inc.,* 138 FERC ¶ 61,233, *order on reh'g and compliance,* 139 FERC ¶ 61,253 (2012); Docket No. ER17–156–000.

[30] *See Sw. Power Pool, Inc.,* 128 FERC ¶ 61,114, *order on compliance,* 129 FERC ¶ 61,226 (2009), *order on compliance,* 133 FERC ¶ 61,139 (2010); *Sw. Power Pool, Inc.,* 147 FERC ¶ 61,201 (2014), *order on reh'g and compliance,* 151 FERC ¶ 61,235 (2015).

[31] *See California Indep. Sys. Operator Corp.,* 124 FERC ¶ 61,292 (2008).

[32] *See* Petition at 8–11.

[33] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 11.

[34] *See* Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 195, 217–34.

[35] *See, e.g.,* 2016 Technical Conference Tr. 20:15–23.

improvements in certainty and the quality of information conveyed at an earlier stage in the interconnection process, some of these withdrawals could be eliminated, and the queue could proceed more quickly. At the same time, fewer withdrawals would benefit transmission providers by reducing the burden of processing requests that are unlikely to reach commercial operation.

34. The Commission also believes that providing interconnection customers with access to more detailed information could enable the interconnection customer to make more informed decisions earlier in the interconnection process. For example, increased knowledge of the assumptions used in interconnection studies could assist an interconnection customer with identifying optimal points of interconnection as well as allow it to better anticipate the duration of the interconnection process and better understand issues that may arise as the result of study outcomes. Interconnection customers may also benefit from a more complete up front understanding of the network upgrades, contingencies, and risks of curtailment that their interconnection requests may face, which could reduce late-stage interconnection request withdrawals and result in fewer restudies and delays. More timely and accurate information regarding an interconnection request, as well as greater transparency of the study process and of congestion, will reduce the incentive for interconnection customers to submit multiple interconnection requests when expecting to interconnect a large generating facility. While interconnection customers may still submit multiple requests, the Commission anticipates that they would submit fewer requests with better information and that the interconnection customer would terminate a non-viable interconnection request earlier.

35. The Commission also proposes reforms that could enhance interconnection processes. The Commission believes that new technologies will drive grid innovation, as well as offer other facility efficiencies and advances. These innovations may reach the market after an interconnection customer has initiated or completed an interconnection request. However, in some circumstances, there are likely ways to inject efficiencies in the traditional interconnection process or to preempt the need for a transmission provider to construct new, unnecessary interconnection facilities and network upgrades. Additionally, the Commission believes there are ways to allow flexibility in the interconnection process to incorporate innovation or developments that transpire while an interconnection request is in the queue.

36. At this time, the Commission does not propose reforms to generator interconnection processes and agreements other than those described herein. This limitation includes any reforms proposed by AWEA in its Petition that are not included in this Proposed Reforms section.

A. Improving Certainty for Interconnection Customers

37. The reforms proposed below would improve certainty by providing interconnection customers more predictability in the interconnection process, including more predictability regarding the costs and the timing of interconnecting to the grid. Increasing certainty for interconnection customers—particularly cost certainty—may decrease the number of late-stage interconnection request withdrawals from the interconnection queue, which could meaningfully ameliorate the cycle of repeated, cascading restudies. In addition to the proposed reforms, the Commission seeks comment on the extent to which capping interconnection customer cost responsibility for actual network upgrade costs to some margin above estimated network upgrade costs can mitigate the potential for serial restudies without inappropriately shifting cost responsibility.

1. Scheduled Periodic Restudies

38. As discussed below, the Commission proposes to revise the *pro forma* LGIP to require transmission providers that conduct cluster studies to establish a schedule for conducting periodic restudies.

a. Current Provisions and Background

39. The current *pro forma* LGIP requires the transmission provider to make reasonable efforts [36] to provide: (i) Feasibility study results within 45 days after receipt of a signed feasibility agreement; (ii) system impact study results within 90 days after receipt of a signed system impact study agreement or after the cluster window closes; and (iii) facilities study results either within 90 days after receipt of a signed facilities study agreement or 180 days after receipt of a signed facilities study agreement, depending on the accuracy margin provided.[37] For the purpose of conducting the system impact study, the current *pro forma* LGIP allows transmission providers the option to process interconnection requests on a serial basis or in groups using clusters.[38]

40. A transmission provider may require a restudy of an interconnection customer's study results if a higher-queued interconnection request drops out of the queue or an interconnection customer modifies its interconnection request.[39] A transmission provider may also require restudy if either the feasibility or system impact studies uncover any unexpected result not contemplated during the scoping meeting that will require re-designation of the point of interconnection. According to the *pro forma* LGIP, restudy of an interconnection feasibility study shall take no longer than 45 days from the date the transmission provider provides notice that such restudy is required. Restudy of an interconnection system impact study or interconnection facilities study shall not take longer than 60 days from the date the transmission provider provides notice to the interconnection customer that such restudy is required.[40] While the current *pro forma* language establishes timeframes in which to complete restudies after an interconnection customer is notified, it does not provide guidance on the frequency at which such restudies should occur for clustered or grouped interconnection requests.

b. AWEA Petition and Comments

41. In its Petition, AWEA recognizes that restudies are often necessary, but it states that, in certain regions, restudies are conducted on an *ad hoc* basis as the need arises.[41] AWEA argues that repeated restudies conducted at irregular intervals may increase or prolong uncertainty for interconnection customers.

42. AWEA further explains that, under the current *pro forma* LGIP, the withdrawal of a higher-queued interconnection request may necessitate a restudy, which may then change the assumptions for other queued interconnection requests within a cluster, necessitating further restudies in a cascading effect. AWEA contends that these cascading restudies prolong

[36] Reasonable Efforts ''shall mean, with respect to an action required to be attempted or taken by a Party under the Standard Large Generator Interconnection Agreement, efforts that are timely and consistent with Good Utility Practice and are otherwise substantially equivalent to those a Party would use to protect its own interests.'' *Pro forma* LGIP Sec. 1 (Definitions).

[37] *See Pro forma* LGIP Sec. 6.3, 7.4 and 8.3.

[38] *See Pro forma* LGIP Sec. 4.2.

[39] *See Pro forma* LGIP Sec. 6.4, 7.6, and 8.5.

[40] *See Pro forma* LGIP Sec. 6.4, 7.6 and 8.5.

[41] Petition at 22.

cost uncertainty, cause delays in finalizing interconnection study results, and delay the execution of LGIAs. As a potential solution, AWEA proposes an annual or periodic restudy process for interconnection requests within a cluster, in which the transmission provider would consider all relevant system condition changes, including higher-queued interconnection requests that withdraw from the queue. AWEA contends that such a restudy process provides certainty because each restudy would be completed according to a schedule, rather than conducted on an *ad hoc* basis due to intervening events.[42]

43. However, AWEA also asserts that when an unplanned restudy becomes necessary outside of the scheduled restudy process, it is of critical importance that the restudy be processed in as timely a manner as possible. AWEA adds that the transmission provider should, if necessary, hire additional consultants or staff to ensure proper resources to process the restudy in a consistent and timely manner.[43]

44. Several commenters, including a number of entities that have been interconnection customers for wind generation such as NRG, EDF, and NextEra, support a scheduled restudy process and offer suggestions for how transmission providers should conduct this process.[44] MISO also acknowledges that the withdrawal of higher-queued interconnection requests creates the need for cascading restudies of lower-queued interconnection requests and that scheduled restudies may alleviate the need for multiple *ad hoc* restudies.[45] NextEra states that, under an annual restudy process, the transmission provider should consider all relevant system condition changes, as well as all higher-queued interconnection requests that dropped out of the queue, in one restudy for the applicable interconnection requests in a cluster or sub-region. Although it believes there may be some efficiency in a group restudy, EDF cautions that, if the restudy were to include different interconnection requests from different clusters, it could result in as many issues and inefficiencies as are produced by the current process.[46]

45. Some commenters oppose scheduled, periodic restudies. ISO–NE., Xcel, and ITC express the belief that an annual, group restudy would not be useful. These commenters assert that the primary cause for restudies—namely, the withdrawal of higher-queued interconnection requests—is out of the transmission provider's control and can occur at any time. These commenters contend that limiting restudies to once a year could force viable generation interconnection requests to wait longer than necessary for restudy results.[47] The ISO/RTO Council states that this proposal is inapplicable to NYISO due to its ''non-serial'' interconnection queue approach, in which an interconnection request is only included in the base case for restudy when it has satisfied certain requirements. The ISO/RTO Council also notes that ISO–NE's interconnection process is merged with the Forward Capacity Market. Thus, the ISO/RTO Council argues, AWEA's proposals for the restudy process could be disruptive.[48]

c. Proposal

46. The Commission proposes to revise the *pro forma* LGIP to require transmission providers that conduct cluster studies to conduct restudies on a scheduled, periodic basis (*e.g.,* annually, semi-annually, quarterly, or a set number of days after the completion of the cluster study). The Commission proposes to require transmission providers to update their LGIPs to specify the frequency of restudies for interconnection customers in a cluster study and post the dates of these restudies on the transmission provider's OASIS.

47. A scheduled, periodic restudy process could enhance the efficiency and certainty of the study process for all parties by mitigating the problem of cascading restudies. This reform could achieve this result because it creates some milestones that can serve as decision points for interconnection customers and allows transmission providers to further revise their interconnection processes as necessary to incorporate scheduled restudies. Further, the Commission notes that it is not proposing that all transmission providers establish the same restudy schedule; rather, the Commission proposes to give transmission providers flexibility in establishing the frequency of restudies to best accommodate the needs of interconnection customers and transmission providers.

48. Accordingly, the Commission proposes to require each transmission provider that conducts cluster studies to revise sections 6.4 and 7.6 of the *pro forma* LGIP as follows (*proposing to delete italicized text*):

> If Re-Study of the [insert appropriate study] Study is required due to a higher queued project dropping out of the queue, or a modification of a higher queued project subject to Section 4.4, or re-designation of the Point of Interconnection pursuant to Section [insert appropriate section] Transmission Provider shall notify Interconnection Customer in writing. *Serially processed Re-Studies Such Re-Study* shall take no longer than [forty-five (45)/sixty (60)] Calendar Days from the date of the notice. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.
>
> *If a Transmission Provider that conducts cluster studies identifies a need for restudies, it will conduct periodic Re-Studies for each cluster [placeholder for time frame proposed by each Transmission Provider]. Re-Study dates for each cluster will also be posted on the Transmission Provider's OASIS. Re-Study shall take no longer than [forty-five (45)/sixty (60)] Calendar Days from the commencement date of the Re-Study. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.*

49. Likewise, the Commission proposes to require each transmission provider that conducts cluster studies to revise section 8.5 of the *pro forma* LGIP as follows (*proposing to delete italicized text*):

> If Re-Study of the Interconnection Facilities Study is required due to a higher queued project dropping out of the queue or a modification of a higher queued project pursuant to Section 4.4, Transmission Provider shall so notify Interconnection Customer in writing. *Serially processed Re-Studies Such Re-Study*-shall take no longer than sixty (60) Calendar Days from the date of the notice. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.
>
> *A Transmission Provider that conducts cluster studies will conduct periodic Re-studies for each cluster [placeholder for time frame proposed by each Transmission Provider]. Re-Study dates for each cluster will also be posted on the Transmission Provider's OASIS. Re-Study of the cluster shall take no longer than sixty (60) Calendar Days from the commencement date of the Re-Study.*

50. The Commission acknowledges the concern held by some stakeholders that a scheduled, periodic restudy process could force viable interconnection requests to wait longer than necessary to progress through the interconnection process. The Commission seeks comment on whether regions that conduct cluster studies and move to periodic re-studies should retain some discretion to conduct restudies outside of the established schedule at the request of interconnection customers or under specific circumstances that deem such

[42] Petition at 22–25.

[43] AWEA 2016 Comments at 30.

[44] NRG 2015 Comments at 4; EDF 2016 Comments at 31; NextEra 2015 Comments at 8–9.

[45] MISO 2016 Comments at 13.

[46] EDP 2016 Comments at 17.

[47] ISO–NE 2016 Comments at 24; Xcel 2016 Comments at 13; ITC 2016 Comments at 8.

[48] ISO/RTO Council 2015 Comments at 5–7.

deviations necessary. The Commission seeks comments on when this discretion should be restricted and the circumstances under which such deviations should be allowed.

51. Additionally, some commenters allege that transmission provider tariffs generally provide insufficient transparency regarding the type of triggers that would require restudy for projects processed through serial or cluster studies; they also contend that transmission providers do not apply such triggers consistently.[49] In contrast, some transmission providers assert that their tariffs sufficiently detail restudy triggers.[50] We believe that the Commission's proposal above to require scheduled, periodic restudies could help address these concerns for interconnection requests processed through cluster studies. However, the Commission also seeks comment on (1) whether the Commission should further revise the *pro forma* LGIP to improve the transparency and application of restudy triggers generally, and (2) if so, what reforms are needed.

2. The Interconnection Customer's Option To Build

52. The Commission proposes to allow the interconnection customer to exercise the option to build unilaterally; that is, the Commission proposes that the interconnection customer's option to assume responsibility for construction of the transmission provider's interconnection facilities and stand alone network upgrades is not contingent on the transmission provider notifying the interconnection customer that it cannot complete such facilities on the schedule proposed by the interconnection customer.

a. Current Provisions and Background

53. Under the current *pro forma* LGIA, the interconnection customer's option to build is contingent on the transmission provider's notification that the transmission provider cannot complete the facilities on schedule. Specifically, under the *pro forma* LGIA, the interconnection customer selects the ''In-Service Date, Initial Synchronization Date, and Commercial Date'' [51] and ''either the Standard Option or Alternative Option'' unless mutually agreed to between the parties to the agreement.[52] Under the standard option, the transmission provider ''shall construct the Transmission Provider's Interconnection Facilities [53] and Network Upgrades using Reasonable Efforts to complete the construction by the dates designated by the Interconnection Customer.'' [54] Under the alternate option, ''Transmission Provider shall construct the Transmission Provider's Interconnection Facilities and Network Upgrades according to the construction completion dates established by the Interconnection Customer, and if it fails to meet those dates, it may be liable for liquidated damages,'' although the transmission provider may decline this option ''within 30 Calendar Days of executing the LGIA.'' [55]

54. Under the current OATT, there are two other options, which are available if the transmission provider informs the interconnection customer that it cannot meet the proposed dates: The ''Option to Build'' and the ''Negotiated Option.'' [56] The ''Option to Build,'' which the *pro forma* LGIA describes in section 5.1.3, provides an interconnection customer with the option to build the transmission provider's interconnection facilities and stand alone network upgrades, but limits that option to circumstances where the transmission provider cannot meet the dates proposed by the interconnection customer. That is, an interconnection customer may ''assume responsibility for the design, procurement and construction of Transmission Provider's Interconnection Facilities and Stand Alone Network Upgrades.'' [57] However, the interconnection customer may only exercise this option if the transmission provider notifies the interconnection customer that the transmission provider cannot meet the interconnection customer's preferred construction completion dates.[58]

55. The ''Negotiated Option'' applies ''if the Transmission Provider notifies the Interconnection Customer that it cannot meet the dates established by the Interconnection Customer, and the Interconnection Customer does not want to assume responsibility for construction.'' [59] Under this option, the ''Interconnection Customer may decide that the Parties shall negotiate in good faith to revise the construction completion dates and other provisions under which the Transmission Provider is responsible for the construction.'' [60] If the parties are unable to reach an agreement during these negotiations, the transmission provider assumes responsibility ''for construction of the Transmission Provider's Interconnection Facilities and Network Upgrades in accordance with the Standard Option.'' [61]

b. Comments

56. Multiple parties that have experience as interconnection customers at the 2016 Technical Conference expressed support for reforms that would allow them to build some interconnection facilities and network upgrades, explaining that they are often able to build more rapidly and at lower cost than transmission owners.[62] Several commenters advocate expanding the option to build to circumstances beyond those described in current section 5.1.3 of the LGIA.[63] They contend that the Commission should not condition the usage of the option to build on timing but should instead allow for an absolute right for interconnection customers to build interconnection facilities and stand alone upgrades.

57. Other commenters oppose expansion of the circumstances under which an interconnection customer may exercise the option to build.[64] For

[49] *E.g.,* AWEA 2016 Comments at 30; Invenergy 2016 Comments at 19–20; EDPR NA 2016 Comments at 16–17.

[50] MISO 2016 Comments at 15; ISO–NE 2016 Comments at 23.

[51] The In-Service Date is ''the date upon which the Interconnection Customer reasonably expects it will be ready to begin use of the Transmission Provider's Interconnection Facilities to obtain back feed power.'' *Pro forma* LGIA Art. 1. The Initial Synchronization Date is ''the date upon which the Generating Facility is initially synchronized and upon which Trial Operation begins.'' *Id.* The Commercial Operation Date is ''the date on which the Generating Facility commences Commercial Operation as agreed to by the Parties pursuant to Appendix E to the Standard Large Generator Interconnection Agreement.'' *Id.*

[52] *Pro forma* LGIA Sec. 5.1.

[53] According to the *pro forma* LGIA:

Transmission Provider's Interconnection Facilities shall mean all facilities and equipment owned, controlled or operated by the Transmission Provider from the Point of Change of Ownership to the Point of Interconnection as identified in Appendix A to the Standard Large Generator Interconnection Agreement, including any modifications, additions or upgrades to such facilities and equipment. Transmission Provider's Interconnection Facilities are sole use facilities and shall not include Distribution Upgrades, Stand Alone Network Upgrades or Network Upgrades.

Pro forma LGIA Art. 1.

[54] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 351.

[55] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 352.

[56] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 353.

[57] *Pro forma* LGIA Sec. 5.1.3.

[58] *See, e.g., ISO New England Inc.,* 149 FERC ¶ 61,274, at P 18 (2014).

[59] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 354.

[60] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 354.

[61] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 354.

[62] 2016 Technical Conference Tr. 121: 1–22.

[63] *E.g.,* E.ON 2016 Comments at 15; Xcel 2016 Comments at 16; Invenergy 2016 Comments at 26; EDP 2016 Comments at 19; EDF 2016 Comments at 40.

[64] ISO–NE 2016 Comments at 27.

instance, ITC suggests that removing the limitation on when the option to build can be exercised would threaten system reliability.[65] Additionally, MISO TOs states that in Order No. 2003–A, the Commission clarified that the transmission provider has no obligation to cede ownership of stand alone network upgrades or the transmission provider's interconnection facilities to the interconnection customer.[66] Some commenters that support expanding the option to build acknowledge that usage of this option should still require that reliability standards be maintained.[67]

c. Proposal

58. The Commission preliminarily finds that limiting the option to build only to circumstances where the transmission provider cannot meet the interconnection customer's requested dates may not be just and reasonable and may be unduly discriminatory or preferential. The limitation may restrict an interconnection customer's ability to efficiently build the transmission provider's interconnection facilities and the interconnection customer's stand alone network upgrades in a cost-effective manner.[68] As a result, an interconnection customer may pay more for the transmission provider's interconnection facilities and standalone upgrades. Furthermore, removing the limitation may provide interconnection customers more control and certainty during the design and construction phase of the interconnection process.

59. The Commission proposes to modify the *pro forma* LGIA to allow an interconnection customer to exercise the option to build regardless of whether the transmission provider can meet the requested construction dates. More specifically, the Commission proposes to modify the *pro forma* LGIA to allow an interconnection customer to design, procure, and construct the transmission provider's interconnection facilities and stand alone network upgrades—even if the transmission provider can meet the requested construction dates—where the interconnection customer and transmission provider (and transmission owner, if applicable) are in agreement as to the transmission provider's interconnection facilities and stand alone network upgrades that would be built, including the design and construction details. Existing responsibilities and protections, including reliability considerations, in section 5.2 of the *pro forma* LGIP under ''General Conditions Applicable to Option to Build'' would continue to apply.

60. The Commission is *not* proposing changes with respect to how transmission provider's interconnection facilities and stand-alone network upgrades are designed or approved, which standards or practices must be followed, or the ownership of transmission provider's interconnection facilities and stand-alone network upgrades that are built under the option to build.[69] Nor is the Commission proposing to expand the types of stand-alone facilities that interconnection customers may construct under the option to build beyond transmission provider's interconnection facilities and stand-alone network upgrades. The proposal instead removes the limitation on when the interconnection customer can exercise the option to build such that an interconnection customer may opt to build in an effort to reduce its costs or improve the timeline for construction. Specifically, the Commission proposes to modify the language in section 5.1 of the *pro forma* LGIA as follows (*proposing to delete italicized text*):

Options. Unless otherwise mutually agreed to between the Parties, Interconnection Customer shall select the In-Service Date, Initial Synchronization Date, and Commercial Operation Date; and either *the* Standard Option or Alternate Option set forth below *for completion of Transmission Provider's Interconnection Facilities and Network Upgrades, as set forth in Appendix A, Interconnection Facilities and Network Upgrades,* and such dates and selected option shall be set forth in Appendix B, Milestones. *At the same time, Interconnection Customer shall indicate whether it elects to exercise the Option to Build set forth in section 5.1.3 below. If the dates designated by Interconnection Customer are not acceptable to Transmission Provider, Transmission Provider shall so notify Interconnection Customer within thirty (30) Calendar Days. Upon receipt of the notification that Interconnection Customer's designated dates are not acceptable to Transmission Provider, the Interconnection Customer shall notify the Transmission Provider within thirty (30) Calendar Days whether it elects to exercise the Option to Build if it has not already elected to exercise the Option to Build.*

61. The Commission also proposes to modify the language in article 5.1.3 of the *pro forma* LGIA as follows (*proposing to delete italicized text*):

Option to Build. *If the dates designated by Interconnection Customer are not acceptable to Transmission Provider, Transmission Provider shall so notify Interconnection Customer within thirty (30) Calendar Days. and unless the Parties agree otherwise,* Interconnection Customer shall have the option to assume responsibility for the design, procurement and construction of Transmission Provider's Interconnection Facilities and Stand Alone Network Upgrades on the dates specified in Article 5.1.2. Transmission Provider and Interconnection Customer must agree as to what constitutes Stand Alone Network Upgrades and identify such Stand Alone Network Upgrades in Appendix A. Except for Stand Alone Network Upgrades, Interconnection Customer shall have no right to construct Network Upgrades under this option.

62. Given the changes proposed above, revisions to the negotiated option are necessary because the current version of the negotiated option references the current limitations on the option to build. For this reason, it is necessary to remove these references in the negotiated option and to address scenarios in which an interconnection customer exercises the option to build and still wishes to negotiate completion times for other facilities, including network upgrades that are not stand alone network upgrades, as well as circumstances in which the interconnection customer does not wish to exercise the option to build. Such revisions are necessary because the ability to exercise the option to build would no longer be contingent upon a transmission provider's inability to meet the interconnection customer's proposed dates. However, the negotiated option must also contemplate the possibility that the transmission provider does not agree to the interconnection customer's proposed dates as to other facilities not covered by the option to build (*i.e.,* other than transmission provider's interconnection facilities and stand-alone network upgrades). That is, even if the interconnection customer elects to exercise the option to build, the transmission provider would still be responsible for the design, procurement, and construction of the interconnection facilities and network upgrades other than transmission provider's interconnection facilities and stand-alone network upgrades. The option to build does not grant any right to the interconnection customer to construct network upgrades that are not stand-alone upgrades. Furthermore, both the

[65] ITC 2016 Comments at 10.

[66] MISO TOs 2016 Comments at 21.

[67] *See* AES 2016 Comments at 9.

[68] The *pro forma* LGIA states that:

Stand Alone Network Upgrades shall mean Network Upgrades that an Interconnection Customer may construct without affecting day-to-day operations of the Transmission System during their construction. Both the Transmission Provider and the Interconnection Customer must agree as to what constitutes Stand Alone Network Upgrades and identify them in Appendix A to the Standard Large Generator Interconnection Agreement.

Pro forma LGIA Art. 1.

[69] *Pro forma* LGIA Sec. 5.2.

transmission provider and the interconnection customer must agree on which facilities are the stand-alone network upgrades and identify them in Appendix A to the LGIA.[70]

63. The Commission therefore proposes to modify the language in article 5.1.4 of the *pro forma* LGIA as follows (*proposing to delete italicized text*):

Negotiated Option. *If Interconnection Customer elects not to exercise its option under Article 5.1.3, Option to Build, Interconnection Customer shall so notify Transmission Provider within thirty (30) Calendar Days, and If the dates designated by Interconnection Customer are not acceptable to Transmission Provider,* the Parties shall in good faith attempt to negotiate terms and conditions (including revision of the specified dates and liquidated damages, the provision of incentives, or the procurement and construction of *a portion of Transmission Provider's Interconnection Facilities and Stand Alone Network Upgrades by Interconnection Customer—all facilities other than Transmission Provider's Interconnection Facilities and Stand Alone Network Upgrades if the Interconnection Customer elects to exercise the Option to Build under Article 5.1.3) pursuant to which Transmission Provider is responsible for the design, procurement and construction of Transmission Provider's Interconnection Facilities and Network Upgrades.* If the Parties are unable to reach agreement on such terms and conditions, *then, pursuant to 5.1.1 (Standard Option),* Transmission Provider shall assume responsibility for the design, procurement and construction of *Transmission Provider's Interconnection Facilities and Network Upgradesall facilities other than Transmission Provider's Interconnection Facilities and Stand Alone Network Upgrades if the Interconnection Customer elects to exercise the Option to Buildpursuant to 5.1.1, Standard Option.*

3. Self-Funding by the Transmission Owner

64. The Commission proposes to require agreement between a transmission owner or provider and interconnection customer before the transmission owner or provider may elect to initially fund network upgrades.

a. Existing Provisions and Background

65. Order No. 2003 laid out a pricing policy with regard to the costs of interconnection. There, the Commission stated that, where the transmission provider is not an RTO/ISO, it is appropriate for the interconnection customer to ''be solely responsible for the costs of Interconnection Facilities'' [71] and for network upgrades [72] to be ''funded initially by the interconnection customer unless the Transmission Provider elects to fund them.'' [73] If the interconnection customer funds the network upgrades, then the interconnection customer is ''entitled to a cash equivalent refund . . . equal to the total amount paid for the Network Upgrades'' paid ''as credits against the Interconnection Customer's payments for transmission services, with the full amount to be refunded . . . within five years of the date the Network Upgrades are placed in service.'' [74] This upfront payment from the interconnection customer ''serves not as a rate for interconnection or transmission service, but simply as a financing mechanism that is designed to facilitate the efficient construction of Network Upgrades'' [75] In Order No. 2003, the Commission explained that, while it is appropriate for the interconnection customer to pay the initial full cost for network upgrades that ''would not be needed but for the interconnection,'' the interconnection customer must receive transmission service credits in return to ensure that it ''will not have to pay both incremental costs and an average embedded cost rate for the use of the Transmission System.'' [76] The Commission further stated that this policy helps ensure that every interconnection ''is treated comparably to the interconnections that a non-independent Transmission Provider completes for its own Generating Facilities.'' [77] The Commission further explained that the costs of network upgrades for a transmission provider's own generation are traditionally rolled into the transmission provider's transmission rates. The Commission allows some pricing flexibility for transmission providers that are part of an RTO/ISO and independent of market participants, as these transmission providers have ''no incentive to use the cost determination and allocation process to unfairly advantage [their] own generation.'' [78]

66. Currently, article 11.3 of the *pro forma* LGIA states that:

Network Upgrades and Distribution Upgrades. Transmission Provider or Transmission Owner shall design, procure, construct, install, and own the Network Upgrades and Distribution Upgrades described in Appendix A, Interconnection Facilities, Network Upgrades and Distribution Upgrades. The Interconnection Customer shall be responsible for all costs related to Distribution Upgrades. Unless Transmission Provider or Transmission Owner elects to fund the capital for the Network Upgrades, they shall be solely funded by Interconnection Customer.

The option for the transmission owner or provider to fund the cost for network upgrades is termed the ''self-fund option.'' Under Order No. 2003, a transmission owner or provider electing the self-fund option provides the up-front funding for the capital cost of the network upgrades and then recovers the costs of those upgrades through its rolled-in transmission rates charged to transmission customers.[79]

67. In 2009, the Commission accepted a MISO proposal to increase the cost responsibility of an interconnection customer to 100 percent of the costs of network upgrades with a possible 10 percent reimbursement for network upgrades that are 345 kV or above.[80] This approach reflects a departure from the *pro forma* LGIA interconnection pricing policy provided in Order No. 2003. In 2013, MISO proposed to allow a transmission owner to elect to initially fund network upgrades and to directly assign those costs to the interconnection customer under MISO's interconnection customer funding policy.[81] In that proceeding, the Commission accepted MISO's proposal for a transmission

[70] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 353.

[71] Interconnection Facilities refer to:

shall mean the Transmission Provider's Interconnection Facilities and the Interconnection Customer's Interconnection Facilities. Collectively, Interconnection Facilities include all facilities and equipment between the Generating Facility and the Point of Interconnection, including any modification, additions or upgrades that are necessary to physically and electrically interconnect the Generating Facility to the Transmission Provider's Transmission System. Interconnection Facilities are sole use facilities and shall not include Distribution Upgrades, Stand Alone Network Upgrades or Network Upgrades.

Pro forma LGIA Art. 1.

[72] Network upgrades refer to:

the additions, modifications, and upgrades to the Transmission Provider's Transmission System required at or beyond the point at which the Interconnection Facilities connect to the Transmission Provider's Transmission System to accommodate the interconnection of the Large Generating Facility to the Transmission Provider's Transmission System.

Pro forma LGIA Art. 1.

[73] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 693–694, 676.

[74] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 676.

[75] Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 612.

[76] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 694.

[77] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 694.

[78] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 694; Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 587.

[79] *See* Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 676. Order No. 2003, however, allows independent entities to depart from the *pro forma* LGIA approach. *See Interstate Power and Light Co.* v. *ITC Midwest, LLC,* 144 FERC ¶ 61,052, at P 38 (2013).

[80] *Midwest Indep. Transmission Sys. Operator, Inc.,* 129 FERC ¶ 61,060, at P 8 (2009).

[81] *Midcontinent Indep. Sys. Operator, Inc.,* 145 FERC ¶ 61,111 (2013) (*Hoopeston*).

owner that elects to initially fund network upgrades under MISO's *pro forma* GIA to recover the capital costs for network upgrades through a network upgrade charge assessed to the interconnection customer.[82]

68. Recently, another transmission owner in MISO sought to unilaterally elect the self-fund option for network upgrades.[83] The Commission found that article 11.3 of MISO's *pro forma* GIA may be unjust, unreasonable, unduly discriminatory or preferential because it allows the transmission owner the discretion to elect to initially fund the upgrades and subsequently assess the interconnection customer a network upgrade charge that is not later reimbursed through the provision of credits. The Commission found that this practice could result in discriminatory treatment by the transmission owner of different interconnection customers.[84] The Commission additionally found that, by *unilaterally* electing to initially fund network upgrades for which the interconnection customer is ultimately financially responsible and does not receive credits for those costs, the affected system operator or transmission owner may deprive the interconnection customer of more favorable network upgrade financing options. For instance, the Commission found that the transmission owner's unilateral election to initially fund network upgrades may increase costs of interconnection service by assigning increased capital costs and a security requirement to the interconnection customer with no corresponding increase in service.[85] As a result, the Commission directed MISO to revise article 11.3 of its GIA to require mutual agreement with the interconnection customer for the transmission owner to elect to initially fund network upgrades.[86]

b. AWEA Petition and Comments

69. In its Petition, AWEA argues that, where the Commission has granted independent entity variations that do not credit back network upgrade costs to the interconnection customer, transmission owners or providers should not have exclusive decision-making authority with respect to the self-fund option. AWEA specifically raises concerns that the self-fund option hinders competition and provides an opportunity for undue discrimination and affiliate abuse. In support, AWEA argues that the self-fund option allows transmission owners or providers to levy large upgrade costs onto the interconnection customer. AWEA requests that the Commission allow the transmission owner or provider to self-fund network upgrades only if the interconnection customer agrees.[87]

70. Some commenters oppose requiring mutual agreement for self-funding in all regions. MISO TOs view the proposal as eliminating a transmission owner's right to self-fund network upgrades, arguing that this could preclude the transmission owner from the ability to earn a return on its investment.[88] ITC agrees, arguing that it is just and reasonable for transmission owners to earn a fair rate of return on constructed network upgrades.[89] EEI argues that the Commission has long permitted transmission owners to self-fund upgrades while collecting the capital costs for such upgrades, further asserting that self-funding is an important aspect of the Commission's interconnection pricing policy. EEI notes that the Commission has clarified that the self-fund option should not include the recovery of costs other than the return of and on the capital costs of the network upgrades.[90] Additionally, several commenters state that self-funding is a regional issue; thus, a generic rulemaking is not needed.[91]

c. Proposal

71. The Commission proposes to revise the *pro forma* LGIA to require mutual agreement between the interconnection customer and the transmission owner or provider for the transmission owner or provider to elect to fund the capital for network upgrades. Specifically, the Commission proposes to revise section 11.3 of the *pro forma* LGIA to include the requirements established in the *Otter Tail Proceedings.* To which, the Otter Tail Proceedings resulted in the changes as indicated below to article 3.2.1 of MISO's Attachment X to read:

> Transmission Owner shall provide Transmission Provider and Interconnection Customer with written notice pursuant to Article 15 that Transmission Owner elects to fund the capital for the Network Upgrades and Transmission Owner's System Protection Facilities, which election shall only be available upon mutual agreement of Interconnection Customer and Transmission Owner; otherwise, such facilities, if any, shall be solely funded by Interconnection Customer.

As such, the Commission proposes to modify the language in article 11.3 of the *pro forma* LGIA as follows:

> Transmission Provider or Transmission Owner shall design, procure, construct, install, and own the Network Upgrades and Distribution Upgrades described in Appendix A, Interconnection Facilities, Network Upgrades and Distribution Upgrades. The Interconnection Customer shall be responsible for all costs related to Distribution Upgrades. Unless Transmission Provider or Transmission Owner elects to fund the capital for the Network Upgrades, *which election shall only be available upon mutual agreement of Interconnection Customer and Transmission Owner or Transmission Provider,* they shall be solely funded by Interconnection Customer.

72. The Commission preliminarily finds that allowing the unilateral option to self-fund to continue for any transmission owner or transmission provider may be unjust, unreasonable, unduly discriminatory, or preferential. The Commission affirmed in the *Otter Tail Proceedings* that the unilateral election to self-fund created the same condition that was of concern in *E.ON Climate & Renewables North America, LLC* v. *Midwest Indep. Transmission Sys. Operator, Inc.,* namely ''unacceptable opportunities for undue discrimination by affording a transmission owner the discretion to increase the costs of interconnection service by assigning both increased capital costs, as well as non-capital costs . . . to particular interconnecting generators, but not others.'' [92] The Commission further added that the unilateral election for the transmission owner to provide initial funding for network upgrades may deprive the interconnection customer of other options to finance the cost of the network upgrades that may provide more favorable terms and rates.[93]

73. The Commission proposes this reform to balance the interconnection customer's ability to manage the cost of

[82] *Hoopeston,* 145 FERC ¶ 61,111 at P 41.

[83] *See Otter Tail Power Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,352 (2015).

[84] *See Otter Tail Power Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,352 at P 14; *Midcontinent Indep. Sys. Operator, Inc.,* 151 FERC ¶ 61,220 (2015); *Otter Tail Power Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 156 FERC ¶ 61,099 (2016) (*Otter Tail Proceedings*).

[85] *Otter Tail Power Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 153 FERC ¶ 61,352 at P 9.

[86] *Midcontinent Indep. Sys. Operator, Inc.,* 151 FERC ¶ 61,220 at P 53.

[87] RENEW and Wind on the Wires support this request. RENEW 2015 Comments at 6; Wind on the Wires 2015 Comments at 3.

[88] MISO TOs 2015 Comments at 18.

[89] ITC 2015 Comments at 12 (citing, *e.g., Ameren Energy Resource Generating Co.* v. *Midcontinent Indep. Sys. Operator, Inc.,* 148 FERC ¶ 61,057, at P 38 (2014)).

[90] EEI 2015 Comments at 44–45 (citing *Hoopeston,* 145 FERC ¶ 61,111 at P 42).

[91] MISO TOs 2015 Comments at 18; MISO 2015 Comments at 21.

[92] *E.ON Climate & Renewables North America, LLC* v. *Midwest Indep. Transmission Sys. Operator, Inc.,* 137 FERC ¶ 61,076, at P 37 (2011), *order on reh'g,* 142 FERC ¶ 61,048, at P 21 (2013).

[93] *Midcontinent Indep. Sys. Operator, Inc.,* 151 FERC ¶ 61,220 at P 49 (citing *E.ON,* 137 FERC ¶ 61,076 at P 37).

interconnection with the transmission owner's or provider's desire to earn a return on any network upgrades. The Commission recognizes that interconnection customers may have internal reasons for funding their own network upgrades and that doing so may enhance the interconnection customer's ability to manage the cost of interconnection. The Commission, in addition, does not believe that requiring mutual agreement in order for the transmission provider or owner to initially fund network upgrades in regions that follow the *pro forma* LGIA crediting approach would harm the transmission provider or owner. To the extent an interconnection customer does not withhold agreement to allow the transmission owner or provider to pay the upfront cost of network upgrades, the transmission provider or owner will be able to earn a return. The Commission invites comment on benefits the interconnection customer may realize by forgoing its opportunity to fund network upgrades and thereby allowing the transmission owner or provider to initially fund the network upgrades. The Commission is similarly interested in the comments regarding the benefits an interconnection customer may realize by funding network upgrades itself. Finally, the Commission seeks further comment on whether extending the requirement for mutual agreement for the transmission owner or provider to initially fund the network upgrades would result in circumstances that could harm an interconnection customer.

74. While the concern motivating this proposed change may typically be more salient in regions where transmission credits are not provided for the costs paid by interconnection customers, there may occasionally be reasons that interconnection customers in regions where transmission credits are provided may want to require mutual agreement with the transmission owner or provider before it could self-fund. Accordingly, the Commission proposes that all transmission providers revise article 11.3 in their *pro forma* LGIA to require mutual agreement between the interconnection customer and transmission owner or provider before the transmission owner or provider can choose to self-fund, but seeks comment as to whether the proposal should apply to all regions, as proposed, or be limited to RTOs/ISOs or regions that do not provide transmission credits.

75. The Commission preliminarily disagrees with MISO TOs and ITC that requiring mutual agreement is akin to removing the option to self-fund. In regions where transmission credits are not provided, transmission owners or providers may still exercise the self-funding option, as long as there is mutual agreement between the interconnection customer and the transmission owner or provider.

76. The Commission agrees that self-funding is an important aspect of the Commission's interconnection pricing policy and that transmission owners or providers opting to self-fund in regions where transmission credits are not provided, pursuant to mutual agreement with the interconnection customer, may recover the return of and on their capital costs. Further, the Commission believes that requiring mutual agreement between the transmission owner or provider and the interconnection customer should not affect the costs recovered by the transmission owner or provider when the self-fund option is utilized.

77. As stated above, the Commission's proposal will clarify article 11.3 of the existing *pro forma* LGIA to require mutual agreement between the transmission owner or provider and interconnection customer before the transmission owner or provider may elect to initially fund network upgrades. The Commission also seeks comment on whether this proposal, if adopted, should apply to all regions as proposed or be limited to RTOs/ISOs or regions that do not provide transmission credits.

4. RTO/ISO Dispute Resolution

78. The Commission proposes that RTOs/ISOs establish interconnection dispute resolution procedures that allow a disputing party to unilaterally seek dispute resolution in RTO/ISO regions. Commenters have not raised dispute resolution procedures outside of RTO/ISO regions as an issue, so the Commission has not proposed changes to non-RTO/ISO dispute resolution procedures in this Proposed Rule. However, as discussed below, the Commission invites comments regarding the adequacy of dispute resolution processes outside of RTO/ISO regions.

a. Current Provisions and Background

79. The current interconnection dispute resolution process is described in article 13.5 of the *pro forma* LGIP. This article states that, if a dispute ''arises out of or in connection with'' the LGIA, LGIP, or either party's performance thereunder, a disputing party provides written notice of dispute to the other party outlining the dispute's terms.[94] If the parties have not resolved the dispute within thirty days, one party may, ''upon mutual consent,'' submit the dispute for external arbitration procedures.[95] If the parties fail to agree upon a single arbitrator within ten days, they may each select an arbitrator, and both arbitrators will have twenty days to select a third arbitrator. Each arbitrator must be knowledgeable ''in electric utility matters, including electric transmission and bulk power issues, and shall not have any current or past substantial business or financial relationships with any party to the arbitration.'' [96] Unless otherwise agreed, the arbitrator(s) must render a decision within ninety days, and the parties must pay their own costs and the costs of the arbitrators.[97]

80. Some RTOs/ISOs have adopted interconnection dispute resolution procedures similar to those laid out in the *pro forma* LGIP; [98] others direct parties to their general dispute resolution procedures.[99]

b. AWEA Petition and Comments

81. Interconnection customers can have disputes with transmission owners about a number of issues, including costs, construction schedules, and the design of interconnection facilities and network upgrades.[100] Multiple renewable interconnection customers state that they consider current RTO/ISO dispute resolution procedures inadequate and argue that the filing of a complaint pursuant to FPA section 206 is not a serviceable substitute for dispute resolution because the complaint process is too expensive and time-consuming, given the time sensitivity of the interconnection process.[101] Nonetheless, commenters

[94] *Pro forma* LGIP Sec. 13.5.1.

[95] *Pro forma* LGIP Sec. 13.5.1.

[96] *Pro forma* LGIP Sec. 13.5.2.

[97] *Pro forma* LGIP Sec. 13.5.3, 13.5.4. Under section 13.5.4, each party must pay (1) the cost of the arbitrator chosen by the party to sit on the three member panel and one half of the cost of the third arbitrator chosen; or (2) one half the cost of the single arbitrator jointly chosen by the parties.

[98] ISO–NE., Transmission, Markets and Services Tariff, Section II, Schedule 22 (9.0.0), Section 13.5; NYISO, NYISO Tariffs, OATT Section 30.13 (2.0.0) (Miscellaneous); CAISO, eTariff, FERC Electric Tariff, OATT, app. DD, Section 15 (1.0.0) (Miscellaneous); SPP, OATT, Attachment V, Section 1.5 (2.0.0).

[99] MISO, FERC Electric Tariff, Attachment X (49.0.0), art. 11.5 (Disputes); *PJM Interconnection, L.L.C.,* 123 FERC ¶ 61,163, at n. 41 (2008) (''dispute resolution procedures in section 12 [PJM, Intra-PJM Tariffs, OATT, Section 12 (0.0.0)] are applicable to disputes arising regarding the interconnection process''). PJM's general dispute resolution procedures are similar to those laid out in section 13.5 of the *pro forma* LGIP.

[100] 2016 Technical Conference Tr. 131: 4–17; 133: 18–21.

[101] Invenergy 2016 Comments at 2, 3, 26; EDF 2016 Comments at 40–41; EDP 2016 Comments at 20; NextEra 2016 Comments at 9–10.

disagree about how to improve RTO/ISO dispute resolution procedures. EDP contends that RTOs/ISOs are often in the best position to mediate such discussions and disputes.[102] NextEra asserts, however, that on occasion, RTOs refuse to be a party to dispute resolution and tell the parties to resolve the issues themselves.[103] Furthermore, EDP argues that there is some question about RTO/ISO independence because RTOs/ISOs ''often lean on'' the transmission owner for assistance in modeling or design information.[104] Similarly, EDF argues that the interconnection customer ''almost always loses'' because issues are judged by the RTO/ISO and fellow transmission owners and transmission providers.[105]

82. Because of its unease with RTOs/ISOs, NextEra states that the Commission is the ''ideal adjudicator'' of such conflicts and asks the Commission to devise an expeditious interconnection dispute adjudication process.[106] NextEra states that this process could involve more formal predictable procedures through the Commission's hotline or some other method to quickly respond to the facts presented.[107] Similarly, Invenergy and AWEA propose that each RTO/ISO establish an in-house ombudsman that can reach out to designated Commission staff to intervene as needed.[108] EDP also voices the need for an independent arbiter to assist in resolving these disputes without relying on the RTO/ISO.[109]

83. Not all commenters argue that the current available procedures are defective or that dispute resolution reform is necessary. For instance, MISO argues that parties rarely take advantage of its dispute resolution process for interconnection issues.[110] Similarly, CAISO and ISO–NE state that issues that require dispute resolution seldom arise.[111] These commenters and others consider the available dispute resolution procedures adequate.[112]

c. Proposal

84. The Commission preliminarily finds that RTO/ISO generator interconnection dispute resolution procedures may not be just and reasonable or may be unduly discriminatory or preferential. The current processes allow a disputing party to pursue a streamlined dispute resolution process only if the other party to the dispute agrees to this process. As a result, disputing parties may have little recourse. Multiple commenters have suggested that the Commission, rather than the RTO/ISO, is in the best position to resolve interconnection disputes. It is not clear whether such commenters are suggesting that the Commission adopt the dispute resolution provisions of the *pro forma* SGIP, which allow disputing parties to contact the Commission's Dispute Resolution Service to assist in either resolving a dispute or in selecting an appropriate dispute resolution venue.[113] Regardless, because RTOs/ISOs are more familiar with the details regarding their respective systems and interconnection processes, the Commission proposes to require that RTOs/ISOs serve as the neutral decision-makers to interconnection disputes. While several commenters have expressed concern about the RTOs'/ISOs' neutrality, independence of market participants was, and is, a foundational requirement of the RTOs/ISOs.[114] The Commission proposes that RTOs/ISOs provide staff member(s) or utilize subcontractor(s) to preside over such dispute resolution (*e.g.,* as mediators or arbitrators) and that such staff member(s) or subcontractor(s) be independent of the influence of transmission owners and interconnection customers and can thus serve as neutral decision-makers. To establish this neutrality, the Commission proposes that the selected staff member(s) or subcontractor(s) shall not have any current or past substantial business or financial relationships with any party to the dispute.[115] This standard is identical to the one provided in section 13.5.2 of the *pro forma* LGIP. Additionally, the RTO/ISO-devised procedures must account for the time sensitivity of the generator interconnection process.

85. The Commission also proposes that RTOs/ISOs eliminate the requirement that a dispute resolution process only be available ''upon the mutual agreement of the Parties.''[116] While no commenter has suggested that the arbitration process embodied in section 13.5 of the *pro forma* LGIP lacks neutrality, this process is effectively unavailable to the interconnection customer if a transmission provider or a transmission owner opposes this arbitration process. The Commission also proposes that each Commission-approved RTO/ISO amend its generator interconnection procedures to provide dispute resolution procedures (*e.g.,* mediation or arbitration) that are tailored to address interconnection process disputes.

86. The comments received regarding dispute resolution procedures only express concerns about dispute resolution within RTOs/ISOs. Accordingly, the Commission has preliminarily concluded that interconnection customers and non-RTO/ISO transmission providers are satisfied with the dispute resolution procedures outside of RTOs/ISOs. In any case, the Commission does not propose to change section 13.5 (Disputes) of the *pro forma* LGIP at this time. Additionally, at this time, the Commission does not propose to adopt procedures in the *pro forma* LGIP similar to those adopted in section 4.2 (Disputes) of the *pro forma* SGIP, which directs disputing parties to address their issues through the Commission's Dispute Resolution Service. The Commission seeks comment, however, on the need for reform to generator interconnection dispute procedures outside of the RTOs/ISOs and the appropriateness of adopting procedures similar to those outlined in the *pro forma* SGIP.

87. To effectuate this proposal, the Commission proposes to revise section 35.28(g)(9) of the Code of Federal Regulations to require every Commission-approved independent system operator or regional transmission organization to maintain tariff provisions governing generator interconnection dispute resolution procedures to allow a disputing party to unilaterally initiate dispute resolution procedures under the respective tariff. Such provisions must provide for independent system operator or regional transmission organization staff member(s) or utilize subcontractor(s) to serve as the neutral decision-maker(s) or presiding staff member(s) or subcontractor(s) to the dispute resolution procedures. Such staff participating in dispute resolution

[102] EDP 2016 Comments at 20.

[103] 2016 Technical Conference Tr. 141:11–16.

[104] EDP 2016 Comments at 20.

[105] EDF 2016 Comments at 40.

[106] NextEra 2016 Comments at 9–10.

[107] NextEra 2016 Comments at 10.

[108] Invenergy 2016 Comments at 2, 3, 26; 2016 Technical Conference Tr. 63:11–18; AWEA 2016 Comments at 38.

[109] EDP 2016 Comments at 40–41.

[110] MISO 2016 Comments at 21.

[111] 2016 Technical Conference Tr. 135: 13–15; 137: 6–9; ISO–NE 2016 Comments at 27.

[112] ISO–NE 2016 Comments at 27; NYISO 2016 Comments at 26; AVANGRID 2016 Comments at 12; MISO 2016 Comments at 21; Modesto Irrigation District at 11–12.

[113] *Pro forma* SGIP Sections 4.2.2 & 4.2.4.

[114] *See Regional Transmission Organizations,* Order No. 2000, FERC Stats. & Regs. ¶ 31,089, at PP 193–94 (1999), *order on reh'g,* Order No. 2000–A, FERC Stats. & Regs. ¶ 31,092 (2000), *aff'd sub nom. Pub. Util. Dist. No. 1* v. *FERC,* 272 F.3d 607 (D.C. Cir. 2001).

[115] *See Pro Forma* LGIP Sec. 13.5.2.

[116] *Pro forma* LGIP Sec. 13.5.1.

procedures shall not have any current or past substantial business or financial relationships with any party. Additionally, such dispute resolution procedures must account for the time sensitivity of the generator interconnection process.

5. Capping Costs for Network Upgrades

a. Existing Provisions and Background

88. The *pro forma* LGIP requires that transmission providers provide a good faith estimate of the cost of interconnection facilities and network upgrades needed to accommodate an interconnection customer's requested level of interconnection service.[117] The transmission provider includes this cost estimate with the facilities study results, typically with a stated accuracy margin within 10 to 20 percent of the estimate.[118] After completion of the construction of the transmission provider's interconnection facilities and network upgrades needed to interconnect a generating facility, the transmission provider conducts a true-up to assess the final cost of construction to the interconnection customer. The transmission provider provides a final invoice to the interconnection customer that details variations between actual and estimated costs. Overpayment by the interconnection customer results in a refund to the interconnection customer, or a surcharge in case of an underpayment.[119]

89. In Order No. 2003–A, the Commission also clarified that the cost of network upgrades originally assigned to a higher-queued interconnection customer that has withdrawn its interconnection request could fall to a lower-queued interconnection customer, if the network upgrades are still necessary to support the interconnection of the lower-queued interconnection customer's generating facility. The Commission acknowledged that this business risk creates uncertainty for the interconnection customer. However, the Commission found that such costs shifts were just and reasonable, as the lower-queued interconnection customer would need the network upgrades to support the interconnection of its generating facility.[120]

90. The Commission has approved an independent entity variation from this Commission policy in the CAISO region.[121] CAISO caps cost responsibility for reliability and local delivery network upgrades[122] at the lower of its Phase I and Phase II study report amounts. Transmission owners are responsible for additional reliability network upgrade and local delivery network upgrade costs beyond the cap, unless they are due to interconnection customer errors or changes.[123] Transmission owners, in turn, reflect these costs in their transmission service rates, which ultimately shifts these costs onto load.[124]

b. AWEA Petition and Comments

91. In its Petition, AWEA claims that interconnection customers frequently pay costs that exceed the higher bound of a transmission provider's cost estimates and that significant excess costs can disrupt an interconnection customer's business model. AWEA asserts that it is just and reasonable to protect interconnection customers from excessive cost overruns. AWEA contends that the transmission provider should be obligated to pay the portion of any final cost beyond the estimated cost accuracy margin for interconnection studies, excluding demonstrated, extraordinary costs beyond its control. AWEA asserts that it is unjust and unreasonable to shift the consequences of a transmission provider's inaccurate cost estimates onto the interconnection customer. It argues that the transmission provider should assume such risk because it has control over the interconnection process. AWEA points to CAISO's phased study approach as an example of a cost cap mechanism that would provide more cost certainty.[125] Several commenters support AWEA's request to cap costs at the higher bound of a stated accuracy margin, absent demonstrated, extraordinary circumstances beyond a transmission provider's control.[126] Six Cities supports establishing maximum cost responsibility for network upgrades but opposes a cap on interconnection facility costs, contending that interconnection customers should bear all cost responsibility for interconnection facilities.[127] CAISO states that its phased study approach, coupled with a cost cap, has helped reduce the need for restudies in its region and provided more certainty to interconnection customers earlier in the study process.[128]

92. Other commenters oppose AWEA's proposal to impose caps on interconnection cost estimates.[129] These commenters argue that this proposal would achieve little because the most significant contributors to cost overruns, such as the withdrawal of higher-queued interconnection requests and inaccurate cost estimates provided by transmission owners, are outside the transmission provider's control.[130] Additionally, commenters express concerns that implementing a cost cap will result in inappropriate cost shifts, particularly to load, that violate traditional cost causation principles.[131] Several commenters also express concern that AWEA's proposal would be problematic in regions in which the Commission has approved cost allocation variations from the *pro forma* GIA. MISO asserts that, because CAISO is a single-state RTO, any cost overruns are ultimately shifted to load, which

[117] *See, e.g., pro forma* LGIP Sec. 6.2 and 7.3.

[118] *Pro forma* LGIP Sec. 8.3.

[119] *Pro forma* LGIA Art. 12.

[120] Order No. 2003–A, FERC Stats. & Regs. ¶ 31,160 at P 320.

[121] *California Indep. Sys. Operator Corp.,* 124 FERC ¶ 61,292.

[122] The CAISO Tariff defines the term ''Reliability Network Upgrade'' as:

The transmission facilities at or beyond the Point of Interconnection identified in the Interconnection Studies as necessary to interconnect one or more Generating Facility(ies) safely and reliably to the CAISO Controlled Grid, which would not have been necessary but for the interconnection of one or more Generating Facility(ies), including Network Upgrades necessary to remedy short circuit or stability problems, or thermal overloads. Reliability Network Upgrades shall only be deemed necessary for system operating limits, occurring under any system condition, which system operating limits cannot be adequately mitigated through Congestion Management, Operating Procedures, or Special Protection Systems based on the characteristics of the Generating Facilities included in the Interconnection Studies, limitations on market models, systems, or information, or other factors specifically identified in the Interconnection Studies. Reliability Network Upgrades also include, consistent with [Western Electricity Coordinating Council] practice, the facilities necessary to mitigate any adverse impact the Generating Facility's interconnection may have on a path's [Western Electricity Coordinating Council] rating.'' CAISO Tariff, Appendix A, Definition—Reliability Network Upgrade.

The CAISO Tariff defines ''Local Deliverability Network Upgrade'' as:

''A transmission upgrade or addition identified by the CAISO in the [Generator Interconnection and Deliverability Allocation Procedures] interconnection study process to relieve a Local Deliverability Constraint.'' CAISO Tariff, Appendix A, Definition—Local Delivery Network Upgrade.

[123] CAISO Tariff, Appendix DD, Sec. 10.

[124] 2016 Technical Conference Tr. 161: 7–23.

[125] AWEA Petition at 47–48.

[126] RENEW 2015 Comments at 6; Wind Coalition 2015 Comments at 3; Wind on the Wires 2015 Comments at 3.

[127] Six Cities 2015 Comments at 8.

[128] 2016 Technical Conference Tr. 83: 17–25, 84: 1–25, 85: 1–4.

[129] CMUA 2015 Comments at 4–6; EEI 2015 Comments at 23–24; KCP&L 2015 Comments at 18; MISO 2015 Comments at 20; MISO TOs 2015 Comments at 10–13; Modesto Irrigation District 2015 Comments at 7–12; NYTOs 2015 Comments at 7; PSEG 2015 Comments at 8.

[130] CMUA 2015 Comments at 5–6; MISO 2015 Comments at 20; MISO TOs 2015 Comments at 12; Modesto Irrigation District 2015 Comments at 7–8; PSEG 2015 Comments at 8.

[131] EEI 2015 Comments at 23; MISO TOs 2015 Comments at 11.

will eventually benefit from any generation resulting from the interconnection. MISO argues, however, that capping costs, whether in aggregate or per unit, and socializing the cost of overruns is not necessarily embraced by regulators in multistate RTOs/ISOs that require generator costs to be more specifically borne by the beneficiaries of the power from the resource.[132] ISO–NE concurs, contending that implementing a cost cap would shift costs to ratepayers that the interconnection customer should bear. That shift, argues ISO–NE, is not an option under its ''but for'' cost allocation design.[133]

c. Request for Comments

93. Several of the proposed reforms in this Proposed Rule seek to provide more certainty to interconnection customers during the interconnection study process, such as the proposal to schedule the frequency of restudies. As noted above, increasing certainty for interconnection customers—particularly cost certainty—may decrease the number of late-stage interconnection request withdrawals from the interconnection queue, which could meaningfully ameliorate the cycle of repeated, cascading restudies. Capping costs at a certain variance above estimates could provide interconnection customers with business certainty useful to more efficiently develop an interconnection request. A cost cap could also discipline the study process to produce more accurate cost estimates. The Commission acknowledges, however, that a cost cap could incentivize transmission providers to overestimate network upgrade costs in order to minimize potential cost shifts.

94. The Commission also recognizes that the prospect of implementing a cost cap raises difficult issues. Several RTO/ISO regions have reached consensus on cost allocation policies under the independent entity variation that differ from the pricing policy laid out in Order No. 2003. These cost allocation policies, in turn, have become embedded in these RTO/ISO regions and have supported other cost allocation strategies, which are not easily disturbed. Implementing a cost cap would diverge from the Commission's ''but for'' cost allocation policy with respect to network upgrades because it would reallocate costs that would not have been necessary but for a particular interconnection request. The Commission appreciates insights into balancing the benefits of increasing cost certainty to interconnection customers against the potential drawbacks of shifting costs to other parties, particularly load.

95. The Commission seeks comment on whether it should revise the *pro forma* LGIP and LGIA to provide for a cost cap that would limit an interconnection customer's network upgrade costs at the higher bound of a transmission provider's cost estimate plus a stated accuracy margin following a certain stage in the interconnection study process. Such a cap could permit the interconnection customer to assume costs that exceed the cap under limited circumstances, such as where there is demonstrable proof that the cause of a cost increase is beyond the transmission provider's control. The cost cap could also specify which party or parties would assume network upgrade costs in excess of the cap. The Commission seeks comment on how to minimize potential cost shifts to other parties if such a cost cap is imposed. The Commission also seeks comments on alternative proposals, or additional steps that the Commission could take, to provide more cost certainty to interconnection customers during the interconnection study process.

B. Promoting More Informed Interconnection

96. The five reforms in this section would improve transparency regarding the interconnection process and provide improved information to the benefit of all participants in the interconnection process. These benefits have the potential to lead to efficiencies in the development process and a reduction in participation disagreements or uncertainty. Additionally, these reforms may address aspects of the interconnection process that may not be just and reasonable or that may be unduly discriminatory or preferential. In addition to the proposed reforms, the Commission seeks comment on proposals or additional steps that the Commission could take to improve the resolution of issues that arise when affected systems are impacted by a proposed interconnection.

1. Identification and Definition of Contingent Facilities

97. The Commission proposes to revise the *pro forma* LGIP to require transmission providers to detail the method they use to determine contingent facilities. The Commission proposes to define contingent facilities as those unbuilt interconnection facilities and network upgrades upon which the interconnection request's costs, timing, and study findings are dependent, and if not built, could cause a need for restudies of the interconnection request or a reassessment of network upgrades and/or costs and timing.

a. Existing Provisions

98. The Commission currently requires transmission providers to identify for interconnection customers contingencies potentially affecting interconnection studies[134] and list applicable contingent facilities in interconnection agreements.[135]

b. AWEA Petition and Comments

99. In its Petition, AWEA asserts that interconnection customers rely on the detailed list of contingent facilities that are listed in studies and their interconnection agreements in order to assess future risk.[136] AWEA states that transmission providers are not consistently providing full and accurate lists of contingent facilities within interconnection studies and interconnection agreements. Moreover, AWEA asserts that transmission providers and transmission owners may add more contingent facilities after the interconnection agreement has been signed or filed with the Commission.[137] AWEA also states that some, but not all, LGIPs or related business practices manuals acknowledge the need to study contingent facilities. AWEA asserts that there is often neither a clear definition of contingent facilities in LGIPs or in business practice manuals, nor an affirmative obligation in the LGIPs to apprise the interconnection customer of such contingencies in the facilities study and interconnection agreement. AWEA further asserts that in some cases, the appendices to an interconnection agreement may contain a long list of contingencies, including higher-queued generators throughout the RTO and numerous transmission upgrades; however, no showing has been made regarding whether these interconnection requests and facilities will impact a particular interconnection request.[138] AWEA supports MISO's practice of listing, in the interconnection agreement, contingent facilities that have a five percent or greater distribution factor impact on an interconnection request. AWEA notes that this practice has resulted in a

[132] MISO 2016 Comments at 2–3.

[133] ISO–NE 2016 Comments at 24.

[134] *Pro forma* LGIP Section 2.3.

[135] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 409 (''[i]f it is apparent to the Parties . . . that contingencies (such as other Interconnection Customers terminating their LGIAs) might affect the financial arrangements, the Parties should include such contingencies in their LGIA and address the effect of such contingencies on their financial obligations'').

[136] Petition at 25–26.

[137] Petition at 26.

[138] Petition at 27.

reduction in the number of contingent facilities listed in interconnection agreements by focusing on those that are electrically-impacted by the proposed interconnection request.[139] In particular, AWEA states that MISO's five percent threshold has resulted in an 85 percent reduction in contingent facilities listed in interconnection agreements.[140]

100. Several commenters assert that there is little clarity on how a transmission provider identifies contingent facilities and request that the Commission require transmission providers to specify the method they use to identify contingent facilities.[141] Invenergy states that the number of contingent facilities can change dramatically from the system impact study phase to the interconnection agreement phase, which can result in disputes between stakeholders regarding the study assumptions that resulted in addition or removal of certain contingent facilities from the list.[142] NextEra encourages the Commission to identify additional best practices that can be implemented in all regions.[143]

101. Some commenters note the potential difficulties in creating a generic methodology for determining the list of contingent facilities or note that a generic methodology may not be applicable to a given region. For example, EEI asserts that providing additional information, in line with MISO's five percent threshold, may increase the time and cost for preparing interconnection studies, cautioning that the five percent threshold might not work outside of MISO.[144] Indicated NYTOs note that developing a contingent facilities method is not applicable to NYISO because of NYISO's Class Year Study process.[145] MISO states that it is currently reviewing ''how to identify the network upgrades [that] a generation interconnection would be contingent upon.'' [146] ISO–NE states that contingent facilities are identified in the system impact study and are memorialized in the interconnection agreement, and the interconnection customer learns about these contingent facilities through the study of its interconnection request.[147]

c. Proposal

102. As noted above, the Commission requires transmission providers to list applicable contingent facilities in interconnection agreements.[148] However, the existing requirements do not specify how transmission providers should determine the list of contingent facilities, and this omission could result in uncertainty for interconnection customers. The Commission preliminarily finds that some practices with regard to these contingent facilities may not be just and reasonable or may be unduly discriminatory or preferential. Therefore, the method for determining contingent facilities must be described in *pro forma* LGIPs, rather than the business practices manuals.

103. The Commission proposes to require transmission providers to detail in the *pro forma* LGIP the method that transmission providers will use to determine the list of contingent facilities in evaluating an interconnection request. The Commission proposes that the transmission provider's method be transparent and sufficiently detailed to determine why a specific contingent facility was included on the list and how it impacts the interconnection request. The Commission also proposes for transmission providers to provide the list of contingent facilities to interconnection customers at the conclusion of the system impact study.

104. The transmission provider should also provide, upon request of the interconnection customer, the estimated network upgrade costs and estimated in-service completion time associated with each identified contingent facility when this information is not commercially sensitive. The Commission believes that such information will inform the interconnection customer about the potential impacts of a contingent facility on an interconnection request.

105. The Commission is considering whether the method for determining contingent facilities used by transmission providers should be harmonized among regions as much as possible. To this end, the Commission seeks comment on how transmission providers currently identify contingent facilities and what improvements to the existing approach(es) would be recommended by interconnection customers or others to determine whether there are identifiable best practices. The Commission also seeks comment on how the process for identifying contingent facilities could be standardized. For example, the Commission seeks comment on the usefulness of requiring transmission providers to include a distribution factor analysis in their methodologies for identifying contingent facilities, and if so, whether a specific distribution factor should be implemented in the *pro forma* LGIP (*e.g.,* a 5 percent distribution factor as referenced by AWEA). The Commission also seeks comment on whether there are alternative methodologies besides a distribution factor analysis that could be used to identify contingent facilities, and that may be better suited for standardization across transmission providers and included in the *pro forma* LGIP.

106. The Commission proposes to add the following new definition to Section 1 of the *pro forma* LGIP:

Contingent Facilities shall mean those unbuilt interconnection facilities and network upgrades upon which the interconnection request's costs, timing, and study findings are dependent, and if not built, could cause a need for restudies of the interconnection request or a reassessment of the network upgrades and/or costs and timing.

107. The Commission proposes to add a new section 3.8 to the *pro forma* LGIP:

3.8 Identification of Contingent Facilities

Transmission Provider shall post in this section a method for identifying the Contingent Facilities to be provided to Interconnection Customer at the conclusion of the System Impact Study and included in Interconnection Customer's GIA. The method shall be sufficiently transparent to determine why a specific Contingent Facility was identified and how it relates to the interconnection request. Transmission Provider shall also provide, upon request of the Interconnection Customer, the estimated interconnection facility and/or network upgrade costs and estimated in-service completion time of each identified Contingent Facility when this information is not commercially sensitive.

108. The Commission seeks comment on the proposed reforms to the *pro forma* LGIP for transmission providers to include a method to identify contingent facilities and to provide the list of contingent facilities to interconnection customers at the conclusion of the system impact study. The Commission also seeks comment on whether estimates of the costs and timing of higher-queued contingent facilities are helpful to the interconnection customer and can be provided to the interconnection customer without disclosing commercially sensitive information.

2. Transparency Regarding Study Models and Assumptions

109. As discussed in the previous section, increasing the transparency of

[139] Petition at 27.

[140] Petition at 27.

[141] EDF 2016 Comments at 38–39; AWEA 2016 Comments at 36–37; Invenergy 2016 Comments at 23–24; NextEra 2015 Comments at 7.

[142] Invenergy 2016 Comments at 23–24.

[143] NextEra 2015 Comments at 7.

[144] EEI 2015 Comments at 25.

[145] Indicated NYTOs 2015 Comments at 4.

[146] MISO 2016 Comments at 19.

[147] ISO–NE 2016 Comments at 26.

[148] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 409.

the network models and underlying assumptions used for interconnection studies, including shift factors and dispatch information, is a key improvement that could be made to the interconnection process. To increase transparency with regard to the interconnection study processes for interconnection customers and to ensure consistency in the analysis of interconnection requests, the Commission proposes a general requirement that transmission providers list all the network models and underlying assumptions used for interconnection studies in their *pro forma* LGIPs and on their OASIS sites. The Commission believes this information will benefit both interconnection customers in the queue as well as those developing interconnection requests by potentially helping them avoid entering the queue with non-viable interconnection requests. The Commission also proposes that transmission providers include non-confidential supporting data on OASIS.

a. Existing Provisions and Background

110. Section 2.3 of the *pro forma* LGIP requires the transmission provider to provide base power flow, short circuit, and stability databases, including all underlying assumptions, and a contingency list upon request, subject to confidentiality provisions in section 13.1 of the *pro forma* LGIP. A transmission provider may require that an interconnection customer sign a confidentiality agreement before the release of commercially sensitive information or Critical Energy Infrastructure Information (CEII) in the base case data.[149]

111. In Attachment A to the individual interconnection study agreements in the *pro forma* LGIP, the interconnection customer and the transmission provider list the assumptions under which the individual studies are to be performed. However, the general assumptions used to form the network models are not universally listed or posted for interconnection customers to examine prior to entering the queue.

112. While some regions allow their network models to be accessed prior to an interconnection customer submitting an interconnection request in order to facilitate development decisions, such access is not consistent across regions. At times, information that would be relevant for prospective interconnection customers to plan interconnection requests is contained within business practice manuals and may not be consolidated in one location or easily found.

b. AWEA Petition and Comments

113. It its Petition, AWEA claims that the study processes and assumptions for forming network models used in interconnection studies are not always transparent. AWEA claims that some transmission providers inconsistently apply certain assumptions, such as shift factors, which can lead to vastly different study results for similar interconnection requests participating in the same market.[150] In its post-technical conference comments about the use of non-disclosure agreements to facilitate the study process, AWEA contends that, once a non-disclosure agreement is provided by the interconnection customer, the transmission provider or transmission owner should not deny or delay providing models or other requested information.[151]

114. Several commenters, such as Wind on the Wires, agree with AWEA that further transparency is necessary with respect to interconnection studies and study assumptions.[152] Additionally, the Wind Coalition asserts that transmission providers should make clear to all stakeholders how they model interconnections.[153] EDF states that study assumptions have a direct effect on generator interconnection study results that determine available capacity and whether network upgrades are necessary to accommodate the level of requested interconnection service. According to EDF, a key study assumption is generation dispatch, *i.e.,* the assumed levels of dispatch during peak and off-peak periods assigned to an interconnection request. EDF claims that it has seen significant variation in study assumptions from RTO to RTO and also within an RTO.[154] EDF also states that interconnection customers need access to models before deciding to enter the interconnection queue and that these models need to take into account up-to-date power flow data.[155]

115. Some commenters do not think it is appropriate for the Commission to require transmission providers to be more transparent about interconnection study assumptions. ISO–NE states that it already provides extensive information about assumptions underlying its interconnection studies.[156] TVA contends that transmission providers may be able to provide more detailed information regarding study process practices, inputs, and results, but certain information cannot be made public and can be provided to customers only under a non-disclosure agreement.[157]

116. While some transmission providers might already provide sufficient information regarding their study assumptions, some commenters do not consider all transmission providers to be sufficiently transparent in this regard.[158]

c. Proposal

117. The Commission believes that stakeholders benefit from increased transparency. The Commission preliminarily finds that clear network model assumptions, made available early in the interconnection process, will provide interconnection customers with data that will allow them to better plan interconnection requests and lead to a more efficient interconnection process. Additionally, the Commission preliminarily finds that interconnection customers' ability to obtain study assumptions will reduce the need for protracted study discussions.

118. The Commission proposes to require transmission providers to make more transparent the assumptions underlying the network models used in conducting interconnection studies. The Commission proposes that transmission providers detail the network model assumptions used during the feasibility study in Attachment A to Appendix 2 of the *pro forma* LGIP. The Commission also proposes that transmission providers detail the network model assumptions used during the system impact study in Attachment A to Appendix 3 of the *pro forma* LGIP.

119. Additionally, because interconnection customers would benefit from an understanding of network models and their underlying assumptions before submitting interconnection requests, the Commission proposes that transmission providers be required to provide network model details on their OASIS sites, including, but not limited to, shift factors, dispatch assumptions, load power factors, and power flows. The Commission proposes modifying section 2.3 of the *pro forma* LGIP:

Base Case Data. Transmission Provider shall provide base power flow, short circuit

[149] *Pro forma* LGIP Sec. 2.3.

[150] AWEA Petition at 33–35.

[151] AWEA 2016 Comments at 32.

[152] Wind on the Wires 2015 Comments at 3.

[153] Wind Coalition 2015 Comments at 2.

[154] EDF 2015 Comments at 21–23.

[155] EDF 2016 Comments at 31.

[156] ISO–NE 2015 Comments at 44.

[157] TVA 2015 Comments at 8.

[158] *See, e.g.,* EDF 2015 Comments at 21–23; Wind Coalition 2015 Comments at 2.

and stability databases, including all underlying assumptions, and contingency list upon request subject to confidentiality provisions in LGIP Section 13.1. *Additionally, Transmission Provider will maintain network models and underlying assumptions on its OASIS site for access by OASIS users.* Transmission Provider is permitted to require that Interconnection Customer *and OASIS site users* sign a confidentiality agreement before the release of commercially sensitive information or Critical Energy Infrastructure Information in the Base Case data. Such databases and lists, hereinafter referred to as Base Cases, shall include all (1) generation projects and (ii) transmission projects, including merchant transmission projects that are proposed for the Transmission System for which a transmission expansion plan has been submitted and approved by the applicable authority.

120. The Commission seeks comment on whether there are other specific network model details and underlying assumptions that transmission providers should post on their OASIS site and should describe in the *pro forma* LGIP. The Commission seeks comment on whether and how transmission providers should provide notice of any variation from posted network model assumptions for a specific study, including whether the Commission should require notice of any variation to be submitted to the Commission.

121. The Commission appreciates that transmission providers have confidentiality and data security concerns associated with providing certain information and system access, *e.g.,* business sensitive information and cybersecurity-related information. However, the Commission believes there are likely safeguards that can be put in place to satisfactorily address these concerns. The Commission seeks comment on any confidentiality or security concerns regarding the posting of specific model assumptions on OASIS or describing them in the *pro forma* LGIP. Commenters should also specify any data elements that should be subject to confidentiality or non-disclosure agreements.

3. Congestion and Curtailment Information

122. The Commission proposes to require transmission providers to post congestion and curtailment information and seeks comment regarding the location of such posting and the level of disaggregation (or granularity) of the information posted. This information can be particularly important for interconnection customers that are considering Energy Resource Interconnection Service (ERIS),[159] as the interconnection customer may interconnect to the transmission system and be eligible to deliver its output using the existing firm or non-firm capacity of that transmission system on an ''as available'' basis.[160] An important consideration for such a customer is the degree to which the customer will be curtailed. Historic congestion and curtailment information can inform the interconnection customer's assessment. This information could also be relevant for any interconnection customer in determining where on the system to request interconnection. For instance, knowledge that a particular location experiences frequent congestion or curtailment may suggest that any ''as-available'' service at such a location will likely be frequently unavailable or may require extensive network upgrades to enable interconnection.

a. Existing Provisions and Background

123. Currently, transmission providers are not required to provide consistent and transparent congestion information to interconnection customers. The level of disaggregation and availability of this data varies per transmission provider. Additionally, how and where this data is posted may be inconsistent from transmission provider to transmission provider.

b. AWEA Petition and Comments

124. In its Petition, AWEA asserts that interconnection studies do not provide system information showing the extent of potential curtailments. AWEA argues that interconnection customers cannot make informed business decisions regarding the financial viability of their interconnection requests and cannot accurately assess the extent of energy deliverability unless they have a reasonable expectation of their curtailment risk. AWEA requests that the Commission require transmission providers to provide curtailment risk information on their Web sites and in interconnection studies. AWEA contends that requiring transmission providers to provide curtailment information on a monthly basis, as well as provide more detailed information on all interfaces, including local interfaces, could improve the deliverability of energy from new generation and improve interconnection customers' ability to optimally site generating facilities.[161]

125. Several commenters concur with AWEA that more information on curtailment and congestion provided by transmission providers would benefit interconnection customers. NRG asserts that accurate reporting of congestion and curtailment information, and having access to congestion and operational data, could play a crucial role in siting generating facilities and lowering the amount of required network upgrades needed to interconnect.[162] E.ON contends that transmission providers have the tools to determine the extent to which historical congestion on local transmission elements may impact an interconnection request, but they do not share this information with interconnection customers.[163]

126. Several commenters make specific suggestions on the types of information they would like transmission providers to share.[164] For example, AWEA requests that the Commission require that transmission providers post, on a monthly basis, information on congested transmission facilities and interfaces covering the previous three years, including flow duration curves, the number of hours of curtailments due to congestion on those facilities and interfaces, and the cause(s) of congestion. AWEA also requests that the Commission require transmission providers to include, in interconnection studies, information on existing usage and congestion on the transmission facilities that are electrically significant to the interconnection request based on system conditions known at the time.[165]

127. ISO–NE and MISO argue that their processes to share curtailment and congestion data are sufficient.[166] ISO–NE notes that it frequently informs stakeholders of areas where curtailment is likely to occur, and MISO states that it posts real-time information on constraints. MISO argues that

[159] Energy Resource Interconnection Service shall mean an Interconnection Service that allows the Interconnection Customer to connect its Generating Facility to the Transmission Provider's Transmission System to be eligible to deliver the Generating Facility's electric output using the existing firm or nonfirm capacity of the Transmission Provider's Transmission System on an as available basis. Energy Resource Interconnection Service in and of itself does not convey transmission service. *See* Standard Large Generator Interconnection Procedures, Section 1, Definitions.

[160] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 752–753.

[161] Petition at 40.

[162] NRG 2015 Comments at 4–5.

[163] E.ON 2016 Comments at 11.

[164] EDF 2016 Comments at 3; E.ON 2016 Comments at 11.

[165] Petition at 43–44.

[166] MISO 2015 Comments at 17–18. MISO states that it does post in real-time information on constraints according to its Business Practice Manuals. ISO–NE states that assumptions underlying planning are already shared according to its Planning Procedures and Planning Guides, and base case data can be requested according to section 2.3 of Schedule 22 of its LGIP.

interconnection customers can hire consultants to investigate curtailment risks, rather than requiring RTOs/ISOs to do this research for them.[167] ISO–NE also argues that system impact studies are discrete testing programs and cannot capture the full range of real-time load and outages. MISO and EEI argue that AWEA's request for more curtailment information would result in administrative burden and further queue delays. Additionally, ISO–NE asserts that AWEA inaccurately implies that ISO–NE's minimum interconnection service grants new generators rights to avoid curtailment risks,[168] arguing that all interconnection customer of new assets face curtailment risk stemming from a competitive market design. Similarly, MISO TOs interpret AWEA's request as a complaint about the lack of certainty associated with ERIS, which by definition is an as-available service.[169] They argue that a customer with ERIS assumes the risk of potentially intermittent service and could choose to pay for Network Resource Interconnection Service (NRIS).[170] Six Cities argues that interconnection customers may misinterpret information on expected congestion as a commitment to future availability of service when interconnecting under ERIS or Energy-Only Deliverability Status procedures.[171]

c. Proposal

128. The Commission preliminarily finds that improving access to congestion and curtailment data may allow interconnection customers to more accurately assess curtailment risks at different locations on the system. As a result, interconnection customers may be better able to assess the value of requesting ERIS relative to NRIS and may be better able to choose where to site their generating facilities. Such better informed decision-making could result in a more efficient use of the transmission system. In addition, improving access to congestion and curtailment data could mitigate the risk of interconnection customers exiting at later stages of the interconnection process, thereby reducing the need for restudies, given that interconnection customers would be better informed on grid conditions through more transparent access to congestion and curtailment data. The Commission proposes revising section 37.6 of its regulations to require that transmission providers post congestion information and curtailment information in one location on their OASIS sites so that interconnection customers can more easily assess information that may aid in their decision-making. The Commission also seeks comment on whether there is congestion and curtailment information that is specific to an interconnection request and whether transmission providers should be required to provide this information to interconnection customers through the interconnection study process.

129. Improving access to curtailment and congestion data could reduce uncertainties associated with as-available service, as well as better inform interconnection customers of the risks surrounding as-available transmission service. With regard to whether interconnection customers may misinterpret information and make assumptions about the availability of service, the Commission finds that this is a reasonable risk of doing business, and it is the interconnection customers' responsibility to make certain decisions based on the best data available.

130. In addition, the Commission proposes to require transmission providers to post disaggregated, or more granular (*e.g.,* hourly and locational data), congestion and curtailment information that is more specific than the information currently provided by some transmission providers.[172] The Commission proposes that the transmission provider must post on OASIS information on congestion data representing (i) total hours of curtailment on all interfaces, (ii) total hours of Transmission Provider-ordered generation curtailment and transmission service curtailment due to congestion on that facility or interface, (iii) the cause of the congestion (*e.g.,* a contingency or an outage), and (iv) total megawatt hours of curtailment due to lack of transmission for that month. The Commission proposes that this data shall be posted on a monthly basis by the 15th day of the following month in one location on the OASIS, and maintained for a minimum of three years. This proposed reform aims to increase transparency regarding congestion and curtailment risks at various points in the transmission system that could help interconnection customers identify interconnection locations in less congested areas. To effectuate this proposal, the Commission proposes to revise section 37.6 of the Code of Federal Regulations to add new section (l) requiring the posting of congestion and curtailment data on a monthly basis by the 15th day of the following month in one location on the OASIS. Transmission providers must maintain these data for at least three years. The information that must be posted is as follows: (i) Total hours of curtailment on all interfaces, (ii) total hours of Transmission Provider-ordered generation curtailment and transmission service curtailment due to congestion on that facility or interface, (iii) the cause of the congestion (*e.g.,* a contingency or an outage), and (iv) total megawatt hours of curtailment due to lack of transmission for that month.

131. The Commission seeks comments on the level of information to be provided, the frequency at which the information should be provided, and how many months/years the provided information should cover. The Commission further seeks comment on the value to interconnection customers of requiring transmission providers to post on OASIS flow duration curves on the major transmission interfaces, based on hourly flow data. The Commission also seeks comment on whether there is detailed, interconnection request-specific congestion and curtailment information that would be more appropriately provided to the interconnection customer through the interconnection study process (*e.g.,* at the scoping meeting).

132. With regard to the sharing of more detailed congestion and curtailment data, several parties raise concerns that this level of detail could expose market sensitive information, such as CEII data, and give interconnection customers a market advantage over other market participants.[173] The Commission does not find these arguments credible. The

[167] MISO 2015 Comments at 17–18.

[168] ISO–NE 2015 Comments at 46.

[169] MISO TOs 2015 Comments at 16 (citing Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 752; *pro forma* LGIA at Art. 1 (definition of ERIS) and Sec. 4.1.1; MISO, FERC Electric Tariff, Attachment X, Sec. 3.2.1.1 (49.0.0)).

[170] If an interconnection customer chooses NRIS, Order No. 2003 requires the transmission provider to conduct interconnection studies similar to how the transmission provider would integrate its own generators to serve load. This approach assumes a portion of the capacity of existing network resources is displaced by the output of the facility seeking to interconnect. Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 754–55.

[171] Six Cities 2015 Comments at 4.

[172] AWEA requests that the Commission require that transmission providers post, on a monthly basis, information on congested transmission facilities and interfaces covering the previous three years, including flow duration curves, the number of hours of curtailments due to congestion on those facilities and interfaces, and the cause(s) of congestion. AWEA also requests that the Commission require transmission providers to include, in interconnection studies, information on existing usage and congestion on the transmission facilities that are electrically significant to the interconnection request based on system conditions known at the time. Petition at 43–44.

[173] EEI 2015 Comments at 38–39; MISO 2015 Comments at 18.

Commission believes that the posting of more detailed congestion and curtailment data will not give undue advantage to interconnection customers over other market participants, as all market participants will have access to this data, and none of the data should include proprietary marginal costs. With regard to concerns that the provision of congestion and curtailment information unnecessarily burdens transmission providers, the Commission notes that the proposal merely requires the posting of congestion and curtailment information in one location on OASIS, which should improve interconnection customers' ability to conduct their own research on which to base their decisions. The Commission seeks comments on the level of detail appropriate for congestion and curtailment information, the frequency of reporting, the length of time reported data should cover, and whether there is interconnection-request-specific congestion and curtailment information that could be provided to interconnection customers as part of the interconnection study process.

133. The Commission seeks comment on further changes to Section 3.3.4 of the LGIP requiring transmission providers and/or transmission owners to provide curtailment and congestion information at the scoping meeting between the transmission provider, transmission owner, and interconnection customer. For example, the Commission could revise Section 3.3.4 of the LGIP to read:

3.3.4 Scoping Meeting. Within ten (10) Business Days after receipt of a valid Interconnection Request, Transmission Provider shall establish a date agreeable to Interconnection Customer for the Scoping Meeting, and such date shall be no later than thirty (30) Calendar Days from receipt of the valid Interconnection Request, unless otherwise mutually agreed upon by the Parties. The purpose of the Scoping Meeting shall be to discuss alternative interconnection options, to exchange information including any transmission data, *including any curtailment and/or congestion information,* that would reasonably be expected to impact such interconnection options, to analyze such information and to determine the potential feasible Points of Interconnection. Transmission Provider and Interconnection Customer will bring to the meeting such technical data, including, but not limited to: (i) General facility loadings, (ii) general instability issues, (iii) general short circuit issues, (iv) general voltage issues, and (v) general reliability issues as may be reasonably required to accomplish the purpose of the meeting. Transmission Provider and Interconnection Customer will also bring to the meeting personnel and other resources as may be reasonably required to accomplish the purpose of the meeting in the time allocated for the meeting. On the basis of the meeting, Interconnection Customer shall designate its Point of Interconnection, pursuant to Section 6.1, and one or more available alternative Point(s) of Interconnection. The duration of the meeting shall be sufficient to accomplish its purpose.

4. Definition of Generating Facility in the *Pro Forma* LGIP and LGIA

134. The Commission proposes to revise the definition of a ''Generating Facility'' in the *pro forma* LGIP/LGIA to include electric storage resources.

a. Existing Provisions and Background

135. While the Commission includes electric storage resources in the definition of a generating facility in the *pro forma* SGIP/SGIA,[174] the Commission has not explicitly set forth a similar definition in the *pro forma* LGIP/LGIA. Although some transmission providers have extended the clarification for electric storage resources to large generating facilities, doing so consistently may ensure that all transmission providers have interconnection procedures and agreements that are applicable to FERC-jurisdictional electric storage resources, regardless of size.

b. Proposal

136. The Commission preliminarily finds that the failure to include electric storage resources in the definition of ''Generating Facility'' in the *pro forma* LGIA/LGIP may pose a barrier to the development of large electric storage resources, which may not be just and reasonable or may be unduly discriminatory or preferential. In Order No. 792, the Commission revised the definition of ''Small Generating Facility'' in the *pro forma* SGIP/SGIA to: ''[t]he Interconnection Customer's device for the production *and/or storage for later injection* of electricity identified in the Interconnection Request, but shall not include the Interconnection Customer's Interconnection Facilities.'' [175]

137. Given the existing precedent for small generators, the inconsistency between the *pro forma* definitions of small generating facilities and large generating facilities, and the potential that development of electric storage resources larger than 20 MW will increase,[176] the Commission proposes a conforming change to the definition of ''Generating Facility'' in the *pro forma* LGIP/LGIA.

138. In consideration of the foregoing, the Commission proposes to amend the definition of Generating Facility in the *pro forma* LGIP/LGIA to:

Generating Facility shall mean Interconnection Customer's device for the production *and/or storage for later injection* of electricity identified in the Interconnection Request, but shall not include the interconnection customer's Interconnection Facilities.

139. This revised definition is also reflected in the proposed revisions to section 1 of the *pro forma* LGIP and the proposed revisions to article 1 of the *pro forma* LGIA.

5. Interconnection Study Deadlines

140. The Commission proposes that transmission providers report on their completion of interconnection studies within established timeframes, in order to improve transparency and to provide greater insight into the causes of processing delays.

a. Existing Provisions and Background

141. Currently in the *pro forma* LGIP, transmission providers must use ''Reasonable Efforts'' [177] to complete feasibility studies in 45 days, system impact studies in 90 days, and the facility studies within 90 or 180 days.[178] While independent entities may propose variations to these study completion timeframes, they must use reasonable efforts to complete interconnection studies within such timeframes. The Commission currently requires transmission providers to post information about transmission service request processing time on the transmission providers OASIS [179] and assesses penalties to transmission providers that complete too many transmission service request studies outside of the study completion timeframes. Transmission providers are able to explain extenuating circumstances in a filing with the Commission to avoid such penalties.

[174] *Small Generator Interconnection Agreement and Procedures,* 78 FR 73,240 (Nov. 22, 2013), Order No. 792, 145 FERC ¶ 61,159 at P 227, *clarifying,* Order 792–A, 146 FERC ¶ 61,214 (2014).

[175] Order No. 792, 145 FERC ¶ 61,159 at P 228 (emphasis in original).

[176] Slaughter, Andrew, ''Electricity Storage Technologies, impacts, and prospects,'' Deloitte Center for Energy Solutions, 2015 at 7; *https://www2.deloitte.com/content/dam/Deloitte/us/Documents/energy-resources/us-er-electric-storage-paper.pdf.*

[177] As noted above, Reasonable Efforts shall mean, with respect to an action required to be attempted or taken by a Party under the Standard Large Generator Interconnection Agreement, efforts that are timely and consistent with Good Utility Practice and are otherwise substantially equivalent to those a Party would use to protect its own interests. *Pro forma* LGIP Sec. 1 (Definitions).

[178] *Pro forma* LGIP at Sec. 6.3, 7.4, and 8.3.

[179] *See* 18 CFR 37.6(h) (2016).

b. AWEA Petition and Comments

142. In its Petition, AWEA voices concern about the nature of study delays and requests elimination of the reasonable effort standard and instituting firm deadlines to give some certainty to the process.[180] Some commenters disagree about AWEA's proposal to remove the reasonable efforts standard from established timeframes to require that transmission providers meet firm deadlines. Several commenters contend that AWEA does not account for the various factors that impact the interconnection study and restudy processes.[181] NYISO states that the performance of interconnection studies requires the active participation and input of multiple parties, including the provision of extensive information and technical data by interconnection customers. NYISO and Indicated NYTOs assert that flexibility in performing interconnection studies is necessary.[182] Similarly, TVA contends that the lack of uniformity in generator interconnection requests does not allow a transmission provider to follow an inflexible, standardized study schedule. TVA argues that differences in size and location of proposed generators result in significant variability in the studies' complexity and the required analysis time, asserting that the process is not entirely within a transmission provider's control.[183] Additionally, some commenters argue that restudy delays are often due to the actions or inactions of the interconnection customer.[184]

143. TVA asserts that if a transmission provider must always meet a fixed study schedule, it would have to either maintain a larger analytical staff that would frequently be idle when there are few interconnection requests or would have to increasingly rely on contractors to conduct studies.[185] KCP&L states that interconnection customers would ultimately pay the additional costs for increased staffing and resources needed to meet firm study deadlines.[186] KCP&L argues that there are costs to faster processing of interconnection requests, costs which are most likely, and appropriately, recovered in higher study fees—fees that AWEA criticizes and seeks to cap.[187] TVA contends that allowing greater flexibility in study completion time allows the transmission provider to balance the legitimate timing needs of generation developers with the costs to load.[188]

144. Several parties with experience as interconnection customers with renewable generating facilities support efforts to provide interconnection study requests and restudy results by the dates listed in the generator interconnection procedures.[189] Sustainable FERC contends that the ability to accurately and timely complete interconnection studies pursuant to interconnections requests is within transmission providers' control but that these delays chiefly affect interconnection customers even though interconnection customers have no control over the process.[190] NRG asserts that the uncertainty created by sliding study dates causes significant risk to interconnection customers, which is, in turn, passed through to all purchasers of renewable power in the form of higher risk premiums.[191]

145. Similarly, RENEW argues that the current interconnection process, which it believes contains embedded unjust, unreasonable, and unduly discriminatory delays, imposes barriers to the development of new generation sources.[192] In addition, Interwest Energy Alliance contends that for renewable energy generators in the West, some interconnection processes have imposed delays and unduly discriminatory costs that resulted in ''increased potential for missed deadlines and disqualification when submitting bids in response to requests for proposals in competitive procurements.'' [193]

c. Proposal

146. The Commission has expressed concerns about interconnection queue delays in other proceedings.[194] In the 2008 Order, the Commission required all RTOs/ISOs to file an interconnection queue status report at the Commission and, as a condition of approving requested queue reforms, required RTOs/ISOs to file periodic queue status updates at the Commission for a period of time.[195]

147. Although the Commission has approved queue reforms to attempt to streamline the interconnection process, there are still delays associated with the interconnection process. Some commenters have asked the Commission to require transmission providers to complete interconnection connection studies within the *pro forma* LGIP time frames rather than simply require the transmission providers to make reasonable efforts to do so. The Commission believes that transmission providers should continue to have flexibility in completing interconnection studies, but is nonetheless concerned that delays in the interconnection process continue. At times, it is not clear to interconnection customers why and where queue delays are occurring, and the underlying causes of queue delays are not always agreed upon by interconnection customers and transmission providers. Providing greater transparency by identifying the geographical locations where these delays are occurring and the causes of these delays would benefit stakeholders.

148. The Commission proposes to require that transmission providers post summary statistics related to processing interconnection studies, pursuant to interconnection service requests, on their OASIS sites on a quarterly basis. This proposal is analogous to the requirement we established in Order No. 890 that transmission providers post information on processing of transmission service request studies within the best efforts timeframes.[196] The Commission proposes to require that a transmission provider that has more than 25 percent of any study type exceeding study deadlines for interconnection requests for two consecutive quarters must file informational reports at the Commission for the next four calendar quarters. For example, if a transmission provider had 35 percent of its interconnection feasibility studies exceeding study deadlines one calendar quarter and 40 percent of them exceeding study deadlines the next calendar quarter, the transmission provider would have to

[180] Petition at 17.

[181] Avista 2015 Comments at 3; EEI 2015 Comments at 21; KCP&L 2015 Comments at 10; NYISO 2015 Comments at 20–21; TVA 2015 Comments at 2.

[182] NYISO 2015 Comments at 21 and Indicated NYTOs 2015 Comments at 6.

[183] TVA 2015 Comments at 2.

[184] Avista 2015 Comments at 3; KCP&L 2015 Comments at 10; NYISO 2015 Comments at 21; PSEG 2015 Comments at 9; TVA 2015 Comments at 3.

[185] TVA 2015 Comments at 2, 3.

[186] KCP&L Comments at 10 (citing Order No. 2003–B, FERC Stats. & Regs. ¶ 31,171 at P 2).

[187] KCP&L 2015 Comments at 8–9.

[188] TVA 2015 Comments at 2, 3.

[189] NRG Companies 2015 Comments at 3; RENEW 2015 Comments at 4; Sustainable FERC 2015 Comments at 2; Wind Coalition 2015 Comments at 2; Wind on the Wires 2015 Comments at 2.

[190] Sustainable FERC 2015 Comments at 2.

[191] NRG 2015 Comments at 3.

[192] RENEW 2015 Comments at 3.

[193] Interwest 2015 Comments at 2.

[194] *See, e.g.,* 2008 Order, 122 FERC ¶ 61,252 at PP 4–6.

[195] *See, e.g., Midwest Indep. Transmission Sys. Operator, Inc.,* 124 FERC ¶ 61,183 at P 164 (directing MISO to file annual updates on interconnection queue metrics and queue improvement efforts from 2009–2011); *California Indep. Sys. Operator Corp.,* 124 FERC ¶ 61,292 at PP 199–200 (directing CAISO to file quarterly reports on the interconnection including the number of interconnection requests received, studies conducted and the reasons for missing study deadlines).

[196] *See* 18 CFR 37.6(h) (2016).

file reports to the Commission for the following four calendar quarters describing the reason for each study (or group of clustered studies) delay and post on OASIS the total number of employee or consultant hours devoted to processing studies that quarter. *The transmission provider must continue to file these reports for four consecutive quarters. If during this period, the transmission provider exceeds more than 25 percent of study deadlines for any study type for two consecutive quarters, the reporting requirement would be retriggered for another four consecutive quarters from the date of the last consecutive quarter to exceed the 25 percent threshold.* For example, if a transmission provider had more than 25 percent of its interconnection feasibility studies exceeding study deadlines every calendar quarter in Year 1, it must begin reporting to the Commission in the third quarter of Year 1 and must continue reporting until at least the fourth quarter of Year 2.

149. To this end, the Commission proposes to modify section 3.4 of the *pro forma* LGIP [197] as follows (*proposing to delete italicized text*):

3.4–3.5.1 OASIS Posting.

3.5.2 The Transmission Provider will maintain on its OASIS summary statistics related to processing Interconnection Studies pursuant to Interconnection Requests, updated quarterly. For each calendar quarter, Transmission Providers must calculate and post the information detailed in sections 3.5.2.1 through 3.5.2.4.

3.5.2.1 Interconnection Feasibility Studies processing time. (A) Number of Interconnection Requests that had Interconnection Feasibility Studies completed within the Transmission Provider's coordinated region during the reporting quarter, (B) Number of Interconnection Requests that had Interconnection Feasibility Studies completed within the Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in the Transmission Provider's LGIP] after receipt by the Transmission Provider of the Interconnection Customer's executed Interconnection Feasibility Study Agreement, (C) At the end of the reporting quarter, the number of active valid Interconnection Requests with ongoing incomplete Interconnection Feasibility Studies where such Interconnection Requests had executed Interconnection Feasibility Study Agreements received by the Transmission Provider more than [timeline as listed in the Transmission Provider's LGIP] before the reporting quarter end, (D) Mean time (in days), Interconnection Feasibility Studies completed within the Transmission Provider's coordinated region during the reporting quarter, from the date when the Transmission Provider received the executed the Interconnection Feasibility Study Agreement to the date when the Transmission Provider provided the completed Interconnection Feasibility Study to the Interconnection Customer, (E) Percentage of Interconnection Feasibility Studies exceeding [timeline as listed in the Transmission Provider's LGIP] to complete this reporting period, calculated as 1—(the sum of 3.5.2.2(A) minus 3.5.2.2(B) and dividing that amount by the sum of 3.5.2.2(A) plus 3.5.2.2(C)).

3.5.2.2 Interconnection System Impact Studies processing time. (A) Number of Interconnection Requests that had Interconnection System Impact Studies completed within the Transmission Provider's coordinated region during the reporting quarter, (B) Number of Interconnection Requests that had Interconnection System Impact Studies completed within the Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in the Transmission Provider's LGIP] after receipt by the Transmission Provider of the Interconnection Customer's executed Interconnection System Impact Study Agreement, (C) At the end of the reporting quarter, the number of active valid Interconnection Requests with ongoing incomplete System Impact Studies where such Interconnection Requests had executed Interconnection System Impact Study Agreements received by the Transmission Provider more than [timeline as listed in the Transmission Provider's LGIP] before the reporting quarter end, (D) Mean time (in days), Interconnection System Impact Studies completed within the Transmission Provider's coordinated region during the reporting quarter, from the date when the Transmission Provider received the executed Interconnection System Impact Study Agreement to the date when the Transmission Provider provided the completed Interconnection System Impact Study to the Interconnection Customer, (E) Percentage of Interconnection System Impact Studies exceeding [timeline as listed in the Transmission Provider's LGIP] to complete this reporting period, calculated as 1—(the sum of 3.5.2.3(A) minus 3.5.2.3(B) and dividing that amount by the sum of 3.5.2.3(A) plus 3.5.2.3(C)).

3.5.2.3 Interconnection Facilities Studies Processing time. (A) Number of Interconnection Requests that had Interconnection Facilities Studies that are completed within the Transmission Provider's coordinated region during the reporting quarter, (B) Number of Interconnection Requests that had Interconnection Facilities Studies that are completed within the Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in the Transmission Provider's LGIP] after receipt by the Transmission Provider of the Interconnection Customer's executed Interconnection Facilities Study Agreement, (C) At the end of the reporting quarter, the number of active valid Interconnection Service requests with ongoing incomplete Interconnection Facilities Studies where such Interconnection Requests had executed Interconnection Facilities Studies Agreement received by the Transmission Provider more than [timeline as listed in the Transmission Provider's LGIP] before the reporting quarter end (D) Mean time (in days), Interconnection Facilities Studies completed within the Transmission Provider's coordinated region during the reporting quarter, from the date when the Transmission Provider received the executed Interconnection Facilities Study Agreement to the date when the Transmission Provider provided the completed Interconnection Facilities Study to the Interconnection Customer, (E) Percentage of delayed Interconnection Facilities Studies this reporting period, calculated as 1—(the sum of 3.5.2.4(A) minus 3.5.2.4(B) and dividing that amount by the sum of 3.5.2.4(A) plus 3.5.2.4(C)).

3.5.2.4 Interconnection Service requests withdrawn from interconnection queue. (A) Number of Interconnection Service requests withdrawn from the Transmission Provider's interconnection queue during the reporting quarter, (B) Number of Interconnection Service requests withdrawn from the Transmission Provider's interconnection queue during the reporting quarter before completion of any interconnection studies or execution of any interconnection study agreements, (C) Number of Interconnection Service requests withdrawn from the Transmission Provider's interconnection queue during the reporting quarter before completion of an Interconnection System Impact Study, (D) Number of Interconnection Service requests withdrawn from the Transmission Provider's interconnection queue during the reporting quarter before completion of an Interconnection Facility Study, (E) Number of Interconnection Service requests withdrawn from the Transmission Provider's interconnection queue after execution of a generator interconnection agreement or Interconnection Customer requests the filing of an unexecuted, new interconnection agreement, (F) Mean time (in days), for all withdrawn Interconnection Service requests, from the date when the request was determined to be valid to when the Transmission Provider received the request to withdraw from the queue.

3.5.3 The Transmission Provider is required to post on OASIS the measures in paragraph 3.5.2.1(A) through paragraph 3.5.2.4(F) for each calendar quarter within 30 days of the end of the calendar quarter. The Transmission Provider will keep the quarterly measures posted on OASIS for three calendar years with the first required reporting year to be 2017.

3.5.4 In the event that any of the values calculated in paragraphs 3.5.2.1(E), 3.5.2.2(E) or 3.5.2.3(E) exceeds 25 percent for two consecutive calendar quarters the Transmission Provider will have to comply with the measures below for the next four consecutive calendar quarters and must continue reporting this information until the

[197] In the ''Utilization of Surplus Interconnection Service'' section, the Commission proposes revisions to the *pro forma* LGIP that result in renumbering of several existing sections. One section that the Commission proposes to be renumbered is section 3.4. For this reason, the proposed revisions to the ''OASIS Posting'' section (current section 3.4) will begin at section 3.5.1.

Transmission Provider reports four consecutive calendar quarters without the values calculated in 3.5.2.1(E), 3.5.2.2(E) or 3.5.2.3(E) exceeding 25 percent for two consecutive calendar quarters:

(i) The Transmission Provider must submit a report to the Commission describing the reason for each study or group of clustered studies pursuant to an Interconnection Request that exceeded its deadline (i.e., 45, 90 or 180 days) for completion (excluding any allowance for Reasonable Efforts). The Transmission Provider must describe the reasons for each study delay and any steps taken to remedy these specific issues and, if applicable, prevent such delays in the future. The report must be filed at the Commission within 45 days of the end of the calendar quarter.

(ii) The Transmission Provider shall aggregate the total number of employee-hours and third party consultant hours expended towards interconnection studies within its coordinated region that quarter and post on OASIS. This information is to be posted within 30 days of the end of the calendar quarter.

150. The Commission preliminarily finds that this proposal will increase transparency into study timeliness and the reason for delays in regions that have consistent study delays. The Commission seeks comment on whether to require fewer or additional interconnection processing statistics to be posted on OASIS by the transmission provider. For example, such additional statistics could include: The number of new valid interconnection requests received by the transmission provider, the average number of days it takes for the transmission provider to determine whether a received interconnection service request is a valid interconnection request, the average number of days it takes for an interconnection request to receive a study agreement, and the number of study agreements executed in the transmission provider's region during the reporting period. The Commission also seeks comment on whether it is proposing the appropriate summary data requirements to enhance transparency into interconnection queue processes and what, if any, customizations of these requirements should be made to adjust for different regional processes.

151. The Commission notes that LGIP Sections 6.3, 7.4 and 8.3 have provisions requiring transmission providers to inform interconnection customers as to the causes of study delays and to provide them with revised study schedules. The Commission requests comment on whether interconnection customers have sufficient information regarding, and transparency into, the cause of study delays under the current LGIP provisions and whether transmission providers should have to provide a more detailed explanation to interconnection customers regarding the cause(s) of study delays. The Commission also seeks comment on whether a transmission provider should have to inform interconnection customers regarding its process for revising study timelines once a delay occurs and whether the transmission provider should also describe in sufficient detail any relevant issues that could further affect the revised timeline for a particular interconnection customer.

6. Improving Coordination With Affected Systems

a. Existing Provisions and Background

152. The interconnection of a new generating facility to a transmission system may sometimes affect the reliability of a neighboring transmission system, termed the affected system. Currently, section 3.5 of the *pro forma* LGIP requires the transmission provider to coordinate required interconnection studies with affected systems [198] and, if possible, include those results within applicable results from the LGIP study process. In Order No. 2003, the Commission found that:

> [a]lthough the owner or operator of an Affected System is not bound by the provisions of the Final Rule LGIP or LGIA, the Transmission Provider must allow any Affected System to participate in the process when conducting the Interconnection Studies, and incorporate the legitimate safety and reliability needs of the Affected System.[199]

Because the transmission operator of the affected system is not bound by the terms of the LGIP or LGIA of a particular interconnection request, the transmission operator of the affected system may choose not to abide by the time limits established for the various interconnection studies.

153. Order No. 2003 further explained that, if the affected system does not provide information in a timely manner, a transmission provider may proceed without taking into account any information that could have been provided by the affected system.[200] Typically, transmission providers do not proceed with the interconnection process until they receive the analysis of reliability impact from the affected system(s). The issue of impacts on an affected system is raised in a recent contested proceeding.[201]

154. Order No. 2003 does not require that transmission providers publicize their process for coordination with affected systems. It also does not require that transmission providers include the affected systems analysis alongside the system impact study and facilities study. During the Order No. 2003 process, the Commission declined Duke's request to require affected systems to participate in the interconnection process with interconnection customers.[202] The Commission reiterated, however, that a transmission provider must allow any affected system to participate in the interconnection study process and incorporate the affected system's legitimate safety and reliability needs.[203]

b. AWEA Petition and Comments

155. Multiple commenters that represent interconnection customers and RTOs/ISOs voiced a need for improved affected system coordination. For example, MISO supports more specific guidance in the *pro forma* LGIP on when and how to engage affected systems, as well as how to impose obligations on affected systems to minimize delays in the interconnection process.[204] AWEA asks the Commission to require a standard contract between affected systems.[205] Additionally, AWEA asks the Commission to require affected systems to share their respective models to ensure that prospective interconnection customers can more readily ascertain the impacts of their interconnection requests in a timely manner.[206] SoCal Edison states that the primary challenge associated with the coordination of affected systems is the enforceability of provisions in a particular balancing

[198] An ''Affected System shall mean an electric system other than the Transmission Provider's Transmission System that may be affected by the proposed interconnection.'' *Pro forma* LGIP, Sec. 1 (Definitions); *Pro Forma* LGIA, Art. 1 (Definitions).

[199] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 121.

[200] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 121. On rehearing, the Commission clarified that delays by an affected system in performing interconnection studies or providing information for such studies is not an acceptable reason to deviate from the timetables established in Order No. 2003 unless the interconnection itself (as distinct from any future delivery service) will endanger reliability. *See* Order No. 2003–A, FERC Stats. & Regs. ¶ 31,171 at P 114.

[201] *See* Docket No. ER17–75–000, in which PJM filed an unexecuted LGIA with Lackawanna, Energy Center, LLC (Lackawanna) at Lackawanna's request. This unexecuted GIA contains non-conforming terms and conditions, including limitations on Lackawanna's output, due to preliminary (and as yet incomplete) affected systems analysis by NYISO.

[202] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at P 121.

[203] Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 120–121.

[204] *Id.* at 9.

[205] AWEA 2016 Comments at 18.

[206] AWEA 2016 Comments at 18.

authority area tariff if those provisions place obligations on potentially affected systems, especially those outside of the Commission's jurisdiction. To address this issue, SoCal Edison proposes that RTOs/ISOs amend existing balancing authority area agreements or enter into new, legally-binding affected system agreements, to implement appropriate, enforceable mechanisms, including cost responsibility for mitigation.

156. El Paso states that it is not always clear how many affected systems an interconnection request may impact until after study work on the request is complete or near completion. El Paso argues that, to improve this process, the transmission provider should invite all electrically-connected transmission owners and operators to participate in the interconnection study process upon receipt of a valid interconnection request. El Paso further suggests that the transmission provider extend this invitation to any other transmission system(s) for which the transmission provider has reason to suspect that the interconnection request may have adverse impacts, given its location, size, type, and other characteristics. Transmission Dependent Utility Systems urge the Commission to clarify the definition of affected system in the *pro forma* LGIP, *pro forma* LGIA, and *pro forma* SGIP to reflect the recognition, articulated in Order No. 2006, that the definition is not limited to transmission facilities but also to ''an electric system . . . that may be affected by the proposed interconnection.'' [207]

157. Some entities, like Modesto Irrigation District, Imperial Irrigation District, Xcel, and MISO TOs, indicate no changes are needed in affected systems provisions.[208]

c. Request for Comments

158. Several of the proposed reforms in this Proposed Rule seek to improve the information provided to interconnection customers through the interconnection process and facilitate the timely interconnection of new generating facilities. Based on the comments received, it appears that transmission providers may not provide sufficient information on the guidelines and timelines they will use to coordinate with affected systems during the interconnection process. Providing these guidelines and timelines could improve the information available to the interconnection customer in the interconnection process and could help to avoid late-stage withdrawals due to unforeseen costly network upgrades on affected systems. Furthermore, a clear set of procedures and timelines regarding the affected system's study of the proposed interconnection memorialized in a Commission-approved agreement regarding affected systems analysis could help to ameliorate delays experienced awaiting study results from affected systems.

159. The Commission seeks comment on whether it should prescribe guidelines for affected systems analyses and coordination or if it should impose study requirements and associated timelines on affected systems that are also public utility transmission providers. The Commission also seeks comment on whether to standardize the process for coordinating an affected system analysis and whether to develop a standard affected system study agreement. Finally, the Commission seeks comments on proposals or additional steps that the Commission could take (*e.g.,* conducting a workshop or technical conference focused on improving issues that arise when affected systems are impacted by a proposed interconnection).

C. Enhancing Interconnection Processes

160. The five proposed reforms in this section would enhance interconnection processes by making use of underutilized interconnection service, providing interconnection service earlier, and accommodating changes in the development process.

1. Requesting Interconnection Service Below Generating Facility Capacity

161. The Commission proposes to allow interconnection customers to request a level of interconnection service for a generating facility that is lower than the generating facility's capacity.[209] The use of a level of interconnection service below generating facility capacity will allow generating facilities that do not intend to use the full generating facility capacity to avoid constructing network upgrades and interconnection facilities to meet a level of interconnection service that is not necessary. For example, the owner of an electric storage resource with a generating facility capacity of 30 MW may choose to always operate the facility in such a way that it only uses 25 MW of interconnection service. Under this proposal, the transmission provider would allow the interconnection customer to apply for the 25 MW it intends to use instead of the entire 30 MW of generating facility capacity. If a facility utilizes this option, it must establish in its interconnection agreement the appropriate hardware and/or software to prevent it from exceeding its interconnection service, consent to penalties if its output does exceed its interconnection service, and be subject to curtailment provisions consistent with 9.7.2 of the LGIA.

a. Existing Provisions and Background

162. There are no current provisions in the *pro forma* LGIP and LGIA that directly speak to this issue. However, in certain regions of the country, there are already generating facilities with a level of interconnection service lower than the generating facility capacity. The details of these limitations have thus far been included in Appendix C of the LGIA.[210]

b. Comments

163. In post-technical conference comments, parties with experience as interconnection customers emphasized their desire for the ability to request interconnection service that meets a facility's needs, even if this service is below the generating facility capacity.[211] Commenters argue that the unique characteristics of electric storage resources, including their fast response times and high controllability, justify interconnection service below the rated capacity of the facility because they can time their charging and discharging of the resource to avoid or mitigate congestion of the transmission grid or to support transmission grid voltage and frequency.[212] SoCal Edison provides examples of interconnection agreements that limited interconnection service to

[207] Transmission Dependent Utility Systems 2016 Comments at 7 (quoting Order No. 2006 at P 543). Transmission Dependent Utility Systems consist of the following rural electric generation and transmission cooperatives: Golden Spread Electric Cooperative, Inc., Kansas Electric Power Cooperative, Inc.; North Carolina Electric Membership Corporation; PowerSouth Energy Cooperative, and Seminole Electric Cooperative, Inc.

[208] Modesto Irrigation District 2015 Comments at 3; Imperial Irrigation District 2016 Comments at 4–6; Xcel 2016 Comments at 11; MISO TOs Comments at 13.

[209] The term generating facility capacity means ''the net capacity of the Generating Facility and the aggregate net capacity of the Generating Facility where it includes multiple energy production devices.'' *Pro forma* LGIA at Art.1.

[210] *See, e.g., S. Cal. Edison Co.,* Docket No. ER16–1459–000 (June 14, 2016) (delegated letter order); *S.Cal. Edison Co.,* Docket No. ER16–44–000 (November 16, 2015) (delegated letter order); *S.Cal. Edison Co.,* Docket No. ER15–2730–000 (November 12, 2015) (delegated letter order).

[211] *See, e.g.,* NextEra 2016 Comments at 10–12; AES 2016 Comments at 15; ESA 2016 Comments at 5; RES Americas 2016 Comments at 3, 5–6; California Energy Storage Alliance 2016 Comments at 12–13.

[212] California Energy Storage Alliance 2016 Comments at 6 (citing *Midcontinent Indep. Sys. Operator, Inc.,* 155 FERC ¶ 61,211 (2016)).

an amount lower than full capacity[213] ESA and NextEra note that PJM and CAISO have allowed interconnection customers to limit injection rights in certain circumstances.[214] NextEra suggests that the structure of interconnection rights could alternatively be set forth in a separate *pro forma* agreement, similar to MISO's Monitoring and Consent Agreement for Net Zero Interconnection Service.[215]

164. The RTOs/ISOs comments suggest they are cautiously open to the idea of allowing interconnection service below the total generating facility capacity if the interconnection request is subject to the proper control technologies and penalties.[216] MISO notes that it is actively discussing the issue with stakeholders.[217] NYISO states that allowing interconnection at a level below the generating facility capacity should not be permitted without adequate provisions for enforcement of the maximum limit, but that interconnection customers should be able to submit proposals for limited interconnection service.[218] ISO–NE notes that it would still need to know the network impacts for the full output of the generating facility capacity.[219]

165. Representatives of the storage industry agree that safeguards to limit output should be in place to ensure safety and reliability when limiting interconnection service.[220] ESA and RES Americas suggest that operational tests and/or demonstrations could validate interconnection customers' intended uses and control technologies.[221] Commenters also suggest that RTOs/ISOs could install physical safeguards and/or impose financial penalties and legal liability.[222] California Energy Storage Alliance suggests that verifiable controls and algorithms, as well as utility equipment already in place (*e.g.,* reclosers), cap the discharge at the point of interconnection and that there is no need to require power relays and other physical equipment.[223] NYISO argues that monitoring and corrective action must maintain reliability if the facility exceeds the maximum power limit.[224] SoCal Edison explains that, pursuant to its current agreements that allow interconnection below generating facility capacity, SoCal Edison will notify the interconnection customer if that customer is violating its maximum output and notes that the customer risks disconnection if the violation persists.[225]

c. Proposal

166. The Commission preliminarily finds that the *pro forma* LGIP and *pro forma* LGIA may not be just and reasonable and may be unduly discriminatory or preferential to the extent that they disallow interconnection service below generating facility capacity. Disallowing the requests for interconnection service below generating facility capacity forces generating facilities intending to utilize lower levels of interconnection service capacity to pay for interconnection facilities and network upgrades they do not need.

167. The Commission proposes to require that transmission providers allow interconnection customers to request interconnection service below their generating facility capacity. The Commission recognizes the concerns raised regarding the need for proper control technologies and penalties to ensure that an interconnection is safe and reliable when a generating facility requests interconnection service below the facility's full capacity. Provided these concerns can be addressed through hardware and/or software installed to prevent a facility from exceeding its interconnection service, as well as penalties and possible curtailment, the Commission believes that there are legitimate reasons for allowing an interconnection customer to request interconnection service at a level less than its generating facility capacity. Reducing the amount of interconnection facilities and network upgrades required for lower interconnection service capability could also result in lower interconnection costs, lower ratepayer costs, and more efficient use of the network upgrades and interconnection facilities that are constructed. Therefore, the Commission preliminarily finds that this proposal will result in just and reasonable and not unduly discriminatory or preferential rates, terms and conditions. The proposal will help to reduce overbuilding of interconnection facilities and network upgrades by tailoring the interconnection facilities and network upgrades to a facility's needed capacity. This means that if a facility, for operational or other reasons, will never exceed its interconnection service limitations, it may request to build upgrades for interconnection service at a lower level to match the intended operation of the facility. This proposal will therefore remove barriers to the development of generating facilities which do not intend to operate at full generating facility capacity. Allowing generating facilities to limit their interconnection costs by avoiding the construction of unnecessary interconnection facilities and network upgrades may also lower costs to customers.

168. The Commission proposes that transmission providers have a process in the *pro forma* LGIP and LGIA in place to consider such requests. The Commission proposes to require that any interconnection customer that seeks interconnection service below its generating facility capacity install appropriate monitoring and control technologies at its generating facility. Such a generating facility or interconnection customer will be subject to reasonable provisions that enforce a maximum export limit, a notification process to a generating facility that has exceeded such limit, and a process for resolving disputes if deemed necessary by the transmission provider and/or transmission owner as part of the *pro forma* LGIP and LGIA. Additionally, the Commission proposes that interconnection customers that request interconnection service below generating facility capacity be subject to reasonable penalties imposed by transmission owners, or transmission providers if more appropriate, if they exceed the limitations for interconnection service established in their interconnection agreements. Such penalties could be financial, could include a requirement to pay the cost of additional interconnection facilities or network upgrades, or could consist of a loss of interconnection rights. The Commission seeks comment on the potential penalties that transmission providers or transmission owners may impose if an interconnection customer exceeds the interconnection service levels agreed upon.

169. In addition to seeking comment on these proposals, the Commission seeks comment on the types and availability of control technologies and protective equipment that could ensure that a generating facility does not exceed its level of interconnection service. The Commission expects that the transmission providers,

[213] SoCal Edison 2016 Comments at 6.

[214] ESA 2016 Comments at 9; NextEra 2016 Comments at 14.

[215] NextEra 2016 Comments at 14.

[216] *See, e.g.,* NYISO 2016 Comments at 28.

[217] MISO 2016 Comments at 12–13.

[218] NYISO 2016 Comments at 28.

[219] ISO–NE 2016 Comments at 28.

[220] Xcel 2016 Comments at 18–19; Exelon 2016 Comments at 16.

[221] RES Americas 2016 Comments at 5–6; ESA 2016 Comments at 9.

[222] SoCal Edison 2016 Comments at 6; ESA 2016 Comments at 9; RES Americas 2016 Comments at 5–6.

[223] California Energy Storage Alliance 2016 Comments at 12–13.

[224] NYISO 2016 Comments at 28.

[225] SoCal Edison 2016 Comments at 6.

transmission owners, and interconnection customers will establish the necessary control technologies, as well as reasonable penalties or other enforcement mechanisms necessary to ensure compliance with the maximum injection limit in Appendix C of the *pro forma* LGIA. The Commission also seeks comment on whether certain protection systems would eliminate the need to study the full generator facility capacity in some circumstances, potentially reducing study costs.

170. This proposal would not eliminate the transmission provider's potential need to study interconnection customers' interconnection facilities and network upgrades at generating facility capacity in addition to the generating facility's requested level of interconnection service when needed to ensure reliability.[226] The Commission seeks comment on what types of studies and under what conditions the transmission provider may need to study the generating facility at its generating facility capacity, even if the interconnection customer does not intend to use that level of interconnection service and agrees to install all necessary equipment to prevent injections of electricity in excess of the requested level of interconnection service.

171. The Commission acknowledges that allowing interconnection customers to request service below their generating facility capacity could result in additional study costs during the interconnection process because the transmission provider may need to study the full generating facility capacity as well as the requested level of interconnection service. The Commission proposes that interconnection customers should bear any additional study costs associated with requesting interconnection service below their generating facility capacity, but the Commission seeks comment on the potential nature and extent of such costs.

172. The Commission also proposes changes to the definitions of ''Large Generating Facility'' and ''Small Generating Facility'' in the *pro forma* LGIP and *pro forma* LGIA so that they are based on the level of interconnection service for the generating facility rather than the generating facility capacity. The Commission considers this proposed change to be consistent with the reform in Order No. 792 where the Commission allowed, subject to certain conditions, transmission providers to measure the capacity of small generating facilities based on the capacity specified in the interconnection request.[227] The Commission seeks comment on the proposed changes to the definitions of ''Large Generating Facility'' and ''Small Generating Facility'' and the impact of such a change, if any, on the interconnection procedures and the interconnection agreement, including the need for other related changes to the *pro forma* LGIP and LGIA.

173. The Commission also seeks comment on whether revisions in addition to those proposed here for the *pro forma* LGIP or LGIA are necessary to accommodate requests for interconnection service below generating facility capacity. We also seek comment on whether in lieu of changes to the Commission's *pro forma* LGIP and LGIA, transmission providers should describe the processes for processing and studying requests for interconnection service below generating facility capacity in their *pro forma* LGIPs and LGIAs on compliance, or if such requests should be processed on an *ad hoc* basis rather than having a specified process in the *pro forma* documents.

174. The Commission proposes to add the following new paragraph at the end of section 3.1 of the *pro forma* LGIP as follows:

The Transmission Provider shall have a process in place to consider requests for Interconnection Service below the Generating Facility Capacity. These requests for Interconnection Service shall be studied at the level of Interconnection Service requested for purposes of Interconnection Facilities, Network Upgrades, and associated costs, but may be subject to other studies at the full Generating Facility Capacity to ensure safety and reliability of the system, with the study costs borne by the Interconnection Customer. Any Interconnection Facility and/or Network Upgrade costs required for safety and reliability also would be borne by the Interconnection Customer. Interconnection Customers may be subject to additional control technologies as well as testing and validation of those technologies consistent with Article 6 of the LGIA. The necessary control technologies and protection systems as well as any potential penalties for exceeding the level of Interconnection Service established in the executed, or requested to be filed unexecuted, LGIA shall be established in Appendix C of that executed, or requested to be filed unexecuted, LGIA.

175. The Commission proposes to add the following language to the end of section 6.3 of the *pro forma* LGIP:

Transmission Provider shall study the interconnection request at the level of service requested by the interconnection customer, unless otherwise required to study the full Generating Facility Capacity due to safety or reliability concerns.

176. The Commission proposes to insert the following language in section 7.3 of the *pro forma* LGIP in line 8 of the second paragraph, just before the sentence ''The Interconnection System Impact Study will provide a list of facilities that are required as a result of the Interconnection Request and a non-binding good faith estimate of cost responsibility and a non-binding good faith estimated time to construct.''

For purposes of determining necessary interconnection facilities and network upgrades, the System Impact Study shall consider the level of interconnection service requested by the Interconnection Customer, unless otherwise required to study the full Generating Facility Capacity due to safety or reliability concerns.

177. The Commission proposes to add the following language to the end of section 8.2 of the *pro forma* LGIP:

The Facilities Study will also identify any potential control equipment for requests for Interconnection Service that are lower than the Generating Facility Capacity.

178. The Commission proposes to add the following language to Appendix 1, Item 5, of the *pro forma* LGIP, as sub-item h:

Requested capacity (in MW) of Interconnection Service (if lower than the Generating Facility Capacity)

179. Lastly, the Commission proposes to change the definition of ''Large Generating Facility'' and ''Small Generating Facility'' in section 1 of the *pro forma* LGIP and article 1 of the *pro forma* LGIA as follows (*proposing to delete italicized text*):

Large Generating Facility shall mean a Generating Facility *for which an Interconnection Customer has having a Generating Facility Capacity requested Interconnection Service* of more than 20 MW.

Small Generating Facility shall mean a Generating Facility *for which an Interconnection Customer has requested Interconnection Service that has a Generating Capacity* of no more than 20 MW.

180. The Commission recognizes that the NERC reliability standards are

[226] ISO–NE suggests that it would always need to evaluate the generating facility capacity to know the network impacts of the full rated capacity and ensure reliability. ISO–NE Comments at 28.

[227] *See* Order No. 792, 145 FERC ¶ 61,159 at P 230 (stating that ''Under section 4.10.3 adopted herein, the Transmission Provider is to measure the capacity of a Small Generating Facility based on the capacity specified in the interconnection request, which may be less than the maximum capacity that a device is capable of injecting into the Transmission Provider's system, provided that the Transmission Provider agrees, with such agreement not to be unreasonably withheld, that the manner in which the Interconnection Customer proposes to limit the maximum capacity that its facility is capable of injecting into the Transmission Provider's system will not adversely affect the safety and reliability of the Transmission Provider's system.'').

generally applicable to generating facilities with a gross nameplate rating of greater than 20 MVA,[228] and do not generally apply to Small Generating Facilities with SGIAs. The Commission clarifies that its proposed revisions to the definition of Large Generating Facility and Small Generating Facility are not intended to conflict with any applicable NERC Reliability Standards or NERC's compliance registration process.

2. Provisional Interconnection Service

181. The Commission recognizes that the length of the interconnection process can pose a challenge for interconnection customers. In some cases, there is a certain amount of interconnection capacity that has already been studied at the point of interconnection. The Commission therefore proposes to adopt a provisional agreement process wherein new generating facilities could interconnect, possibly under limited operation, using interconnection service pursuant to existing and regularly updated studies while they wait to complete the additional studies needed to satisfy their full interconnection request.

a. Existing Provisions and Background

182. There are no current provisions in the *pro forma* LGIP or *pro forma* LGIA that allow for provisional agreements where new generating facilities could interconnect, possibly under limited operation, using interconnection service pursuant to existing and regularly updated studies while they wait to complete the additional studies needed to satisfy their full interconnection request. Under the current interconnection process, an interconnection customer that seeks to interconnect quickly, possibly under limited operation, and is willing to bear the financial risk of network upgrades that will be identified after the interconnection process has been completed, may not use interconnection service that is available as indicated by existing and regularly updated studies. Only at the end of the interconnection process—after the transmission provider has studied the final form of the proposed generating facility and its effects, and has evaluated the need for any interconnection facilities and network upgrades—may the interconnection customer begin injection onto the grid. Thus, the *pro forma* LGIP/LGIA do not provide for provisional arrangements that would allow interconnection customers to interconnect using existing capacity on the transmission system prior to the completion of the interconnection study process.

183. However certain regions, such as SPP and MISO, already permit interconnection customers to execute provisional agreements prior to the completion of the full interconnection process.[229] In MISO, interconnection customers are able to request provisional agreements to provide a limited amount of service prior to completion of the interconnection process, *i.e.,* prior to the completion of any network upgrades, based on the availability of existing studies.[230] To do so, interconnection customers must demonstrate that sufficient facilities exist for the level of output requested in the provisional agreement and must re-verify that determination on a regular basis.[231] Extending this policy to other transmission providers could help facilitate the interconnection of generating facilities that have a desire to build and/or provide service prior to completion of the full interconnection process.

b. Comments

184. Multiple commenters, particularly those in the electric storage industry, expressed a desire to expedite the interconnection process and to employ existing interconnection and network facilities as a way to do so. Several note that increasing the speed of interconnection for resources such as electric storage is important because these resources can physically come on-line before completion of the interconnection process.[232]

c. Proposal

185. The Commission preliminarily finds that the lack of a process in the *pro forma* LGIP and the lack of a provision in the *pro forma* LGIA for an interconnection customer to obtain a provisional agreement for interconnection service weakens competition due to the inability of interconnection customers to leverage prior investments in interconnection studies and related facilities to provide wholesale services. This lack of provisional interconnection service may also raise costs due to the inability to use some existing interconnection facilities and network upgrades, thereby leading to unjust and unreasonable rates for customers. Although a transmission provider may be able to provide interconnection service at the currently studied and approved level of interconnection capacity while it is studying a larger interconnection request, the *pro forma* LGIP and *pro forma* LGIA do not currently provide for such flexibility for provisional service at currently studied levels. Therefore, lack of a process for provisional interconnection service precludes the interconnection customer from providing wholesale services during the pendency of its interconnection request.

186. The Commission therefore proposes to allow interconnection customers to enter into provisional agreements for limited interconnection service prior to the completion of the full interconnection process. Such provisional agreements could benefit interconnection customers by permitting limited operation based on existing and regularly updated studies, and prior to the completion of studies and network upgrades being built for the larger interconnection service that is requested. Provisional agreements could also benefit interconnection customers with short development lead times, such as electric storage resources, which can provide some services prior to completion of the full interconnection process. Under this proposal, interconnection customers with provisional agreements would be able to begin operation up to the MW level as permitted by existing and regularly updated studies. The transmission provider may require milestone payments prior to submission of the provisional agreement. The provisional agreement would be in effect while awaiting the final results of the interconnection studies, finalization of a final interconnection agreement, and the construction of any additional interconnection facilities and network upgrades and cost assignments for the network upgrades that may result from the full interconnection process. The Commission also proposes that provisional large generator interconnection agreements and the associated provisional interconnection service would terminate upon completion of construction of network upgrades. At this point, the interconnection customer would proceed according to the terms of the interconnection agreement.

187. Provisional agreements may also mitigate interconnection customer risk associated with unknown final network

[228] *See* NERC Statement of Compliance Registry Criteria (effective: July 1, 2014), *http://www.nerc.com/FilingsOrders/us/RuleOfProcedureDL/Appendix_5B_RegistrationCriteria_20140701.pdf.*

[229] SPP, OATT, Attachment V, app. 6 (6.1.0). MISO, FERC Electric Tariff, Att. X, Section 11.5 (47.0.0).

[230] MISO, FERC Electric Tariff, Att. X, Section 11.5 (47.0.0).

[231] MISO, FERC Electric Tariff, Att. X, Section 11.5 (47.0.0).

[232] *See, e.g.,* AES 2016 Comments at 3.

upgrade costs by creating revenue streams earlier in an interconnection customer's life. However, the Commission proposes that such interconnection customers must still assume all risks and liabilities associated with the required interconnection facilities and network upgrades for their interconnection that are identified pursuant to the interconnection studies for the requested interconnection service.

188. The Commission therefore proposes to require that transmission providers allow interconnection customers to request provisional interconnection service and operate under provisional interconnection agreements based on existing and regularly updated studies that demonstrate that necessary interconnection facilities and network upgrades are in place to meet applicable North American Electric Reliability Corporation (NERC) or other regional reliability requirements for new, modified, and/or expanded generating facilities. If available studies do not demonstrate whether provisional interconnection service can be reliably accommodated, the transmission provider shall perform additional studies as necessary. An evaluation of provisional service by the transmission provider shall determine whether stability, short circuit, and/or voltage issues would arise if the interconnection customer seeking provisional interconnection service interconnects without modifications to the generating facility or the transmission provider's system. The Commission also proposes that transmission providers must assess any safety or reliability concerns posed by provisional agreements, and establish a process for the interconnection customer that will mitigate any reliability risks associated with operation pursuant to provisional agreements. The costs of such mitigation, if necessary, would be borne by the interconnection customer. The Commission is interested in additional comments on this proposal and the means by which transmission providers and interconnection customers could mitigate any risks and liabilities for provisional interconnection service. Additionally, acknowledging that transmission providers have limited resources to conduct studies, we also seek comment on the circumstances under which provisional interconnection service would be beneficial and how common such circumstances would be for potential interconnection customers.

189. The Commission proposes to add the following new definitions to Section 1 of the *pro forma* LGIP, as well as to article 1 of the LGIA:

Provisional Interconnection Service shall mean interconnection service provided by the Transmission Provider associated with interconnecting the Interconnection Customer's Generating Facility to the Transmission Provider's Transmission System and enabling that Transmission System to receive electric energy and capacity from the Generating Facility at the Point of Interconnection, pursuant to the terms of the Provisional Large Generator Interconnection Agreement and, if applicable, the Tariff.

Provisional Large Generator Interconnection Agreement shall mean the interconnection agreement for Provisional Interconnection Service established between the Transmission Provider and/or the Transmission Owner and the Interconnection Customer. This agreement shall take the form of the Large Generator Interconnection Agreement, modified for provisional purposes.

190. Additionally, the Commission proposes a new section 5.10 for the *pro forma* LGIA that defines the requirements for transmission providers to provide provisional interconnection service and the responsibilities of the interconnection customer. The Commission has not developed a *pro forma* Provisional Large Generator Interconnection Agreement because such agreements could either be established on an *ad hoc* basis for provisional interconnection service, or transmission providers could establish their own *pro forma* provisional agreements. However, the Commission seeks comment on the need for the Commission to establish a *pro forma* Provisional Large Generator Interconnection Agreement as part of the *pro forma* LGIA as well as any important details related to the service, *e.g.,* the stage in the interconnection process where the customer would be able to request this service and whether all milestone payments would be required to be paid upon submission of the provisional agreement. The Commission proposes to add the following new section 5.10 to the *pro forma* LGIA:

5.10 Provisional Interconnection Service. Upon the request of Interconnection Customer, and prior to completion of requisite Network Upgrades, the Transmission Provider may execute a Provisional Large Generator Interconnection Agreement or Interconnection Customer may request the filing of an unexecuted Provisional Large Generator Interconnection Agreement with the Interconnection Customer for limited interconnection service at the discretion of Transmission Provider based upon an evaluation that will consider the results of available studies. Transmission Provider shall determine, through available studies or additional studies as necessary, whether stability, short circuit, thermal, and/or voltage issues would arise if Interconnection Customer interconnects without modifications to the Generating Facility or Transmission Provider's system. Transmission Provider shall determine whether any Network Upgrades, Interconnection Facilities, Distribution Upgrades, or System Protection Facilities that are necessary to meet the requirements of NERC, or any applicable Regional Entity for the interconnection of a new, modified and/or expanded Generating Facility are in place prior to the commencement of interconnection service from the Generating Facility. Where available studies indicate that such Network Upgrades, Interconnection Facilities, Distribution Upgrades, and/or System Protection Facilities that are required for the interconnection of a new, modified and/or expanded Generating Facility are not currently in place, Transmission Provider will perform a study, at the Interconnection Customer's expense, to confirm the facilities that are required for provisional interconnection service. The maximum permissible output of the Generating Facility in the Provisional Large Generator Interconnection Agreement shall be studied and updated on a quarterly basis. Interconnection Customer assumes all risks and liabilities with respect to changes between the Provisional Large Generator Interconnection Agreement and the Large Generator Interconnection Agreement, including changes in output limits and Network Upgrades, Interconnection Facilities, Distribution Upgrades, and/or System Protection Facilities cost responsibilities.

3. Utilization of Surplus Interconnection Service

191. Based on comments received during this proceeding, it has become clear that a number of interconnection customers would like to co-locate new generating facilities with existing generating facilities which may not be fully utilizing an existing generating facility's interconnection service. Commenters provided examples of circumstances when this can happen, including instances where an existing variable energy resource is paired with a new electric storage resource. In this example, the variability in the variable energy resource's output may prevent it from fully utilizing its interconnection capacity during some hours. To address these comments, the Commission proposes to require transmission providers to include in their tariffs and the *pro forma* LGIP an expedited process for interconnection customers to utilize or transfer surplus interconnection service at existing generating facilities. The Commission further proposes that this process give an existing generating facility owner or its affiliate priority to use the surplus interconnection service, but that the tariffs and *pro forma* LGIP also establish

an open and transparent process for the sale of that surplus interconnection service if the owner and its affiliates elect not to use it, and elect to make it available to another party. Lastly, the Commission proposes that this expedited process for surplus interconnection service be available for any quantity of surplus interconnection service, regardless of whether it is above or below the 20 MW threshold for small and large generator interconnection.

a. Existing Provisions and Background

192. On occasion, interconnection customers request more interconnection service for an interconnection request than they may need at any given time. As a result, they may have surplus interconnection service that the relevant transmission provider has already studied and approved. An interconnection customer with an existing interconnection agreement might want to add resources, such as electric storage resources, which were not planned as part of the original interconnection request, or it may wish to sell surplus interconnection service without conveying the originally planned generating facility as part of the sale. In these instances, it is difficult for an interconnection customer at present to utilize this surplus interconnection service. The Commission has addressed the desire for an interconnection customer to retain access to excess capacity on interconnection customer interconnection facilities.[233] These reforms were motivated by phased generating facilities that have built additional interconnection customer interconnection facility capacity beyond that needed by the initial phases of development. However, there are other circumstances when an interconnection customer may have surplus interconnection service and the *pro forma* LGIP and *pro forma* LGIA do not address the utilization or transfer of surplus interconnection service where there is no transfer of the underlying generating facility.

193. MISO's tariff offers Net Zero Interconnection Service, which MISO designed to allow an existing interconnection customer to increase the gross generating capacity at the point of interconnection of an existing generating facility without increasing the total interconnection service at the point of interconnection.[234] Under MISO's approach, a new generating facility could use this service to interconnect at an existing point of interconnection.[235] In MISO, Net Zero Interconnection Service entails a separate interconnection process for interconnection service that an existing interconnection customer wishes to make available for a new interconnection customer.[236] This process includes an energy displacement agreement between the existing and the new interconnection customers,[237] a monitoring and consent agreement between the new interconnection customer and the transmission owner,[238] as well as the appropriate studies, and an evaluation process for Net Zero Interconnection Service.[239]

194. As implemented in MISO, Net Zero Interconnection Service is a restricted form of Energy Resource Interconnection Service. The interconnection study consists of reactive power, short circuit/fault duty, and stability analyses. Steady-state (thermal/voltage) analyses may be performed as necessary to ensure that all required reliability conditions are studied. Moreover, if the existing generating facility was not studied under off-peak conditions, off-peak steady state analyses will be performed to the required level necessary to demonstrate reliable operation of the Net Zero Interconnection Service. If no system impact study was available for the existing generation, both off-peak and peak analysis may need to be performed for the generating facility seeking Net Zero Interconnection Service in accordance with the LGIP. The interconnection study will identify the interconnection facilities required and the network upgrades necessary to address reliability issues.

195. In its order accepting MISO's proposal for Net Zero Interconnection Service, the Commission expressed concern about the ''lack of transparency'' and failure to ''provide a clear and consistent way in which generators seeking Net Zero Interconnection Service may identify opportunities for [such service] or how such a generator would be chosen for such service.'' [240] For these reasons, the Commission directed MISO to submit a compliance filing to ensure that MISO offers Net Zero Interconnection Service ''on a fair, transparent, and non-discriminatory basis and that comply with the filing requirements of FPA section 205.'' [241]

b. Comments

196. The Commission received multiple comments that support Commission action to improve the interconnection process with regard to surplus interconnection service. Some commenters stressed the importance of getting resources, especially electric storage resources, on-line more quickly. For instance, NextEra states that a program that allows for utilization of surplus interconnection capacity could result in faster processing of requests to co-locate batteries with existing generation.[242] ESA argues that customers that wish to install electric storage resources without additional injection rights should be able to limit interconnection service to the level established in the existing interconnection agreement. ESA also suggests that interconnection customers should be able to transfer some of their injection rights to others, with thermal studies required only for the incremental service.[243]

[233] *Open Access and Priority Rights on Interconnection Customer's Interconnection Facilities,* Order No. 807, 150 FERC ¶ 61,211 (2015).

[234] MISO FERC Electric Tariff, Att. X, Section 1 (Definitions) (47.0.0) (''Net Zero Interconnection Service shall mean a form of Energy Resource Interconnection Service that allows an interconnection customer to alter the characteristics of an existing generating facility, with the consent of the existing generating facility, at the same POI such that the Interconnection Service limit remains the same'').

[235] *Midwest Indep. Transmission Sys. Operator,* 138 FERC ¶ 61,233 at P 16.

[236] MISO FERC Electric Tariff, Att. X, Section 1 (Definitions) (47.0.0) (''Net Zero Interconnection Service shall mean a form of Energy Resource Interconnection Service that allows an interconnection customer to alter the characteristics of an existing generating facility, with the consent of the existing generating facility, at the same POI such that the Interconnection Service limit remains the same'').

[237] MISO FERC Electric Tariff, Att. X, Section 1 (Definitions) (47.0.0) (''Energy Displacement Agreement shall mean an agreement between an Interconnection Customer with an existing generating facility on the Transmission Provider's Transmission System and an Interconnection Customer with a proposed Generating Facility seeking to interconnect with Net Zero Interconnection Service. The Energy Displacement Agreement specifies the term of operation, the Generating Facility Interconnection Service limit, and the mode of operation for energy production (common or singular operation)'').

[238] MISO FERC Electric Tariff, Att. X, Section 1 (Definitions) (47.0.0) (''Monitoring and Consent Agreement shall mean an agreement that defines the terms and conditions applicable to a Generating Facility acquiring Net Zero Interconnection Service. The Monitoring and Consent Agreement will list the roles and responsibilities of an Interconnection Customer seeking to interconnect with Net Zero Interconnection Service and Transmission Owner to maintain the total output of the Generating Facility inside the parameters delineated in the GIA'').

[239] MISO FERC Electric Tariff, Att. X, Sections 3.2.3 & 3.3.1 (47.0.0).

[240] *Midwest Indep. Transmission Sys. Operator, Inc.,* 138 FERC ¶ 61,233, at P 301 (2012) (First Net Zero Order).

[241] First Net Zero Order, 138 FERC ¶ 61,233 at P 302.

[242] *See, e.g.,* NextEra 2016 Comments at 13. MISO notes that its Net Zero Interconnection Service product is available to any new resources. MISO 2016 Comments at 24–25.

[243] ESA 2016 Comments at 8–10.

197. Commenters also assert that co-locating electric storage resources with generators that have existing interconnection rights should require less modeling and should not require thermal injection studies.[244] NextEra suggests that studies should be tailored to the service requested, with a focus on stability studies and thermal withdrawal studies only if they are necessary. NextEra suggests that these changes should apply to both electric storage resources that seek to interconnect at existing generation sites and to new brownfield electric storage resources co-located with new generation.[245]

198. During the technical conference, transmission providers noted that processes and procedures would need to be in place to determine whether the requested interconnection service was available, including having service, rights, and descriptions that are clear and implementable.[246]

c. Proposal

199. The Commission is concerned that existing interconnection service is underutilized. The Commission also recognizes changes in the industry that have created greater opportunities for co-located facilities, such as generation and electric storage resources. It is appropriate to incentivize the utilization of surplus interconnection service because creating an expedited process for interconnection customers to utilize or transfer the utilization of surplus interconnection service will help reduce system costs by leveraging existing assets. Doing so could also improve competition in the wholesale markets by accelerating the interconnection process and facilitating the use of new complementary technologies such as electric storage resources that can further improve reliability and competition. Therefore, the Commission preliminarily finds that facilitating the use of surplus interconnection service will reduce costs and improve competition, helping to ensure just and reasonable rates as required of the Commission under the FPA.

200. The Commission preliminarily finds that providing an expedited process for interconnection customers to utilize or transfer surplus interconnection service at existing generating facilities could remove barriers to the interconnection of a new generator, or to the modification and/or expansion of the existing generating facility. Expediting the use of surplus interconnection service could be particularly beneficial to electric storage and other resources that can be developed and constructed faster than existing interconnection processes often allow. Allowing interconnection customers to better leverage existing assets, whether for their own purposes or for transfer to another interconnection customer, will help prevent stranded costs and improve access to the transmission system, thereby enhancing competition and helping to ensure just and reasonable rates, terms, and conditions.

201. The Commission proposes to add a new definition for Surplus Interconnection Service to section 1 of the *pro forma* LGIP and to article 1 of the *pro forma* LGIA that provides an expedited process for interconnection customers to utilize or transfer surplus interconnection service at existing generating facilities. The Commission further proposes that this process give an existing generating facility owner or its affiliates priority to use the surplus interconnection service, but that the transmission providers would also establish an open and transparent process for the transfer of that surplus interconnection service if the generating facility owner and its affiliates elect not to use it, and the generating facility owner elects to make it available to another party.

202. The Commission proposes that the studies for surplus interconnection service shall consist of reactive power, short circuit/fault duty, and stability analyses, and that steady-state (thermal/voltage) analyses may be performed as necessary to ensure that all required reliability conditions are studied. The Commission proposes that if the surplus interconnection service was not studied under off-peak conditions, off-peak steady state analyses shall be performed to the required level necessary to demonstrate reliable operation of the surplus interconnection service. The Commission also proposes that if the original System Impact Study is not available for the surplus interconnection service, both off-peak and peak analysis may need to be performed for the existing generating facility associated with the request for surplus interconnection service. Additionally, the Commission proposes that this process for the use or transfer of surplus interconnection service be available for any quantity of surplus interconnection service that currently exists.

203. The Commission proposes that a new interconnection agreement for surplus interconnection service must be executed, or filed unexecuted, by the transmission provider, transmission owner (as applicable), and the surplus interconnection service customer. The surplus interconnection service customer may be the interconnection customer for the existing generating facility, one of its affiliates, or a new interconnection customer selected through an open and transparent solicitation process. In addition to the new interconnection agreement for surplus interconnection service, we recognize that other contractual arrangements may also be necessary. For example, the interconnection customer for the existing generating facility and the surplus interconnection service customer will likely want to memorialize their rights and obligations with regard to the operation of the existing generating facility and the new generating facility that will use the surplus interconnection service.

204. While the Commission does not propose specific contractual arrangements with respect to surplus interconnection service in this Proposed Rule, the Commission seeks comment on how these arrangements should work and on whether requirements for such arrangements should be established in the Commission's *pro forma* LGIP and LGIA. The Commission notes that the *pro forma* LGIA only permits survival of the LGIA under limited circumstances.[247] For this reason, one important consideration for the new interconnection agreement for surplus interconnection service is whether the surplus interconnection service should survive the retirement of the existing generating facility. The Commission seeks comment on whether the interconnection agreement for surplus interconnection service should terminate upon the retirement of the existing generating facility, or whether there are circumstances under which the surplus interconnection service customer may operate its generating facility under terms of the surplus interconnection service agreement after the retirement of the existing generating facility. If the transmission provider, transmission owner (as applicable), and

[244] NextEra 2016 Comments at 13; California Energy Storage Alliance 2016.

[245] NextEra 2016 Comments at 13.

[246] Review of Generator Interconnection Agreements and Procedures, American Wind Energy Association, Docket No RM16–12–000, Technical Conference Transcript at 251.

[247] Article 2.6 provide that an LGIA:

shall continue in effect after termination to the extent necessary to provide for final billings and payments and for costs incurred hereunder, including billings and payments pursuant to this LGIA; to permit the determination and enforcement of liability and indemnification obligations arising from acts or events that occurred while this LGIA was in effect; and to permit each Party to have access to the lands of the other Party pursuant to this LGIA or other applicable agreements, to disconnect, remove or salvage its own facilities and equipment.

Pro forma LGIA Art. 2.6 (Survival).

the surplus interconnection service customer choose to provide for survival of the surplus interconnection service agreement for the surplus interconnection service customer after the retirement of the existing generating facility, they must memorialize this arrangement in the surplus interconnection service agreement. The Commission notes, however, that in recent precedent, the Commission stated that procedures that allow retiring generators to transfer their interconnection service must ''ensure that the opportunity to replace or increase the capacity of the retiring facility is offered on a fair, transparent, and nondiscriminatory basis.'' [248] For this reason, the Commission anticipates that, upon the retirement of the existing generating facility, any interconnection service could only be transferred on a fair, transparent, and nondiscriminatory basis.

205. While some commenters suggest that other transmission providers should adopt a process similar to MISO's process for Net Zero Interconnection Service, upon further consideration of the MISO Net Zero Interconnection Service proceeding, the Commission proposes to modify its position with regard to utilization of surplus interconnection service so that the existing generating facility owners have priority to utilize such surplus interconnection service. In revisiting these previous findings, the Commission notes that existing generating facility owners (or their predecessors) have already paid for the interconnection studies and interconnection facilities and have real property interests and other assets associated with those existing generating facilities, such as real estate and permits. After executing an interconnection agreement, a generating facility owner is entitled to the interconnection service contained therein, and is not required to make such service available unless it elects to.

206. Under this proposal, an existing generating facility owner or its affiliate would have priority to use any surplus interconnection service and would be able to execute, or request the filing of an unexecuted, new interconnection agreement for surplus interconnection service without posting or going through an open solicitation. However, if an existing generating facility owner that has surplus interconnection service wishes to transfer this surplus interconnection service, and it does not wish to use the surplus interconnection service itself or to transfer it to one of its affiliates, the existing generator must conduct an open and transparent solicitation process for that surplus interconnection service. The proposal to grant existing generating facility owners priority over their surplus interconnection service is similar to the Commission's findings in Order No. 807 where the Commission waived certain open access requirements and granted interconnection customers priority over their interconnection customer's interconnection facilities.[249] While the Commission proposes that priority be given to the existing generating facility owner of the surplus interconnection service or its affiliates, the Commission seeks comment on whether any further limitations should be placed on the entities with priority use of that surplus interconnection service.

207. In consideration of the foregoing, the Commission proposes to add a new definition for Surplus Interconnection Service to section 1 of the *pro forma* LGIP and to article 1 of the *pro forma* LGIA. Additionally, the Commission proposes to add new sections 3.3, 3.3.1 and 3.3.2 to the *pro forma* LGIP that define the requirements of the transmission provider regarding requests for the use of surplus interconnection service and the solicitation process for surplus interconnection service that the existing generating facility owner must follow if it, or one of its affiliates, elects not to use the surplus interconnection service and wants to transfer that service to another interconnection customer.

208. The Commission proposes to add the following new definition to Section 1 of the *pro forma* LGIP and to article 1 of the *pro forma* LGIA:

Surplus Interconnection Service shall mean any unused portion of Interconnection Service established in a Large Generator Interconnection Agreement, such that if Surplus Interconnection Service is utilized the Interconnection Service limit at the Point of Interconnection would remain the same.

209. The Commission proposes to add a new section 3.3 to the *pro forma* LGIP that requires the transmission provider to establish a process for the use of surplus interconnection service. This section will displace the current section 3.3, changing the numbering of current sections 3.3, 3.4, 3.5, and 3.6 to 3.4, 3.5, 3.6, and 3.7, respectively.[250]

Utilization of Surplus Interconnection Service. The Transmission Provider must provide a process that allows an Interconnection Customer to utilize or transfer Surplus Interconnection Service at an existing Generating Facility. The original Interconnection Customer or one of its affiliates shall have priority to utilize Surplus Interconnection Service. If the existing Interconnection Customer or one of its affiliates does not exercise its priority, then that service may be made available to other potential interconnection customers through an open and transparent solicitation process.

210. The Commission proposes to add a new section 3.3.1 to the *pro forma* LGIP that describes the process for using surplus interconnection service:

Surplus Interconnection Service Requests

Surplus Interconnection Service requests may be made by the existing Generating Facility or one of its affiliates. Surplus Interconnection Service requests also may be made by another Interconnection Customer selected through an open and transparent solicitation process. The Transmission Provider shall provide a process for evaluating interconnection requests for Surplus Interconnection Service. Studies for Surplus Interconnection Service shall consist of reactive power, short circuit/fault duty, stability analyses, and any other appropriate studies. Steady-state (thermal/voltage) analyses may be performed as necessary to ensure that all required reliability conditions are studied. If the Surplus Interconnection Service was not studied under off-peak conditions, off-peak steady state analyses shall be performed to the required level necessary to demonstrate reliable operation of the Surplus Interconnection Service. If the original System Impact Study is not available for the Surplus Interconnection Service, both off-peak and peak analysis may need to be performed for the existing Generating Facility associated with the request for Surplus Interconnection Service. The reactive power, short circuit/fault duty, stability, and steady-state analyses for Surplus Interconnection Service will identify any additional Interconnection Facilities and/or Network Upgrades necessary.

211. The Commission proposes to add a new section 3.3.2 to the *pro forma* LGIP that establishes the open and transparent solicitation process for surplus interconnection service:

Solicitation Process for Surplus Interconnection Service

If the existing Generating Facility owner elects to transfer rights for Surplus Interconnection Service to an unaffiliated Interconnection Customer, it must do so through an open and transparent solicitation process. The existing Generating Facility owner must first request that the Transmission Provider post on its Web site that it is willing to accept requests for Surplus Interconnection Service at the existing Point of Interconnection. Such posting will include the name of the existing Generating Facility, the exact electrical location of the physical termination point of the Surplus Interconnection Service,

[248] *Midwest Indep. Transmission Sys. Operator, Inc.,* 153 FERC ¶ 61,313, at P 27 (2015).

[249] Order No. 807, Open Access and Priority Rights on Interconnection Customer's Interconnection Facilities, 150 FERC ¶ 61,211.

[250] Renumbering detailed in Appendix B of this Proposed Rule.

including proposed breaker position(s) within its substation, the state and county of the existing Generating Facility, and a valid email address and phone number to contact the representative of the existing Generating Facility. The existing Generating Facility owner must provide the Transmission Provider with the System Impact Study performed for the existing Generating Facility with its request for posting Surplus Interconnection Service or indicate that such study is not available.

After the existing Generating Facility owner requests that the Transmission Provider post the availability of Surplus Interconnection Service, the Transmission Provider will also post on its Web site a description of the selection process for transferring rights to the Surplus Interconnection Service that will include a timeline and the selection criteria developed by the existing Generating Facility owner. The selection process may vary among existing Generating Facility owners but the existing Generating Facility owner will choose the winning request after all necessary studies have been performed by the Transmission Provider. The existing Generating Facility owner will submit to the Transmission Provider, for posting on the Transmission Provider's Web site, the results of the selection process and will include a description of whose proposal for the Surplus Interconnection Service was selected and why. After an Interconnection Customer has been chosen, the new Interconnection Customer will execute, or request the filing of an unexecuted, interconnection agreement with the Transmission Provider and Transmission Owner (as applicable) upon completion of all necessary studies for its new Generating Facility.

4. Material Modification and Incorporation of Advanced Technologies

212. It is not uncommon for equipment manufacturers to make technological advancements to equipment while an interconnection request progresses through the interconnection process since the process can span several years. Technological advancements to equipment may achieve cost efficiencies and/or electrical grid performance benefits. These changes may include, for example, advancements to turbines, inverters, plant supervisory controls, or may affect a generating facility's ability to provide ancillary services. However, the *pro forma* LGIP does not include clear guidelines on what technology changes constitute material modifications and how these changes can be incorporated into an interconnection request. The *pro forma* LGIP also does not contain guidance regarding the analysis and modeling for the incorporation of technological advancements into an existing interconnection request. The Commission proposes to require that transmission providers develop: (1) A definition of permissible technological advancements pursuant to an interconnection request that the interconnection process can accommodate and (2) an accompanying procedure that will be used to accommodate the incorporation of technological advancements to interconnection requests for synchronous and non-synchronous generating facilities. Further, the Commission proposes that this definition should contemplate advancements that provide cost efficiency and/or electrical performance benefits.

a. Existing Provisions and Background

213. Under the *pro forma* LGIP, an interconnection customer must submit to the transmission provider, in writing, modifications to any information provided in the interconnection request.[251] An interconnection customer retains its queue position if the modifications are either allowed explicitly under the *pro forma* LGIP or if the transmission provider determines that the modifications are not Material Modifications.[252] The *pro forma* LGIP directs transmission providers to commence any necessary additional studies related to the interconnection customer's modification request no later than 30 calendar days after receiving notice of the request.[253] If a transmission provider finds a proposed modification to be material, the interconnection customer can choose whether to abandon the proposed modification or to proceed with the modification and lose its existing queue position.

b. Comments

214. During the 2016 Technical Conference, some panelists questioned whether interconnection customers should be able to incorporate technological advancements into their interconnection requests as they move through the interconnection study process. The Commission subsequently solicited post-technical conference comments on whether technological advancements could be incorporated without presenting system reliability concerns and causing delays to the interconnection study process.[254] Multiple commenters assert that the interconnection process could benefit from the additional flexibility to accommodate technological advancements that do not cause significant reliability issues or timing delays.[255] Some commenters state that these advancements should be permissible as long as they do not trigger the Material Modification provision of the LGIP and do not disrupt other interconnection requests.[256] PacifiCorp proposed a formal procedure for transmission providers to evaluate technological advancements.[257] In particular, PacifiCorp's proposal would require interconnection customers to provide formal notification and a $10,000 deposit for the performance of a technological change study that the transmission provider would complete within 30 days.[258] MISO asserts that a new approach to account for technological advancements would require manufacturers to provide validation documentation that the advancement performs equally or better than without the technological change. MISO further asserts that if a technological advancement would result in improved performance, in most cases, a transmission provider study is unnecessary.[259] Xcel acknowledges that new technologies may not be appropriately modeled in the existing analytical software, and states that developing sufficient modeling parameters should be made clear to interconnection customers' technology vendors.[260] Xcel argues that confidentiality issues should not preclude the sharing of functional specifications sufficient to model the new equipment.[261]

215. With regard to the timing of technological change requests, most commenters did not identify an appropriate deadline within the interconnection process beyond which transmission providers could not accommodate technological advancements. EDF argues that technological advancements should be accommodated as an interconnection request proceeds through the LGIP process up until the commercial operation date, because advancements provide benefits to all customers.[262] NYISO, on the other hand, asserts that

[251] *See Pro forma* LGIP at Section 4.4.

[252] *See Pro forma* LGIP at Sections 4.4.1, 4.4.2, 4.4.3, 4.4.4.

[253] *See Pro forma* LGIP at Section 4.4.4.

[254] *See* Notice Inviting Post-Technical Conference Comments, Question 1.13 Docket Nos. RM16–12–000 and RM15–21–000 (June 3, 2016).

[255] *See, e.g.,* PacifiCorp 2016 Comments at 3–4; AWEA 2016 Comments at 27; Invenergy 2016 Comments at 18; MISO 2016 Comments at 14; EDF 2016 Comments at 25; NYISO 2016 Comments at 19; ISO–NE 2016 Comments at 20–21.

[256] *See, e.g.,* Xcel 2016 Comments at 12–13; MISO 2016 Comments at 14; EDP 2016 Comments at 14–15; Invenergy 2016 Comments at 18.

[257] PacifiCorp 2016 Comments at 3–4.

[258] *Id.*

[259] MISO 2016 Comments at 14.

[260] Xcel 2016 Comments at 12–13.

[261] Xcel 2016 Comments at 12–13.

[262] EDF 2016 Comments at 25.

technological advances and other modifications can be incorporated into an interconnection request only if they are proposed at appropriate stages.[263]

c. Proposal

216. The Commission preliminarily finds that the provisions regarding material modifications in the *pro forma* LGIP provide the transmission provider with significant discretion in determining whether a modification is deemed material, and that this discretion can lead to unjust and unreasonable rates, terms, and conditions, and unduly discriminatory or preferential practices when transmission providers evaluate technological advancements under the existing material modification construct.

217. The Commission thus proposes to require transmission providers to establish a technological change procedure to assess and, if necessary, study whether they can accommodate a technological change request without the change considered to be a material modification. The Commission proposes that transmission providers include the technological change procedure in their *pro forma* LGIPs. The Commission proposes an approach below for how this new procedure should be structured and proposes to require that transmission providers use this approach when developing their technological change procedure.

218. The Commission proposes that an interconnection customer that seeks to incorporate technological advancements into an interconnection request must formally notify the relevant transmission provider. In order for the transmission provider to determine that a proposed technological change is not a material modification,[264] the interconnection customer's formal technological change request would include analyses to demonstrate that the proposed incorporation of the technological advancement would result in electrical performance that is equal to or better than the electrical performance expected prior to the technology change. In some instances, a transmission provider may determine that no additional study is necessary to accommodate a proposed technological advancement without a loss of queue position.

219. In other instances, a transmission provider may require a study for a proposed technological advancement to not be considered a material modification. The Commission proposes that, in this scenario, the interconnection customer should tender an appropriate study deposit and provide the necessary modeling data that sufficiently models the behavior of the new equipment and any other required data about the technological advancement to the transmission provider. The transmission provider should then provide the study results within 30 days.

220. Under this proposal, the technological change procedure should specify what technological advancements can be incorporated at various stages of the interconnection process and the procedure should clearly specify which requirements apply to the interconnection customer and which apply to the transmission provider. The procedure should, for example, state that an interconnection customer that seeks to incorporate technological advancements into its generating facility should submit a formal technological change request. Additionally, the procedure should specify the necessary information that should be submitted by the interconnection customer as part of a formal technological change request and, to the extent practicable, specify the conditions when a study will or will not be necessary. If a study is necessary, the procedure should clearly specify the information that the interconnection customer needs to provide, including study scenarios, modeling data, and any other assumptions. The procedure should also clearly indicate what types of information and/or study results are necessary from the interconnection customer and explain how the transmission provider will evaluate the technological change request. In the instance where the transmission provider performs the study, the interconnection customer may be required to tender a deposit, and the procedure should specify the amount of the study deposit and include the timeframe for the transmission provider to perform the study and return the results to the interconnection customer. If a proposed technological advancement cannot be accommodated without triggering the material modification provision of the *pro forma* LGIP or be completed through an abbreviated assessment that does not affect the interconnection customer's queue position, the Commission proposes to require the transmission provider to provide an explanation to the interconnection customer. The Commission seeks comment on reasonable study deposits and time frames.[265]

221. Consistent with the discussion above, the Commission proposes to revise Section 4.4.2 of the *pro forma* LGIP as follows (*proposing to delete italicized text*):

> 4.4.2 Prior to the return of the executed Interconnection Facility Study Agreement to the Transmission Provider, the modifications permitted under this Section shall include specifically: (a) Additional 15 percent decrease in plant size (MW), *and* (b) Large Generating Facility technical parameters associated with modifications to Large Generating Facility technology and transformer impedances; provided, however, the incremental costs associated with those modifications are the responsibility of the requesting Interconnection Customer; *and (c) certain technological advancements for the Large Generating Facility after the submission of the interconnection request. Section 4.4.4 specifies a separate Technological Change Procedure including the requisite information and process that will be followed to assess whether the Interconnection Customer's proposed technological advancement under section 4.4.2(c) is a Material Modification. Section 1 contains a definition of technological advancements.*

222. Pursuant to this proposal, the Commission also proposes to require transmission providers to develop a definition of technological advancements in their LGIPs. This definition should consider technological changes to equipment that may achieve cost and grid performance efficiencies. Examples of technological advancements that fit within these parameters include, but are not limited to, upgrades to turbines, inverters, and plant supervisory controls.

223. This proposal should reduce barriers to the implementation of technological advancements that improve the electrical characteristics of a generating facility and that perform equally or better than the performance of previous equipment and/or provide cost efficiencies. The Commission proposes that transmission providers use sound engineering judgment to determine whether they can accommodate the proposed technological changes so that they would not require a material modification. The Commission proposes to permit interconnection customers to submit requests to incorporate technological advancements prior to the execution of the interconnection facilities study agreement, and the

[263] NYISO 2016 Comments at 19.

[264] The *pro forma* LGIP defines Material Modification as ''those modifications that have a material impact on the cost or timing of any Interconnection Request with a later queue priority date.'' *See pro forma* LGIP at Section 1.

[265] In its 2016 Comments, PacifiCorp proposes a $10,000 study deposit and 30-day timeframe for the study to be performed. PacifiCorp 2016 Comments at 4–5.

Commission seeks comment as to whether this is the appropriate stage in the interconnection process to implement the technological change procedure.

5. Modeling of Electric Storage Resources for Interconnection Studies

224. The Commission proposes to require that transmission providers evaluate their methods for modeling electric storage resources for interconnection studies, identify whether their current modeling and study practices adequately and efficiently account for the operational characteristics of electric storage resources, and report to the Commission why and how their existing practices are or are not sufficient.

a. Existing Provisions and Background

225. Electric storage resources present unique interconnection challenges because they are able to both receive electricity from the grid and inject electricity onto the grid. For this reason, transmission providers must study them in a way that measures their potential impact as both generation and load. It is not currently clear to the Commission whether making electric storage resources fit into the existing procedures for generation and load is the most effective means of evaluating these interconnection requests. The fact that generation studies and load studies are often conducted separately appears to complicate the way electric storage resources are modeled during the interconnection process and was a source of frustration among interconnection customers of electric storage resources that filed post-technical conference comments.

b. Comments

226. At the 2016 Technical Conference, panelists and staff discussed the modeling of electric storage resources for interconnection studies, including potential means for interconnection studies to better reflect the intended operation of electric storage resources. The Commission requested comment on whether current interconnection studies adequately account for the operational characteristics of electric storage resources in its request for post-technical conference comments. In response, several commenters note that two changes would improve the functionality of the interconnection study process: (1) Changing the way storage is evaluated and modeled to follow California's ''negative generation'' approach; and (2) allowing interconnection customers to specify the charge/discharge parameters to be used by the transmission provider in interconnection studies.[266] Commenters also recommend that interconnection studies model the impacts of storage resources under their planned use cases and argue that they include the operational characteristics of storage and the benefits it provides for reliability.[267] AES notes that its software eliminates the potential for voltage flicker and that transmission providers should be able to take into account that a particular interconnection customer can operate without voltage flicker.[268]

227. The RTOs/ISOs generally believe that their practices for modeling electric storage resources for interconnection studies are adequate. MISO asserts that the generator interconnection process is an appropriate process to study new storage interconnections and that only minor changes from that process are necessary for it to study storage interconnection.[269] NYISO contends that interconnection studies currently account for the operating characteristics of electric storage resources to the extent necessary under the minimum interconnection standard. However, NYISO states that it has experienced challenges with the accuracy of modeling information used to evaluate electric storage resources in the interconnection process.[270] ISO–NE claims that its current interconnection studies adequately account for the operational characteristics of electric storage resources.[271]

228. CAISO's approach to modeling electric storage resources (or Non-Generator Resources) as ''negative generation'' was identified as a best practice during the 2016 Technical Conference and in the post-technical conference comments.[272] NextEra states that allowing electric storage resources to provide better information about their resources for interconnection studies would benefit the study process, and NYISO indicates that it has experienced challenges with the accuracy of modeling information.[273] Both NextEra's and NYISO's concern suggests that more specific information requirements for modeling electric storage resources would be appropriate.

c. Proposal

229. The Commission proposes to require that transmission providers evaluate their methods for modeling electric storage resources for interconnection studies, identify whether their current modeling and study practices adequately and efficiently account for the operational characteristics of electric storage resources, and provide their responses to the Commission in comments to this Proposed Rule regarding why and how their existing practices are or are not sufficient. Specifically, transmission providers and others should comment on whether establishing a unified model for studying electric storage resources would expedite the study process and therefore reduce the time and costs expended by the transmission providers for studying the interconnection of electric storage resources. For example, the negative-generation practice in CAISO may allow transmission providers to better account for the transitions of electric storage resources between generation and load and may better enable the use of existing generator interconnection procedures and agreements due to their treatment as negative generation instead of load. This approach to studying electric storage resources may also expedite their interconnection by allowing the transmission provider to study them as a single resource and perform one study (as opposed to separate studies for generation and load impacts). In addition, this approach may also help ensure the applicability of existing interconnection agreements and procedures to electric storage resources.

230. Additionally, commenters should describe what information electric storage resources should provide that is not already consistently provided with interconnection requests. Since transmission providers evaluate electric storage resources using existing processes for generation and load, it is unclear to the Commission whether the existing information requirements for new interconnection customers that want to interconnect electric storage resources are adequate to capture the operational characteristics of electric storage resources. Bringing electric storage resources onto the system as efficiently as possible may enhance competition in the wholesale markets and improve reliability. If there are approaches to studying electric storage resources that capture their unique

[266] *See, e.g.,* ESA Comments at 5, RES Americas Comments at 3. The Commission notes that RES Americas would prefer a separate process but alternatively suggests using the negative generation approach. NextEra Comments at 10–11.

[267] Energy Storage Association Comments at 7–8; RES Americas Comments at 5; California Energy Storage Alliance Comments at 11; Invenergy Comments at 28; AES comments at 3–4; NextEra Comments at 11; Xcel Comments at 18.

[268] AES Comments at 14.

[269] MISO Comments at 23.

[270] NYISO Comments at 27–28.

[271] ISO–NE Comments at 28.

[272] ESA Comments at 5; RES Americas Comments at 3.

[273] NextEra Comments at 11; NYISO Comments at 28.

characteristics and facilitate their interconnection, the Commission would like to identify those potential improvements as best practices for all transmission providers.

V. Proposed Compliance Procedures

231. The Commission proposes to require each public utility [274] transmission provider to submit a compliance filing within 90 days of the effective date of the final rule in this proceeding revising its LGIP and LGIA, as necessary, to demonstrate that it meets the requirements set forth in any final rule issued in this proceeding.

232. Some public utility transmission providers may have provisions in their existing LGIPs and LGIAs that the Commission has previously deemed to be consistent with or superior to the *pro forma* LGIP and *pro forma* LGIA. Where these provisions would be modified by the final rule, public utility transmission providers must either comply with the final rule or demonstrate that these previously-approved variations continue to be consistent with or superior to the *pro forma* as modified by the final rule. The Commission also proposes to permit appropriate entities to seek ''regional reliability variations'' or ''independent entity variations'' from the proposed revisions to the *pro forma.*[275]

233. The Commission will assess whether each compliance filing satisfies the proposed requirements stated above and issue additional orders as necessary to ensure that each public utility transmission provider meets the requirements of the subsequent final rule.

234. The Commission proposes that Transmission Providers that are not public utilities will have to adopt the requirements of this Proposed Rule as a condition of maintaining the status of their safe harbor tariff or otherwise satisfying the reciprocity requirement of Order No. 888.[276]

VI. Information Collection Statement

235. The following collection of information contained in this Proposed Rule is subject to review by the Office of Management and Budget (OMB) regulations under section 3507(d) of the Paperwork Reduction Act of 1995.[277] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[278] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this Proposed Rule will not be penalized for failing to respond to the collection of information unless the collection of information displays a valid OMB control number.

236. The reforms proposed in this Proposed Rule would revise the Commission's *pro forma* LGIP, *pro forma* LGIA, and the Commission's regulations in accordance with section 35.28(f)(1) of the Commission's regulations.[279] This Proposed Rule proposes that each public utility transmission provider will amend its LGIP and LGIA to improve the interconnection process. The Commission anticipates the revisions proposed in this Proposed Rule, once implemented, will not significantly change currently existing burdens on an ongoing basis. The Commission will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[280]

237. While the Commission expects the revisions proposed in this Proposed Rule will provide significant benefits, the Commission understands that implementation can be a complex and costly endeavor. The Commission solicits comments on its need for this information, whether the information will have practical utility, the accuracy of the provided burden and cost estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing the respondents' burdens.

Burden Estimate and Information Collection Costs: The Commission believes that the burden estimates below are representative of the average burden on respondents. The estimated burden and cost [281] for the requirements contained in this Notice of Proposed Rulemaking follow.

FERC 516F

	Number of applicable registered entities	Annual number of responses per respondent	Total number of responses	Average burden (hours) and costs per response [283]	Total annual burden hours and total annual cost
	(1)	(2) [282]	(1) * (2) = (3)	(4)	(3) * (4) = (5)
Issue A1—Scheduled periodic restudies	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue A2—Interconnection customer's option to build	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue A3—Self-funding by the transmission owner	Non-RTO/ISO (126)	N/A	N/A	N/A	N/A.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.

[274] A public utility is a utility that owns, controls, or operates facilities used for transmitting electric energy in interstate commerce, as defined by the FPA. *See* 16 U.S.C. 824(e) (2012). A non-public utility that seeks voluntary compliance with the reciprocity condition of an OATT may satisfy that condition by filing an OATT, which includes an SGIA.

[275] *See, e.g.,* Order No. 2003, FERC Stats. & Regs. ¶ 31,146 at PP 822–827; Order No. 2006, FERC Stats. & Regs. ¶ 31,180 at PP 546–550.

[276] *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission on Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036, at 31,760–763 (1996).

[277] 44 U.S.C. 507(d) (2012).

[278] 5 CFR 1320.11 (2016).

[279] 18 CFR 35.28(f)(1) (2016).

[280] 44 U.S.C. 3507(d) (2012).

[281] The estimates for cost per response are derived using the following formula: Average Burden hours per Response * $74.50 per Hour = Average Cost per Response. The hourly cost figure comes from the Commission average salary of $154,647. Subject matter experts found that industry employment costs closely resemble the Commission's regarding the FERC–516F information collection.

[282] Any figures labeled as ''Year 2'' should be considered ongoing response or burden amounts.

[283] ($154,647/year)/(2,080 hours/year) = $74.349 per hour and is rounded to $74.50 per hour.

FERC 516F—Continued

	Number of applicable registered entities (1)	Annual number of responses per respondent (2)[282]	Total number of responses (1) * (2) = (3)	Average burden (hours) and costs per response[283] (4)	Total annual burden hours and total annual cost (3) * (4) = (5)
Issue A4—RTO/ISO dispute resolution	Non-RTO/ISO (126)	N/A	N/A	N/A	N/A.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue A5—Capping costs for network upgrades	Non-RTO/ISO (126)	N/A	N/A	N/A	N/A.
	RTO/ISO (6)	N/A	N/A	N/A	N/A.
Issue B1—Identification and definition of contingent facilities.	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—80	Year 1–10,080.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—80	Year 1—480.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue B2—Lack of transparency in the interconnection process.	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—80	Year 1—10,080.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—80	Year 1—480.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue B3—Curtailment concerns	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—12	Year 2– 1512	Year 2—4	Year 2—6,048.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—12	Year 2—72	Year 2—4	Year 2—288.
Issue B4—Definition of generating facility	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue B5—Interconnection study deadlines	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—4	Year 2—504	Year 2—4	Year 2—2,016.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—4	Year 2—24	Year 2—4	Year 2—96.
Issue C1—Requesting interconnection service below generating facility capacity.	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue C2—Provisional agreements	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue C3—Utilization of surplus interconnection service.	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue C4—Material modification and incorporation of advanced technologies.	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—4	Year 1—504.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—4	Year 1—24.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Issue C5—Modeling of electric storage resources	Non-RTO/ISO (126)	Year 1—1	Year 1—126	Year 1—80	Year 1–10,080.
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
	RTO/ISO (6)	Year 1—1	Year 1—6	Year 1—80	Year 1—480
		Year 2—0	Year 2—0	Year 2—0	Year 2—0.
Total	Non-RTO/ISO, Year 1		276	34,776.	
	Non-RTO/ISO, Ongoing		64	8,064.	
	RTO/ISO, Year 1		284	1,704.	
	RTO/ISO, Ongoing		64	384.	

Cost to Comply: The Commission has projected the total cost of compliance as follows: [284]

Year 1: $2,590,812 ($20,562/non-RTO/ISO utility), $126,948 ($21,158/RTO/ISO utility) [285]

Year 2: $600,768 ($4,768/non-RTO/ISO utility), $28,608 ($4,768/RTO/ISO utility) [286]

Year 1 costs reflect filing of new LGIP and LGIA language with the Commission, as well as certain efforts to review and revise existing interconnection procedures. Year 2 represents ongoing costs that the transmission provider will face on an ongoing basis to fulfill the directives of this Notice of Proposed Rulemaking. The reforms proposed in this Notice of Proposed Rulemaking, once implemented, would not significantly change existing burdens on an ongoing basis.

Title: FERC–516, Electric Rate Schedules and Tariff Filings.

Action: Proposed revision to an information collection.

OMB Control No.: TBD.

Respondents for Proposal: Businesses or other for profit and/or not-for-profit institutions.

Frequency of Information: One-time during year one. Multiple times during subsequent years.

Necessity of Information: The Commission issues this Proposed Rule to address interconnection practices that may be resulting in unjust and unreasonable or unduly discriminatory or preferential rates, terms, and conditions. The Commission seeks to improve certainty in the interconnection process, to promote more informed interconnection decisions by interconnection customers, and to enhance interconnection processes.

Internal Review: The Commission has reviewed the proposed changes and has determined that such changes are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements.

238. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873. Comments concerning the collection of information and the associated burden estimate(s) in the Proposed Rule should be sent to the Commission in this docket and may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–0710, fax: (202) 395–7285]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov.* Comments submitted to OMB should include FERC–516D and OMB Control No. 1902–0288.

VII. Regulatory Flexibility Act

239. The Regulatory Flexibility Act of 1980 (RFA) [287] generally requires a description and analysis of rules that will have significant economic impact on a substantial number of small entities. The RFA does not mandate any particular outcome in a rulemaking. It only requires consideration of alternatives that are less burdensome to small entities and an agency explanation of why alternatives were rejected.

240. The Small Business Administration (SBA) revised its size standards (effective January 22, 2014) for electric utilities from a standard based on megawatt hours to a standard based on the number of employees, including affiliates. Under SBA's standards, some transmission owners will fall under the following category and associated size threshold: Electric bulk power transmission and control, at 500 employees.[288]

241. The Commission estimates that the total number of public utility transmission providers that would have to modify the LGIPs and LGIAs within their currently effective OATTs is 132. Of these, the Commission estimates that approximately 43 percent are small entities (approximately 57 entities). The Commission estimates the average total cost to each of these entities will be between $20,562 and $21,158 in Year One and $4,768 in subsequent years. According to SBA guidance, the determination of significance of impact ''should be seen as relative to the size of the business, the size of the competitor's business, and the impact the regulation has on larger competitors.'' [289] The Commission does not consider the estimated burden to be a significant economic impact. As a result, the Commission certifies that the revisions proposed in this Proposed Rule will not have a significant economic impact on a substantial number of small entities.

VIII. Environmental Analysis

242. 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.[290] The Commission concludes that neither an Environmental Assessment nor an Environmental Impact Statement is required or the revisions proposed in this Proposed Rule under section 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts and regulations that affect rates, charges, classification, and services.[291] The revisions proposed in this Proposed Rule fall within the categorical exemptions provided in the Commission's regulations, and as a result neither an Environmental Impact Statement nor an Environmental Assessment is required.

IX. Comment Procedures

243. The Commission invites persons to submit comments on the matters and issues proposed in this Notice of Proposed Rulemaking to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due March 14, 2017. Comments must refer to Docket No. RM17–8–000, and must include the commenter's name, the

[284] The costs for Year 1 would consist of filing proposed changes to the LGIP and LGIA with the Commission within 90 days of the effective date of the final revision plus initial implementation. The costs for year 2 represent ongoing requirements that would persist in subsequent years.

[285] Non-RTO/ISO utility costs (Year One): 34,776 hours * $74.50 = $2,590,812; $2,590,812 ÷ 126 = $20,562. RTO/ISO utility costs: 384 hours * $74.50 = $28,608; $28,608 ÷ 6 = $4,768.

[286] Non-RTO/ISO utility costs (Year 2 and ongoing): 8,064 hours * $74.50 = $600,768; $600,768 ÷ 126 = $4,768. RTO/ISO utility costs: 384 hours * $74.50 = $28,608; $28,608 ÷ 6 = $4,768.

[287] 5 U.S.C. 601–12 (2012).

[288] 13 CFR 121.201, Sector 22 (Utilities), NAICS code 221121 (Electric Bulk Power Transmission and Control) (2016).

[289] U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the Regulatory Flexibility Act,* at 18 (May 2012), *https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.*

[290] *Regulation Implementing National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

[291] 18 CFR 380.4(a)(15) (2016).

organization they represent, if applicable, and their address.

244. 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.

245. 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.

246. 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.

X. Document Availability

247. 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/or 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.

248. 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/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

249. 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

18 CFR Part 35

Electric power rates. Electric utilities, Reporting and recordkeeping requirements.

18 CFR Part 37

Electric power rates, Electric utilities, Reporting and recordkeeping requirements.

By direction of the Commission.

Dated: December 15, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend Parts 35 and 37 Chapter I, Title 18, *Code of Federal Regulations,* as follows.

PART 35—FILING OF RATE SCHEDULES AND TARIFFS

■ 1. The authority citation for Part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r; 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Amend § 35.28 by adding paragraph (g)(9) to read as follows:

§ 35.28 Non-discriminatory open access transmission tariff.

* * * * *

(g) * * *

(9) *Generator Interconnection Dispute Resolution Procedures.* Every Commission-approved independent system operator or regional transmission organization tariff must contain provisions governing generator interconnection dispute resolution procedures to allow a disputing party to unilaterally initiate dispute resolution procedures under the respective tariff. Such provisions must provide for independent system operator or regional transmission organization staff member(s) or utilize subcontractor(s) to serve as the neutral decision-maker(s) or presiding staff member(s) or subcontractor(s) to the dispute resolution procedures. Such staff participating in dispute resolution procedures shall not have any current or past substantial business or financial relationships with any party. Additionally, such dispute resolution procedures must account for the time sensitivity of the generator interconnection process.

PART 37—OPEN ACCESS SAME-TIME INFORMATION SYSTEMS

■ 1. The authority citation for Part 37 continues to read as follows:

Authority: 5 U.S.C. 551–557; 16 U.S.C. 791a–825r; 31 U.S.C. 9701; 42 U.S.C. 7107–7352.

■ 2. Amend § 37.6 by adding paragraph (l) as follows:

§ 37.6 Information to be posted on the OASIS

* * * * *

(l) *Posting of congestion and curtailment data.* (1) The Transmission Provider must post on OASIS information as to congestion data representing:

(i) Total hours of curtailment on all interfaces;

(ii) Total hours of Transmission Provider-ordered generation curtailment and transmission service curtailment due to congestion on that facility or interface;

(iii) The cause of the congestion (*e.g.,* a contingency or an outage); and

(iv) Total megawatt hours of curtailment due to lack of transmission for that month.

(2) This data shall be posted on a monthly basis by the 15th day of the following month and shall be posted in one location on the OASIS. The Transmission Provider should maintain this data for a minimum of three years.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 418, et al.

Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 418, 440, 484, 485 and 488

[CMS–3819–F]

RIN 0938–AG81

Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

DATES: These regulations are effective on July 13, 2017.

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SUPPLEMENTARY INFORMATION:

I. Background Information

A. The Home Health Benefit

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act). These services, provided under a plan of care that is established and periodically reviewed by a physician, must be furnished by, or under arrangement with, a home health agency (HHA) that participates in the Medicare or Medicaid programs. Services are provided on a visiting basis in the beneficiary's home, and may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical residency training program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when the services involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484, Home Health Services. Current regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare Conditions of Participation (CoPs). Section 1861(o)(6) of the Act requires that an HHA must meet the CoPs specified in section 1891(a) of the Act, and other CoPs as the Secretary finds necessary in the interest of the health and safety of patients. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home health aide training and competency, and compliance with applicable federal, state, and local laws. The CoPs for HHAs protect all individuals under the HHA's care, unless a requirement is specifically limited to Medicare beneficiaries. Section 1861(o) of the Act describes an HHA for purposes of participation in the Medicare program. All the requirements are stated generally, and are applicable to the HHA's overall activity, not specifically to Medicare patients. This provision, which was reaffirmed by the Congress in the Omnibus Budget Reconciliation Act (OBRA), 1987 amendments to section 1891(a) of the Act, has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA, and to promote the effective and efficient use of Medicare funds. To implement this requirement, State Survey Agencies and CMS-approved accrediting organizations conduct surveys of HHAs to determine whether they are complying with the CoPs.

B. Previous HHA Conditions of Participation Rules

On March 10, 1997 (62 FR 11004), we published a proposed rule, entitled, ''Revision of the Conditions of Participation for Home Health Agencies and Use of the Outcome and Assessment Information Set (OASIS) as Part of the Revised Conditions of Participation for Home Health Agencies,'' that would have revised the entire set of HHA CoPs. Due to the significant volume of public comments and the rapidly changing nature of the HHA industry at that time, this rule, in its entirety, was never finalized.

Rather than finalizing all portions of the March 1997 rule, we published a final regulation (64 FR 3764, January 25, 1999) that only finalized the OASIS regulations. The January 1999 final rule required that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's medical, nursing, rehabilitation, social, and discharge planning needs.

We also issued an interim final rule with comment period on the same day (64 FR 3748) that required HHAs to use the OASIS data collection instrument that standardizes parts of the assessment and to transmit the data to CMS. That rule implemented sections 1891(c)(2)(C) and 1891(d)(1) of the Act, which require the Secretary to establish a standardized assessment instrument for measuring the quality of care and services furnished by HHAs. The OASIS data collection instrument and data transmission rule was finalized on December 23, 2005 (70 FR 76199).

Although the OASIS requirements were finalized in separate rules, we intended to proceed with another rule to finalize the remainder of the requirements of the March 1997 proposed rule. However, section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1871(a)(3) to the Act. This section provided that, effective December 8, 2003, the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), would have to establish and publish regular timelines for the publication of Medicare proposed regulations based on the previous publication of Medicare proposed or interim final regulations. Section 902 of the MMA further provided that the timeline could vary among different regulations, but could

not be longer than 3 years, except under exceptional circumstances. Pursuant to the MMA, we issued a notice implementing this provision in the **Federal Register** on December 30, 2004 (69 FR 78442). In that notice, we interpreted section 902 as rendering ineffective any proposed Medicare regulations that had been outstanding for 3 years or more as of December 8, 2003; this included the proposed HHA CoPs. Therefore, out of an abundance of caution, we decided not to finalize the remaining provisions of the March 10, 1997 proposed rule, but begin rulemaking again.

On October 9, 2014, we set forth proposed rules for HHAs that choose to participate in Medicare and Medicaid (79 FR 61164). We proposed to revise all of the existing CoPs, and to add several new CoPs to address aspects of home health care that we believe need attention.

C. Transforming the HHA Conditions of Participation

As the single largest payer for health care services in the United States, the Federal government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. Facilities not meeting requirements would either correct the inappropriate practice(s) or would be terminated from participation in the Medicare or Medicaid programs. We have found that this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

Obtaining quality health care for Federal beneficiaries from CMS-certified providers and suppliers requires taking advantage of continuing advances in the health care delivery field. As a result, we are revising the home health agency requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. Before we began development of new proposed CoPs for Medicare and Medicaid participating HHAs, we received recommendations from home health providers, professional associations and practitioner communities, consumer advocates and state and other governmental agencies with an interest or responsibility in HHA regulation and oversight. We also took into account the comments that were submitted by the public on the March 1997 proposed rule and suggestions submitted by the HHA industry in the summer of 2011, as well as developments since that time within the industry. In light of this information, we have used the following principles to assist in the development of the new HHA CoPs:

- Develop a more continuous, integrated care process across all aspects of home health services, based on a patient-centered assessment, care planning, service delivery, and quality assessment and performance improvement.
- Use a patient-centered, interdisciplinary approach that recognizes the contributions of various skilled professionals and their interactions with each other to meet the patient's needs. Stress quality improvements by incorporating an outcome-oriented, data-driven, quality assessment and performance improvement program specific to each HHA.
- Eliminate the focus on administrative process requirements that lack adequate consensus or evidence that they are predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients.
- Safeguard patient rights.

We believe that the overall approach of the CoPs provides HHAs with greatly enhanced flexibility. At the same time, we believe the new requirements improve performance results for HHAs, in terms of achieving needed and desired outcomes for patients, and increasing patient satisfaction with services provided.

D. Organization of This Rule

This final rule is organized in the following manner:

- *Background Information.* This section summarizes the Home Health benefit, previous HHA CoP rules, and transforming the HHA CoP.
- *Provisions of the Proposed Regulations.* This section briefly summarizes all of the proposed requirements in numerical order by CoP number.
- *Home Health Crosswalk.* This section cross references former requirements to their new location.
- *Analysis of and Responses to Public Comments.* This section summarizes and responds to all public comments that were received in numerical order by CoP number.
- *Provisions of the Final Rule.* This section lists all changes that were made from the proposed version of the rule to the final version of the rule.
- *Good Cause to Waive Notice and Comment Rulemaking.* This section explains why notice-and-comment is impracticable, unnecessary, or contrary to the public interest.
- *Collection of Information and Regulatory Impact Analysis.* These sections describe the anticipated estimated burdens and savings that will result from the implementation of this final rule in a statistically typical HHA.
- *Regulatory Text.* This section sets forth the regulations that are being finalized in this rule.

II. Provisions of the Proposed Regulations

A. Overview

We proposed to make extensive changes in the organizational scheme to group together all CoPs directly related to patient care and place them near the beginning of part 484. Regulations concerning the organization and administration of an HHA would follow in a separate subpart entitled ''Organizational Environment.''

B. Proposed Subpart A, General Provisions

We proposed to reorganize this section to clarify the basis and scope of this part. Part 484 is based on sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program. Part 484 is also based on section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet. These provisions serve as the basis for survey activities for the purposes of determining whether an agency meets the requirements for participation in Medicare.

At § 484.2, we proposed to clarify some of the definitions for terms used in the HHA CoPs. We proposed to modify the definition for ''branch office'' by adding the requirement that the parent agency offer more than the sharing of services; specifically, that it provide supervision and administrative control of branches on a daily basis to the extent that the branch depends upon the parent agency's supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity. Though the definition would no longer require the branch office to be ''sufficiently close,'' the parent agency would have to be

available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of the agency. A violation of a CoP in one branch office would apply to the entire HHA.

We also proposed minor changes in the language of the current definitions for ''clinical note,'' ''parent home health agency,'' ''proprietary agency,'' and ''subdivision.'' We also proposed to eliminate current definitions of the terms ''bylaws'' and ''supervision,'' ''home health agency,'' ''progress notes,'' and ''subunit.'' On the effective date of this rule, any existing subunits, which already operate under their own provider number, will be considered distinct HHAs and will be required to independently meet all CoPs, including having an independent governing body and administrator. Subject to state-specific laws and regulations, this federal regulatory change will permit a subunit to apply to become a branch of its existing parent HHA if the parent provides ''. . . direct support and administrative control'' of the branch. The State Survey Agency and CMS Regional Office will continue to be responsible for approving an HHA's application for a branch office, in accordance with current CMS guidance as set out in various survey and certification letters and section 2182.4B of the State Operations Manual. No new subunits will be approved upon implementation of this regulation, only ''branch offices.''

Finally, we proposed to add definitions for the terms ''in advance,'' ''quality indicator,'' ''representative,'' ''supervised practical training,'' and ''verbal order.'' We proposed to define the term ''representative'' in a patient-centered manner that enables patients to choose their representatives, if they wish to do so. We proposed to define the term ''verbal orders'' to mean those physician orders that are delivered verbally (meaning spoken), by the physician, to a nurse or other qualified medical personnel, and recorded in the plan of care.

As discussed in detail in section III.D.4 of this preamble, we proposed modifications to the current personnel qualifications requirements, and proposed to relocate those requirements to § 484.80, ''Home health aide services,'' and § 484.115, ''Personnel qualifications.''

We also proposed to retain the current definitions of ''primary home health agency,'' ''public agency,'' and ''summary report'' without change.

C. Proposed Subpart B, Patient Care

1. Release of Patient Identifiable OASIS Information (Proposed § 484.40)

At § 484.40, we proposed to recodify the current requirements of § 484.11, which require an HHA and its agents to ensure the confidentiality of all patient-identifiable information in the clinical record, including the OASIS data.

2. Reporting OASIS Information (Proposed § 484.45)

In this CoP, we proposed to include most of the current requirements of § 484.20, which relate to the electronic reporting of the OASIS data. We proposed to remove the requirement that an HHA transmit data using electronic communications software that provides a direct telephone connection from the HHA to the state agency or CMS OASIS contractor. In its place, we proposed to add a requirement that the OASIS data be transmitted in accordance with current CMS transmission policy, which currently requires HHAs to transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140–2, issued May 25, 2001).

3. Patient Rights (Proposed § 484.50)

At § 484.50, we proposed revised patient rights provisions under six standards: (1) Notice of rights; (2) Exercise of rights; (3) Rights of the patient; (4) Transfer and discharge; (5) Investigation of complaints; and (6) Accessibility. In proposed § 484.50(a), we stated that each patient and patient representative (if the patient has one), would have the right to be informed of his or her rights in a language and manner the individual understands.

More specifically, under § 484.50(a)(1), we proposed that the HHA provide the patient and patient's representative with verbal notice of the patient's rights in the primary or preferred language of the patient or representative, and in a manner that the individual can understand, during the initial evaluation visit, and in advance of care being furnished by the HHA. We also proposed to require that the patient be provided a written copy of the patient rights information. The written information would be required to be provided in alternate formats free of charge for persons with disabilities, when necessary, to ensure effective communication. In addition, written notice would be required to be understandable to persons who had limited English proficiency. Furthermore, HHAs would be required to inform patients of the availability of the services and instruct patients how to access those services.

Proposed § 484.50(a) (2) would require the HHA to provide each patient with specific business contact information for the HHA's administrator so that patients and caregivers could report complaints and specific patient rights violations to the HHA administrator, and could ask questions about the care being provided. We also proposed at § 484.50(a)(3) that the HHA provide a copy of the OASIS privacy notice to all patients from whom the OASIS data are collected at the same time that the general notice of rights is provided to the patient. Finally, at § 484.50(a)(4), we proposed to require that the HHA obtain the patient's or representative's signature confirming that he or she received a copy of the notice of rights and responsibilities.

At § 484.50(b), ''Exercise of rights,'' we proposed that, in the event that a patient was declared incompetent under state law by a court of proper jurisdiction, the rights of that patient could be exercised by the person appointed by the state court. If a state court had not made a declaration, any representative, as chosen by the patient, could exercise the rights of the patient in accordance with the patient's preferences. In situations where a patient has been adjudged to lack legal capacity under state law by a court of proper jurisdiction, the patient would be allowed to exercise his or her rights to the extent allowed by the court order.

Proposed § 484.50(c) set forth the explicit rights of each home health patient. At § 484.50(c) (1), we proposed that the patient would have a right to have his or her property and person treated with respect. At § 484.50(c) (2), we proposed that the patient would have a right to be free from verbal, mental, sexual and physical abuse, including injuries of unknown source, neglect, and misappropriation of property. Under proposed § 484.50(c)(3), the patient would have a right to make complaints to the HHA regarding treatment or care that was (or failed to be) furnished which the patient and/or their family believe was inappropriate. Under proposed § 484.50(c)(4), patients and their representatives would also have the right to participate in, be informed about, and consent to or refuse care. Moreover, each patient would have the right to participate in and be informed about the patient-specific comprehensive assessment, including an assessment of the patient's goals and care preferences. Additionally, each patient would have the right to participate in and be informed about the care that the HHA plans to furnish

based on the needs identified during the comprehensive assessment, establishing and revising that plan, the disciplines that will furnish care, the frequency of visits, identifying expected outcomes of care, and any factors that could impact treatment effectiveness. In accordance with proposed § 484.50(c)(4)(iii), each patient would also have the right to receive a copy of his or her individualized HHA plan of care, including all updated plans of care, as described in proposed § 484.60. HHAs would be required at § 484.50(c)(4)(viii) to inform the patient about any changes in the care to be furnished in advance of those changes being made in the patient's plan of care. In addition to being involved in the care planning process, we proposed to add a requirement at § 484.50(c)(5) that patients have the right to receive all of the services outlined in the plan of care. Additionally, we proposed to retain the current requirements from current § 484.10(d), which concern the patient's right to the confidentiality of his or her clinical records, under proposed § 484.50(c)(6). Proposed § 484.50(c)(7) would retain the requirements of the current standard at § 484.10(e), Patient liability for payment. This patient liability requirement would be related to the home health advance beneficiary notice (ABN) and home health change of care notices; therefore, we proposed to reference the current requirements at § 411.408(d)(2) and § 411.408(f). HHAs would be required to comply with all ABN requirements, including restrictions related to who may receive the ABN on the patient's behalf.

At § 484.50(c)(8), we proposed that a patient would have the right to receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. We proposed to incorporate a cross-reference to the regulations regarding expedited reviews, found at 42 CFR part 405, subpart J.

We proposed to retain the current regulations regarding the home health hotline at proposed § 484.50(c)(9). Patients would be advised that the purpose of the hotline was to receive complaints or questions about local HHAs. Additionally, under § 484.50(c)(10), patients would be advised of the names, addresses, and telephone numbers for relevant federally and state-funded consumer information, consumer protection, and advocacy agencies.

We also proposed at § 484.50(c)(11), that patients have the right to be free from discrimination or reprisal for exercising their rights, whether by voicing grievances to the HHA or to an outside entity. Finally, we proposed at § 484.50(c)(12) that patients have the right to be informed of their right to access auxiliary aids and language services, and to be provided instruction on how to access these services.

We proposed to add a new standard at § 484.50(d), which would mandate that all patients and representatives (if any), have the right to be informed of the HHA's policies governing admission, transfer, and discharge in advance of the HHA providing care. This proposed standard set forth the criteria by which an HHA could discharge or transfer a patient. Under this proposed standard, an HHA could only transfer, discharge, or terminate care for the following reasons: (1) If the physician responsible for the HHA plan of care and HHA agreed that the HHA could no longer meet the patient's needs, based on the patient's acuity; (2) when the patient or payer could no longer pay for the services provided by the HHA; (3) if the physician responsible for the HHA plan of care and HHA agreed that the patient no longer needed HHA services because the patient's health and safety had improved or stabilized sufficiently; (4) when the patient refused HHA services or otherwise elected to be transferred or discharged (including if the patient elected the Medicare hospice benefit); (5) when there was cause; (6) when a patient died; or (7) when the HHA ceased to operate.

In accordance with the requirements of proposed § 484.50(d)(1), if the care needs of a patient exceeded the HHA's ability to provide services, the HHA would be required to ensure that the patient received a safe and appropriate transfer to another care entity better suited to meeting the patient's needs.

We proposed to specify at § 484.50(d)(5) that we would permit discharge for cause if the patient's (or other persons in the patient's home) behavior was so disruptive, abusive, or uncooperative that the delivery of care to the patient or the ability of the HHA to operate effectively and safely was seriously impaired. Before discharging a patient for cause, the HHA would be required to advise the patient, the representative (if any), the physician who was responsible for the home health plan of care, and the patient's primary care practitioner or other health care professional who would be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause was being considered, make efforts to resolve the problem(s) presented by the patient's behavior or by other person(s) in the home (as applicable), or situation (such as a dangerous animal being loose in the home), document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records. Additionally, we proposed that the HHA would be required to provide the patient and representative (if any), with contact information for other agencies or providers who were potentially able to provide care following the discharge.

Given the vulnerability of home health patients and in the interest of patient safety, we proposed a standard at § 484.50(e), ''Investigation of complaints,'' that would require the HHA to investigate complaints made by patients, representatives, caregivers, and families regarding treatment or care that was (or failed to be) furnished, or was furnished inconsistently or inappropriately. In addition, HHAs would be required to investigate allegations of mistreatment, neglect, or verbal, mental, psychosocial, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by anyone furnishing services on behalf of the HHA. Proposed § 484.50(e)(1)(ii) would require the HHA to document both the existence and the resolution of the complaint, while § 484.50(e)(1)(iii) would require the HHA to take immediate action to prevent further potential abuse while the complaint was being investigated.

Proposed § 484.50(e)(2) would require any HHA staff, regardless of whether they are employed directly or obtained under arrangements with another entity, to immediately report to the HHA or other appropriate authorities any incidences of mistreatment, neglect, or abuse, and/or any misappropriation of patient property, which they have noticed during the normal course of providing services to patients.

To address effective communication with patients who are limited English proficiency (LEP) or have disabilities, we proposed a new standard at § 484.50(f), ''Accessibility.'' We proposed that information that is provided to patients would have to be provided to the individual in plain language, and in a manner that is both accessible and timely.

In accordance with the requirements of the Medicare provider agreement, HHAs must not discriminate against Medicare beneficiaries, and if a participating HHA accepts non-Medicare patients at any given level of acuity, it must also accept Medicare beneficiaries at a similar level of acuity

as a condition of participating in the Medicare program. HHAs that provide services to non-Medicare patients while refusing services to Medicare patients in similar situations risk having their provider agreements terminated, in accordance with § 489.53(a)(2).

4. Comprehensive Assessment of Patients (Proposed § 484.55)

We proposed to retain the majority of the substantive requirements of current § 484.55, with significant reorganization. We proposed to retain the requirement that each patient be required to receive a patient-specific comprehensive assessment. We also proposed to retain the requirement that, for Medicare beneficiaries, the HHA would be required to verify the patient's eligibility for the Medicare home health benefit, including the patient's homebound status, at the specified timeframes. Furthermore, we proposed to retain all requirements related to the initial assessment visit at standard (a), as well as the completion of the comprehensive assessment requirements at standard (b).

We proposed to establish a new standard (c), ''Content of the comprehensive assessment,'' that would incorporate much of the content currently set forth in the introductory paragraph of the CoP, the drug regimen review currently set forth in standard (c), and the incorporation of the OASIS data items requirement currently set forth at standard (e). We also proposed new content requirements, such as an assessment of psychosocial and cognitive status, which we believe would provide for a more holistic patient assessment. We believe that these assessment areas are essential in the establishment of a more complete understanding of the patient's condition (both medically and non-medically), strengths and limitations, preferences, and risk factors. Developing a more complete understanding of the patient will enable HHAs and physicians to develop a plan of care that is more comprehensive and more likely to achieve desired outcomes. We proposed to require that the comprehensive assessment must accurately reflect the patient's status, and would assess or identify (as applicable) the following:

- The patient's current health, psychosocial (new), functional (new), and cognitive (new) status;
- The patient's strengths, goals, and care preferences, including the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA (new);
- The patient's continuing need for home care;
- The patient's medical, nursing, rehabilitative, social, and discharge planning needs;
- A review of all medications the patient is currently using;
- The patient's primary caregiver(s), if any, and other available supports (new); and
- The patient's representative (if any) (new).

The assessment would also be required to incorporate items from the information collection set out in the OASIS data set, using the language and groupings of the OASIS items, as specified by the Secretary.

We proposed to retain the majority of the content of the requirements of current § 484.55(d), with one change. We proposed to revise § 484.55(d)(2) to allow for a physician-ordered resumption of care date. Adding the physician ordered resumption of care date as an alternative to the fixed 48 hour time frame for a post-hospital reassessment allows physicians to specify a resumption of care date that is tailored to the particular needs and preferences of each patient.

5. Care Planning, Coordination of Services, and Quality of Care (Proposed § 484.60)

We proposed to create a new condition of participation, ''Care planning, coordination of services, and quality of care'' at § 484.60. This section would specify that the HHA would have to provide the patient a plan of care that would set out the care and services necessary to meet the patient-specific needs identified in the comprehensive assessment, and the outcomes that the HHA anticipates would occur as a result of developing the individualized plan of care and subsequently implementing its elements.

In the CoP, we proposed that patients be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, rehabilitative, and social needs could be met adequately by the agency in the patient's place of residence. Each patient would receive an individualized written plan of care which would specify the care and services necessary to meet the patient's needs, including the patient and caregiver education and training that the HHA will provide, specific to the patient's care needs. The individualized plan of care would be revised or added to at intervals as necessary to continue to meet patient care needs. We also proposed that the plan of care include the patient-specific measurable outcomes which the HHA anticipates would result from its implementation.

Under proposed § 484.60(a)(1), Plan of care, we proposed that all home health services furnished to patients would follow an individualized written plan of care, setting out, among other things, the frequency and duration of therapeutic interventions. The plan would be established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatric medicine acting within the boundaries of all applicable state laws and regulations. Under paragraph (a)(2), the individualized plan of care would be required to include all pertinent diagnoses; the patient's mental, psychosocial, and cognitive status; the types of services, supplies, and equipment required; the frequency and duration of visits to be made; prognosis; rehabilitation potential; functional limitations; activities permitted; nutritional requirements; all medications and treatments; safety measures to protect against injury; patient and caregiver education and training to facilitate timely discharge or referral; patient-specific measurable outcomes/goals; and any additional interventions/orders the HHA or physician chose to include.

Under paragraph (a)(3), if HHA services are initiated following a patient's hospital discharge, we proposed to require that the HHA include an assessment of the patient's level of risk for hospital emergency department visits and hospital re-admission. We proposed that HHAs would be required to include in the patient's individualized plan of care all appropriate interventions that are necessary to address and mitigate identified risk factors that contribute to the HHA's establishment of a particular risk level for a patient.

Proposed § 484.60(b), ''Conformance with physician orders,'' would provide that drugs, services, and treatments be administered only as ordered by the physician who is responsible for the home health plan of care. We proposed to retain the current influenza and pneumococcal vaccination requirement at § 484.60(b)(2). Proposed § 484.60(b)(3) would maintain the requirement that only personnel authorized by applicable state laws and regulations and the HHA's internal policies, may accept verbal orders from physicians. We proposed at § 484.60(b)(4) that a registered nurse (RN) or other qualified practitioner licensed to practice by the state must document a verbal order in writing in the patient's clinical record, with a signature, time, and date. Verbal orders would also have to be recorded in the patient's plan of care. If a

physician faxed orders or otherwise transmitted them through other electronic methods from his or her office, those orders would also be required to be included in the patient's clinical record and plan of care. We would also require that verbal orders be authenticated, dated, and timed by the physician according to the HHA's internal policies and applicable state laws and regulations.

Under § 484.60(c), ''Review and revision of the plan of care,'' we proposed that the individualized plan of care be reviewed and revised by the physician who was responsible for the HHA plan of care and the HHA as frequently as the patient's condition or needs requires, but no less frequently than once every 60 days, beginning with the start of care date. We proposed that the HHA promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that would suggest that measurable outcomes are not being achieved and/or that the HHA should alter the plan. At § 484.60(c)(2), we proposed to require that the HHA revise the plan of care, as necessary, to reflect current information from the patient's updated comprehensive assessment, and to record the patient's progress towards meeting the patient-specific measurable outcomes and goals selected by the HHA and patient, as specified in the plan of care.

Furthermore, we proposed at paragraph (c)(3) that it would be the HHA's responsibility to notify the patient, representative (if any), caregivers, and the physician who is responsible for the HHA plan of care, when the individualized plan of care is updated due to a significant change in the patient's health status. We also proposed that, when the HHA makes updates related to plans for the patient's discharge, the HHA would communicate these changes with the patient and representative, caregivers, the physician who is responsible for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services (if any) to the patient after discharge from the HHA.

In § 484.60(d), ''Coordination of care,'' we proposed in paragraph (d)(1) to require that the HHA must integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness, the coordination of care provided by all disciplines, and communication with the physician. The proposed standard at § 484.60(d)(2) would also require the HHA to coordinate care delivery to meet each patient's needs, and to involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities. Finally, under proposed § 484.60(d)(3), we proposed that the HHA ensure that each patient and caregiver, where applicable, receive ongoing training and education from the HHA regarding the care and services identified in the plan of care that the patient and caregiver are expected to implement. The HHA would be required to ensure that each patient and caregiver receives any training necessary for a timely discharge from the HHA. Each skilled professional would be expected to be responsible for educating the patient and/or caregiver about the care and services as appropriate to the discipline.

At § 484.60(e), ''Discharge or transfer summary,'' we proposed that HHAs be required to compile a discharge or transfer summary for each discharged or transferred patient. The summary would be required to include the following:

- The initial reason for referral to the HHA;
- A brief description of the patient's HHA care;
- A description of the patient's clinical, mental, psychosocial, cognitive, and functional status at the start of care;
- A list of all services provided by the HHA to the patient;
- The start and end dates of HHA care;
- A description of the patient's clinical, mental, psychosocial, cognitive; and functional status at the end of care;
- The patient's most recent drug profile;
- Any recommendations for follow-up care;
- The patient's current individualized plan of care; and
- Any additional documentation that would assist in the continuity of post-discharge or transfer care, or that was requested by the receiving practitioner or facility.

6. Quality Assessment and Performance Improvement (QAPI) (Proposed § 484.65)

As part of our effort to reduce medical errors, and improve the quality of health care in all settings, we propose to replace two current HHA CoPs, § 484.16, ''Group of professional personnel,'' and § 484.52, ''Evaluation of the agency's program,'' with a single, new CoP, at § 484.65, ''Quality Assessment and Performance Improvement'' (QAPI). We have organized this new CoP into the following five standards: (1) Program scope; (2) Program data; (3) Program activities; (4) Performance improvement projects; and (5) Executive responsibilities.

In § 484.65(a), ''Program scope,'' we proposed that this data-driven QAPI program would be capable of showing measurable improvement in indicators for which there was evidence that the improvement led to improved health outcomes (for example, reduced hospitalizations and readmissions), safety, and quality of care for patients. The HHA would also have to measure, analyze, and track quality indicators, including adverse patient events, as well as other indicators of performance so that the agency could adequately assess its processes, services, and operations.

We proposed, at § 484.65(b), ''Program data,'' that an HHA's QAPI program utilize quality indicator data, including measures derived from the OASIS (CMS provided reports), where applicable, and other relevant data, to assess the quality of care provided to patients, and identify and prioritize opportunities for improvement. Quality assessment efforts, including data collection, should focus on high priority safety and health conditions, and other goals identified by an HHA. The tools, collected data, and associated quality measures would be used by the HHA to monitor the effectiveness and safety of its services, as well as the quality of its care. In addition, the HHA would use the quality measures that are calculated based on the data collected to identify opportunities for improvement. We also proposed that the HHA's governing body would be responsible for approving the frequency of, and level of detail to be used in data collection.

At § 484.65(c), ''Program Activities,'' we would require an HHA's QAPI program activities to focus on high risk, high volume, or problem-prone areas of service, and to consider the incidence, prevalence, and severity of problems in those areas. We also proposed that the HHA immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Additionally, the HHA's QAPI activities would have to track incidents and adverse patient events, as well as analyze those events, so that preventive actions and mechanisms could be implemented by the HHA. We also proposed that after steps have been taken to improve an area of concern, the HHA would continue to monitor the area in order to assure that improvements were sustained over time.

Proposed § 484.65(d), ''Performance improvement projects,'' would require that the HHA's performance improvement projects, conducted at least annually, reflect the scope, complexity, and past performance of the HHA's services and operations. An agency would need to focus on those areas of past performance which have proven to be problematic for the HHA over time or areas where there was clear evidence of poor patient outcomes, as well as areas of high-risk and high-volume. Within this standard, we also proposed that the HHA document the QAPI projects undertaken, the reasons for conducting these projects, and the measurable progress achieved.

Finally, under proposed § 484.65(e), ''Executive responsibilities,'' we would require that the HHA's governing body assume responsibility for the agency's QAPI program. This subsection would require that the governing body assume the overall responsibility for ensuring that the QAPI program reflected the complexity of the HHA and its services, involved all services (including those provided under contract or arrangement), focused on indicators related to improved outcomes, and took actions that addressed the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The governing body would be required to define, implement, and maintain a program for quality improvement and patient safety that was ongoing and agency-wide. The governing body would be required not only to ensure that performance improvement efforts were prioritized, but that they were also evaluated for effectiveness. We note that it is the governing body which would be ultimately responsible for establishing the HHA's expectations for patient safety through an agency-wide QAPI program. Therefore, we proposed that the governing body establish clear expectations for patient safety. We also proposed that the governing body would appropriately address any findings of fraud or waste in order to assure that resources are appropriately used for patient care activities and that patients are receiving the right care to meet their needs.

7. Infection Prevention and Control (Proposed § 484.70)

We proposed to establish a new CoP at § 484.70, ''Infection prevention and control,'' organized under the following three standards: (1) Prevention, (2) Control, and (3) Education. We proposed in § 484.70(a) that HHAs follow infection prevention and control best practices, which include the use of standard precautions, to curb the spread of disease. Under proposed standard § 484.70(b), ''Control,'' we would expect the HHA to maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases. Additionally, under this proposal, the program would be expected to be an integral part of the agency's QAPI program. We proposed an education standard within this CoP at § 484.70(c). HHAs would be expected to provide education on ''current best practices'' to staff, patients, and caregivers.

8. Skilled Professional Services (Proposed § 484.75)

This proposed new condition would set forth the requirements for skilled professional services. Instead of specifically identifying tasks, we proposed to broadly describe the expectations of the skilled professionals who participate in the interdisciplinary team approach to home health care delivery. Skilled professionals, within this context, would provide services to HHA patients directly as employees of the HHA or under a contractual agreement. We proposed that skilled professionals actively participate in the coordination of all aspects of care where appropriate. We have organized this proposed condition into three areas: (1) Skilled professional services; (2) Responsibilities of skilled professionals; and (3) Supervision of skilled professional assistants. Skilled professional services, as proposed in § 484.75(a), include physician services, skilled nursing services, physical therapy, speech-language pathology services, occupational therapy, and medical social work services. Provision of services by skilled professionals, as proposed in § 484.75(b), would specify that skilled professional services may only be provided by health care professionals who meet the appropriate criteria spelled out in proposed § 484.115, ''Personnel qualifications,'' and who practice according to the HHA's policies and procedures.

We proposed in § 484.75(b), ''Responsibilities of skilled professionals,'' that skilled professionals who provide services to HHA patients directly, or under arrangement, participate in coordinating all aspects of care, including:

- Assuming responsibility for the ongoing interdisciplinary assessment and development of the individualized plan of care in partnership with the patient, representative (if any), and caregiver(s);
- Providing services that are ordered by the physician as indicated in the plan of care;
- Providing patient, caregiver, and family counseling;
- Providing patient and caregiver education;
- Preparing clinical notes;
- Communicating with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current home health plan of care; and
- Participating in the HHA's quality assessment and performance improvement program and HHA-sponsored in-service training.

In addition to the requirements for licensed professional services described above, we proposed to include a requirement governing the supervision of skilled professional assistants at § 484.75(c). This would require an RN identified by the HHA to supervise the care provided by nurses such as licensed vocational nurses and licensed practical nurses. We also proposed that all rehabilitative therapy assistant services would be provided under the supervision of a physical therapist (PT) or occupational therapist (OT) who meets the appropriate requirements of § 484.115. Furthermore, we believe that it is essential for all medical social services to be provided under the overall supervision of a Master of Social Work (MSW) prepared social worker who meets the requirements of § 484.115.

9. Home Health Aide Services (Proposed § 484.80)

We proposed to organize the home health aide requirements as nine standards under § 484.80: (1) Home health aide qualifications; (2) content and duration of home health aide classroom and supervised practical training; (3) competency evaluation; (4) in-service training; (5) qualifications for instructors conducting classroom and supervised practical training; (6) eligible training and competency evaluation organizations; (7) home health aide assignments and duties; (8) supervision of home health aides; and (9) individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

At proposed § 484.80(a)(1), we would specify the necessary requirements for an individual to be considered a qualified home health aide. A qualified home health aide would be an individual who has successfully completed one of the following: (1) A training and competency evaluation program that meets the requirements

described in § 484.80(b) and § 484.80(c); or (2) a competency evaluation program that meets the requirements described in § 484.80(c); or (3) a nurse aide training and competency evaluation program that is approved by the state as meeting the requirements of § 483.151 through § 483.154 and is currently listed in good standing on the state nurse aide registry; or (4) a state licensure program that meets the requirements described in § 484.80(b) and § 484.80(c).

Under proposed § 484.80(a)(2), we would specify when a home health aide is deemed to have completed a program (as specified in proposed § 484.80(a)(1)). This determination would be based on whether, since the most recent completion of a program, there was a period of 24 months or greater since completion of the last home health aide training during which none of the services furnished by the aide were for compensation. We would also stipulate that, if there had been a 24-month or greater lapse in furnishing services, the aide would need to complete another program before the home health aide can provide services, as specified in § 484.80(a)(1).

We proposed, at § 484.80(b), to set forth the requirements for training content and its duration, training methods (classroom and practical), and training documentation. At § 484.80(b)(4), we proposed to require the HHA to maintain documentation that the requirements for content and duration of home health aide classroom and supervised practical training have been met.

We proposed to address various requirements for the competency evaluation of home health aides in § 484.80(c). We proposed to retain the requirement currently found at § 484.36(b)(1), which states that an individual may furnish home health aide services on behalf of an HHA only after the successful completion of a competency evaluation program as described in that section. In accordance with proposed § 484.80(c)(2), the competency evaluation described in this paragraph may be offered by any organization, except an organization that falls under one of the exceptions specified in the regulation as described in proposed paragraph (f) of this section. Section 484.80(c)(3) would maintain the current requirement that an RN must perform the competency evaluation. In addition to the RN, we proposed that the competency evaluation be done in consultation with other skilled professionals, as appropriate. We proposed that, if a home health aide is going to perform a task for which he or she was rated ''unsatisfactory,'' it must be performed under the supervision of a licensed nurse (either a licensed practical nurse or an RN) until he or she achieves an evaluation of ''satisfactory.''

At § 484.80(d), we would retain 12 as the minimum number of hours of in-service training required for a 12-month period. The training could occur while an aide was furnishing care to a patient. Proposed § 484.80(b) would set forth the elements that must comprise home health aide classroom and supervised practical training, thus suggesting that those elements of training should form a basis for ongoing in-service training. We proposed that aide in-service training could be offered by any organization, and that the training would be required to be supervised by an RN.

We proposed to relocate the requirement that the RN that conducts training possess a minimum of 2 years of nursing experience, of which at least 1 year is in home health care, to standard (e), ''Qualifications for instructors conducting classroom and supervised practical training.'' We continue to believe that RNs with nursing experience in the home health field should be the principal instructors in the basic training of home health aides. While other individuals could provide instruction to home health aides, classroom and practical training would be required to be under the general supervision of an RN who possessed a minimum of 2 years nursing experience, at least 1 year of which would have to be in home health care.

We proposed to retain the current requirements regarding organizations that offer aide training at § 484.80(f), ''Eligible training and competency evaluation organizations.'' We proposed to retain the current requirement that home health aide training may be provided by any organization, except an organization that falls under one of the exceptions specified in the regulation. These exceptions include, but are not limited to, agencies that have been found out of compliance with the home health aide requirements any time in the last 2 years, agencies that permitted an unqualified individual to function as a home health aide, and agencies that have been found to have compliance deficiencies that endangered patient health and safety. The full list of exceptions are included in the regulatory text.

We proposed, at § 484.80(g), ''Home health aide assignments and duties,'' to set forth aide responsibilities and duties. Proposed § 484.80(g)(1) would provide that the home health aide would be assigned to a specific patient by the RN or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist). Proposed § 484.80(g)(2) would require that the home health aide provide services that are ordered by the physician in the plan of care, that the home health aide is permitted to perform under state law, and that are consistent with the home health aide training. In § 484.80(g)(3), we proposed to retain the inclusive listing of duties for home health aides currently under § 484.36(c)(2). At § 484.80(g)(4) we proposed a requirement that home health aides be members of the interdisciplinary team, must report changes in the patient's condition to an RN or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

On-going home health aide supervision, as described in proposed § 484.80(h), ''Supervision of home health aides,'' is a necessary component of quality care for HHAs, and ensures that services provided by home health aides are in accordance with the agency's policies and procedures and in accordance with state and federal law. In this proposed standard, we would differentiate the aide supervision requirements based on the skill level of the care required by the patient. In proposed § 484.80(h)(1), we proposed that if a patient is receiving skilled care, the home health aide supervisor (RN or therapist) must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide would not have to be present during this visit. If a potential deficiency in home health aide service was noted by the home health aide supervisor, then the supervisor would have to make an on-site visit to the location where the patient was receiving care in order to observe and assess the home health aide while he or she is performing care. In addition to the regularly scheduled 14-day supervision visits and the as-needed observation visits, HHAs would be required to make an annual on-site visit to a patient's home to observe and assess each home health aide while he or she is performing patient care activities. The HHA would be required to observe each home health aide with at least one patient.

In proposed § 484.80(h)(2), we would require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each home

health aide while he or she is performing care.

At proposed § 484.80(h)(3), we would require that if a deficiency in home health aide services was verified by the home health aide supervisor during an on-site visit, then the agency would have to conduct, and the home health aide would have to complete, a competency evaluation in accordance with paragraph (c) of this section.

We also proposed to add a new paragraph at § 484.80(h)(4) to ensure that home health aide supervision visits focus on the aide's ability to demonstrate initial and continued satisfactory performance in meeting essential criteria. Supervision visits would be required to assess the home health aide's success in following the patient's plan of care; completing tasks assigned to the home health aide; communicating with the patient, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights.

Proposed § 484.80(h)(5) would retain, with minor revisions, the current requirements found under § 484.36(d)(4) as they relate to the HHA's responsibilities for home health aides who are furnishing services under arrangement (that is, the aides are not employees of the HHA). The HHA would be required to ensure the quality of home health aide services, supervise aides as proposed in this section, and ensure that aides have met the training and competency evaluation requirements of this proposed part.

At proposed § 484.80(i), ''Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit,'' we proposed to retain the requirements at current § 484.36(e), with some minor clarifying revisions. Under this provision, a Medicare-certified HHA that provides personal care aide services to Medicaid patients under a State Medicaid personal care benefit would be required to determine and ensure the competency of individuals for those Medicaid-approved services performed. In addition, the reference to § 440.170 in the current regulation at § 484.36(e)(2) is incorrect; it should read § 440.167. Therefore, we proposed to make the necessary correction.

D. Proposed Subpart C, Organizational Environment

1. Compliance With Federal, State, and Local Laws and Regulations Related to Health and Safety of Patients (Proposed § 484.100)

We proposed that HHAs must be in compliance with all Federal, State and local laws related to the health and safety of patients, and that HHA services must be furnished in accordance with accepted professional standards and principles. We also proposed specific disclosure of ownership requirements. At § 484.100(a), we proposed to continue to require HHAs to comply with the requirements of part 420, subpart C by disclosing the names and addresses of all persons with an ownership or controlling interest, the name and address of each officer, director, agent, or managing employee, and the name and address of the entity responsible for the management of the HHA along with the names and addresses of the CEO and chairperson of the board of that entity.

Under the provisions of proposed § 484.100(b), an HHA, its branches, and its staff would be licensed, certified, or registered, as applicable, by the state licensing authority if the state had established licensure requirements. If a state requires an HHA to have a license, then we would require that the provider be in compliance with that state's law or regulation.

Finally, we proposed at § 484.100(c), ''Laboratory services,'' to require that HHAs engaged in certain types of lab testing, with an appliance that has been approved for that purpose by the Food and Drug Administration, conduct testing in compliance with the requirements of 42 CFR 493 (Laboratory Requirements). This section would also prohibit HHAs from substituting their own self-administered testing equipment in lieu of a patient's self-administered testing equipment when assisting a patient in administering the test. In addition, this section would provide that if the HHA chose to refer specimens for laboratory testing, the referral laboratory would have to be certified in accordance with the applicable requirements of part 493. The laboratory services standard is a federal requirement in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

2. Organization and Administration of Services (Proposed § 484.105)

We proposed at § 484.105(a), ''Governing body,'' to require the governing body to be able to assess the HHA's financial needs and to assume responsibility for effectively managing its financial resources, as well as assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, the review of the budget and operational plans, and the agency's quality assessment and performance improvement program.

Proposed § 484.105(b), ''Administrator,'' described the role of the administrator and provisions for when the administrator is not available. We proposed that the administrator be appointed by the governing body, be responsible for all day to day operations of the HHA, and be responsible for ensuring that a skilled professional as described in § 484.75 is available during all operating hours. We proposed that, any time when the administrator is not available, a pre-designated person, who is authorized in writing by the administrator and governing body, would assume the same responsibilities and obligations as the administrator, including the responsibility to be available during all operating hours.

In addition to the overall management of the HHA by the governing body and the administrator, we proposed a new clinical manager role at § 484.105(c). The clinical manager would be a qualified licensed physician or registered nurse, identified by the HHA, who is responsible for the oversight of all personnel and all patient care services provided by the HHA, whether directly or under arrangement, to meet patient care needs. The supervision of HHA personnel would include assigning personnel, developing personnel qualifications, and developing personnel policies.

In § 484.105(d), we proposed a new standard, ''Parent-branch relationship,'' to focus on the ability of the parent HHA to demonstrate that it can monitor all services provided in its entire service area, furnished by any branch offices, to ensure compliance with the CoPs. We would require that HHAs report their branch locations to the state survey agency at the time of an HHA's initial certification request, at each survey, and at the time any proposed additions or deletions were made.

We proposed at § 484.105(e), ''Services under arrangement,'' to govern all services provided under arrangement with another agency or organization. The agency providing services under arrangement may not have been denied Medicare enrollment; been terminated from Medicare, another federal health care program, or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been

debarred from participating in any government program. We proposed to require that the primary HHA have a written agreement with another agency, with an organization, or with an individual, that it has contracted with to provide services to its patients, which stipulates that the primary HHA would maintain overall responsibility for all HHA care provided to a patient in accordance with the patient's plan of care, whether the care is provided directly or under arrangement. If the primary HHA chooses to furnish some services under arrangement, then it retains management, service oversight, and financial responsibility for all services that are provided to the patient by its contracted entities. All services provided by contracted entities would be authorized by the primary HHA, and furnished in a safe and effective manner by qualified personnel. In addition to this revision, we proposed to correct a typographical error in the cross-reference citation for the United States Code.

As stated in proposed § 484.105(f)(1), skilled nursing and one of the therapeutic services must be made available on a visiting basis in the patient's home. At least one service would be required to be provided directly by the HHA.

We proposed a requirement for compliance with accepted professional standards and principles at § 484.105(f)(2). We would require that HHAs furnish all services in accordance with accepted professional standards of practice. We also proposed to require that all HHA services be provided in accordance with current clinical practice guidelines.

We proposed to relocate the requirements for outpatient physical therapy or speech pathology services to § 484.105(g), without change.

Finally, we proposed to retain the ''Institutional planning'' standard as required for HHAs under section 1861(z) of the Act at § 484.105(h). We did not propose any revisions to this content.

3. Clinical Records (Proposed § 484.110)

We proposed to retain, with some additional clarification, many of the long-standing clinical record requirements. The primary requirement under the proposed clinical records CoP would be that a clinical record containing pertinent past and current relevant information would be maintained for every patient who was accepted by the HHA to receive home health services. We proposed to add the requirement that the information contained in the clinical record would need to be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care and appropriate HHA staff. The clinical record would be required to exhibit consistency between the diagnosed condition, the plan of care, and the actual care furnished to the patient.

Proposed § 484.110(a), ''Contents of clinical record,'' would retain the requirement that the record include clinical notes, plans of care, physician orders, and a discharge summary. We proposed to require that the clinical record include: (1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical visit notes, and individualized plans of care; (2) all interventions, including medication administration, treatments, services, and responses to those interventions, which would be dated and timed in accordance with the requirements of proposed § 484.110(b); (3) goals in the patient's plan of care and the progress toward achieving the goals; (4) contact information for the patient and representative (if any); (5) contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and (6) a discharge or transfer summary note that would be sent to the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA within 7 calendar days, or, if the patient is discharged to a facility for further care, to the receiving facility within 2 calendar days of the patient's discharge or transfer.

We proposed to add a new standard at § 484.110(b) to require authentication of clinical records. We proposed that all entries be legible, clear, complete, and appropriately authenticated, dated, and timed.

At § 484.110(c), we proposed to require that clinical records be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time. We would require, in § 484.110(c)(2), that HHA policies provide for retention of records even if the HHA discontinues operations. We also proposed that the HHA would be required to notify the state agency as to where the agency's clinical records would be maintained.

We also proposed at § 484.110(d) to require that clinical records, their contents, and the information contained therein, be safeguarded against loss or unauthorized use.

We proposed to add a new standard at § 484.110(e), ''Retrieval of clinical records.'' We proposed that a patient's clinical records (whether hard copy or electronic) be made readily available to a patient or appropriately authorized individuals or entities upon request. The provision of clinical records must be in compliance with the rules regarding protected health information set out at 45 CFR, parts 160 and 164.

Finally, in the preamble material explaining § 484.110, we provided information regarding the HHS Policy Priority to Accelerate Interoperable Health Information Exchange, including Use of Certified Electronic Health Record Technology.

4. Personnel Qualifications (Proposed § 484.115)

We proposed a new ''Personnel qualifications'' CoP, with conforming amendments to the regulations for the other provider types that cross-reference the HHA personnel requirements. We proposed to retain the current personnel qualifications for the following professions: Audiologist, home health aide, licensed practical nurse, occupational therapist, occupational therapy assistant, physical therapist, physical therapist assistant, physician, registered nurse, social work assistant, and social worker. We also proposed to replace the term ''practical (vocational) nurse,'' currently found in § 484.4, with the more widely used and accepted term, ''licensed practical nurse.''

We also proposed to revise the current personnel qualifications for HHA administrators. Specifically, we proposed that an HHA administrator would be required to be a licensed physician, or hold an undergraduate degree, or be a registered nurse. We also proposed that an administrator would have at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Finally, we proposed at § 484.115(m) to revise the personnel qualifications for speech-language pathologists (SLP) in order to more closely align the regulatory requirements with those set forth in section 1861(ll)(4)(A) of the Act. We proposed that a qualified SLP is an individual who has a master's or doctoral degree in speech-language pathology, and who is licensed as a speech-language pathologist by the state in which he or she furnishes these services. Should a state choose to not offer licensure at some point in the future, we proposed a second, more specific, option for qualification. In that

circumstance, we would require that a SLP has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience); performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and successfully completed a national examination in speech-language pathology approved by the Secretary.

III. Home Health Crosswalk (Cross Reference of Former to New Requirements)

The table below shows the relationship between the former sections to the new regulations.

Current CoPs	*Revised CoPs*
§ 484.1, Basis and scope	Revised at § 484.1
§ 484.2, Definitions	Revised at § 484.2
§ 484.4, Personnel qualifications	Revised at § 484.115
Home health aide qualifications	Revised at § 484.80
§ 484.10, Patient rights	§ 484.50, Patient rights
§ 484.10(a)	Revised at § 484.50(a)
§ 484.10(b)	Revised at §§ 484.50(b), (c), and (e)
§ 484.10(c)	Revised at § 484.50 (c)
§ 484.10(d)	Revised at § 484.50(c)
§ 484.10(e)	Revised at § 484.50(c)
§ 484.10(f)	Revised at § 484.50(c)
	New standard at § 484.50(d), Transfer and discharge.
	New standard at § 484.50(e), Investigation of complaints.
§ 484.11, Release of patient identifiable OASIS information	**§ 484.40, Release of patient identifiable OASIS information.**
§ 484.12, Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.	**§ 484.100, Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.**
§ 484.12(a)	Revised at § 484.100 and § 484.100(b)
§ 484.12(b)	Redesignated at § 484.100(a).
§ 484.12(c)	Revised at § 484.60, § 484.70, and § 484.105(f)
§ 484.14, Organization, services, and administration	**§ 484.105, Organization and administration of services.**
§ 484.14(a)	Revised at § 484.105(f).
§ 484.14(b)	Revised at § 484.105(a).
§ 484.14(c)	Revised at § 484.105(b).
§ 484.14(d)	Revised at § 484.105(b), and § 484.105(c)
§ 484.14(e)	Revised at § 484.75(b) and § 484.115.
§ 484.14(f)	Revised at § 484.105(e).
§ 484.14(g)	Revised at § 484.60(d) and § 484.105(c).
§ 484.14(h)	Revised at § 484.105(e).
§ 484.14(i)	Revised at § 484.105(h).
§ 484.14(j)	Revised at § 484.100(c).
§ 484.16, Group of professional personnel	**Deleted, see § 484.65, Quality assessment and performance improvement (QAPI).**
§ 484.18, Acceptance of patients, plan of care, and medical supervision.	**§ 484.60, Care planning, coordination of services, and quality of care.**
§ 484.18(a)	Revised at § 484.60(a).
§ 484.18(b)	Revised at § 484.60(c).
§ 484.18(c)	Revised at § 484.60(b).
	New standard at § 484.60(e), Written information to the patient.
§ 484.20, Reporting OASIS information	**§ 484.45, Reporting OASIS information.**
§ 484.30, Skilled nursing services	**§ 484.75, Skilled professional services.**
§ 484.32, Therapy services	**§ 484.75, Skilled professional services.**
§ 484.34, Medical social services	**§ 484.75, Skilled professional services.**
§ 484.36, Home health aide services	**§ 484.80, Home health aide services.**
§ 484.36(a)(1)	Revised at § 484.80(b).
§ 484.36(a)(2)(i)	Revised at § 484.80(f).
§ 484.36(a)(2)(ii)	Revised at § 484.80(e).
§ 484.36(a)(3)	Revised at § 484.80(b).
§ 484.36(b)(1)	Revised at § 484.80(c).
§ 484.36(b)(2)(i)	Revised at § 484.80(c).
§ 484.36(b)(2)(ii)	Revised at § 484.80(h).
§ 484.36(b)(2)(iii)	Revised at § 484.80(d).
§ 484.36(b)(3)(i)	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(ii)	Revised at § 484.80(c) and (d).
§ 484.36(b)(3)(iii)	Revised at § 484.80(c).
§ 484.36(b)(4)	Revised at § 484.80(c).
§ 484.36(b)(5)	Redesignated at § 484.80(c).
§ 484.36(b)(6)	Deleted.
§ 484.36(c)	Revised at § 484.80(g).
§ 484.36(d)	Revised at § 484.80(h).
§ 484.36(e)	Revised at § 484.80(i).
§ 484.38, Qualifying to furnish outpatient physical therapy or speech pathology services.	Revised at § 484.105(g).
§ 484.48, Clinical records	**§ 484.110, Clinical records.**
§ 484.48(a)	Revised at § 484.110(c).

Current CoPs	*Revised CoPs*
§ 484.48(b)	Revised at § 484.110(d). New standard at § 484.110(a), Contents of clinical record. New standard at § 484.110(b), Authentication. New standard at § 484.110(e), Retrieval of clinical records.
§ 484.52, Evaluation of the agency's program	**Deleted, see § 484.65, Quality assessment and performance improvement and § 484.70, Infection prevention and control.**
§ 484.55, Comprehensive assessment of patients	**§ 484.55, Comprehensive assessment of patients.**

IV. Analysis of and Responses to Public Comments

We received 199 letters of public comment from HHA industry associations, patient advocacy organizations, HHAs, and individuals. A summary of the major issues and our responses follow.

Effective Date

Comment: The vast majority of commenters made suggestions related to the effective date of the final rule. Commenters strongly expressed a need for a significant period of time to prepare for implementation of the new rules, noting that HHAs would need to adjust resource allocation, staffing, and potentially even infrastructure. Recommended implementation time frames ranged from 6 months to 5 years. The most frequent suggestion was to implement the final rule 1 year following its publication.

Response: We agree that it is appropriate to allow additional time to implement the final rule in order to allow HHAs adequate time to prepare for these changes. We believe that requiring HHAs to comply with the requirements of this rule on July 13, 2017 is sufficient to allow for appropriate HHA preparations to implement these changes. Therefore, we are finalizing an effective date of July 13, 2017.

Definitions

Comment: We received a few comments in support of the branch and parent office definition. One commenter strongly supported the change and emphasized with the automation age and web-based storage and access, the parent office can easily identify and investigate exceptions to standards of care for all patients and all employees, focusing administrative time on investigation, action and improvement. One commenter suggested CMS use the term of ''Service Location'' in lieu of ''Branch Office.'' Several commenters asked that CMS clarify some concerns regarding the branch office definition. The commenters asked that CMS provide guidance on what constitutes an adequate level of supervision on a ''daily basis.'' They specifically asked if there is a certain amount or type of communication between the branch and parent offices. In addition, one commenter asked whether a survey citation for a violation in a branch office would apply to the entire HHA.

Response: We appreciate the public comments regarding this issue. We will continue to use the term ''branch location'' because it has been in use for more than a decade, and both HHAs and surveyors are accustomed to the term. To change the terminology without a pressing reason to do so would risk unnecessary and unwanted confusion among HHAs and surveyors. The concept of an adequate level of supervision on a daily basis is longstanding, and refers to the parent HHA's ability to demonstrate administrative control over each branch. We did not propose, nor are we finalizing, any specific requirements for communication because our primary concern relates to the evidence of control rather than the process for achieving it. As stated in the proposed rule, a violation that occurred in care and services being provided by a branch location would be considered a violation by the HHA as a whole. Therefore, it is essential for the parent to exercise adequate control, supervision, and guidance for all branches under its leadership.

Comment: We received several comments supporting the inclusion of the proposed definition of quality indicator. One commenter stated it is a much needed addition. Another commenter stated the addition of quality indicator as a definition would allow an HHA to take into account its patient population and unique characteristics while meeting the needs of the patients.

Response: We appreciate support from the public regarding this definition, and are finalizing it without change.

Comment: Several commenters submitted comments regarding the proposed definition of the term ''representative.'' Commenters supported our goal of creating a patient-centered definition that acknowledges the importance of patient choice, patient involvement in his or her care, and the role of family, friends, and caregivers. A commenter stated that this definition should facilitate more timely communication and cooperation between the HHA, patient, and representatives and family members. However, a few commenters expressed concern with the potential for confusion between legally designated representatives, such as a legal guardian, and patient-designated representatives. One commenter stated that HHAs may face questions of whom to listen to in situations where a patient has designated a representative who may not have legal status to make health care decisions. Another commenter stated that state laws regarding the rights and responsibilities of those with health care power of attorney can sometimes prevent an HHA from responding to communications and requests from a caregiver or loved one. The commenter suggested that the definition of ''representative'' should clearly acknowledge that legal limitations may exist that limit the HHA's ability to be responsive to communications and requests from patient-identified representatives at any given point in time. Recognition of this fact in the definition will assist agencies in managing those complex and conflicted situations that arise in the delivery of home health services. Similarly, another commenter suggested that the term ''representative'' be used only where the requirements include decision-making authority, while a different term, such as ''caregiver'' be used when the requirement is in relation to those individuals that provide support to the patient.

Response: We appreciate the broad-based support for this patient-centered definition of the term ''representative.'' We acknowledge that patients may have several different representatives, each serving a different support and/or decision making role in the patient's life. Although conflicts between representatives who have legal authority and those who do not do have legal authority exist, we believe that these situations are relatively uncommon. The resolution of such conflicts would be dependent upon the exact scope of the legal representation. For example, an

individual may serve as a patient's representative solely for financial decision making, meaning that the individual would not have health care decision making authority, and would therefore be in no more significant of a position than any other individual chosen by the patient to serve as a patient-selected representative. If an individual was the legally designated or appointed health care decision maker, the HHA would be expected to act in accordance with the decisions made by that individual while still giving preference to patient choices within the boundaries of that legal representation relationship. As stated in the proposed rule (79 FR 61168), if an HHA has reason to believe that the representative is not acting in accordance with what the patient would want, is making decisions that could cause harm to the patient, or otherwise cannot perform the required functions of a representative, we would expect the HHA to make referrals and/or reports to the appropriate agencies and authorities to assure the health and safety of the patient. We do not believe that it would be appropriate to revise the definition of the term ''representative'' in an attempt to factor in the wide variety of legal relationships that may or may not exist; as such an attempt would inevitably fail to account for every possibility. We do agree that it is necessary to distinguish between those representatives that are chosen by a patient, but who may not have legal standing, and those representatives who are acting on legal authority to make health care decisions for a patient. While a commenter suggested that the term ''caregiver'' would be appropriate for those representatives that are chosen by a patient, but who do not have legally established decision making authority, we believe that the phrase ''patient-selected representative'' is a more appropriate way to express this concept. Likewise, when referring to those representatives who are acting on legal authority to make health care decisions for a patient, we will use the term ''legal representative.'' We believe that using the modifiers ''patient-identified'' and ''legal'' when referring to the types of ''representatives'' that a patient may have will help clarify the expectations for HHAs.

Comment: A commenter suggested that, if a representative is not following what the patient requests or is causing harm to the patient in any way, the HHA staff should report such disagreements or harm to HHA management so that HHA management can take appropriate steps to ensure the safety of the patient, including reporting harm to outside entities.

Response: We agree with this statement. As we stated in the proposed rule, ''If an HHA has reason to believe that the representative is not acting in accordance with what the patient would want, is making decisions that could cause harm to the patient, or otherwise cannot perform the required functions of a representative, we would expect the HHA to make referrals and/or reports to the appropriate agencies and authorities to assure the health and safety of the patient.''

Comment: We received a few comments that directly asked for CMS to revise or clarify the requirements for verbal orders. The commenters stated that other licensed practitioners, such as physician's assistants and nurse practitioners, should be permitted to give verbal orders for treatment. Another commenter requested additional clarification of the word ''spoken.''

Response: Section 1861(m) of the Act requires the HHA plan of care to be under the direction of a physician. We do not have statutory authority to allow other licensed practitioners to give verbal orders for treatment, as such an allowance would mean that the plan of care would no longer be under a plan established by a physician because pieces of that plan would be established by non-physicians. We intended a plain language meaning of the term ''spoken'' as meaning a communication that is said aloud or communicated by sign language.

Comment: One commenter stated that he or she disagrees with what appears to be another sub-regulatory process for the definitions of ''in advance,'' ''quality indicator'' and ''supervised practical training.''

Response: The proposed rule included definitions for these terms within the regulation. Thus, we did not propose a ''sub-regulatory'' process for these definitions.

Comment: One commenter asked if CMS meant to remove the definition of ''nonprofit agency'' in the proposed rule.

Response: Removing the definition of the term ''nonprofit agency'' was intentional. This term is not used within the regulatory text; therefore it is not necessary to define a term that no longer exists.

Comment: One commenter stated they did not support the ''subregulatory process'' and deletion of the terms ''bylaws'' and ''supervision'' in the proposed rule because they feel the two definitions are important in the delivery of care and organizational structure.

Response: We proposed to delete a definition of the term ''bylaws'' because the term is not included in the regulatory text. It is not necessary to define a term that is not used. We proposed to delete the term ''supervision'' because a single definition of the term cannot adequately encompass the variety of ways in which the term is used in this rule. To set forth a single definition of the term would create more confusion rather than resolve it.

Comment: Several commenters asked CMS to amend § 484.14(a) to define ''agency employee'' by referencing common law definition of employee, or issue other guidance clarifying that CMS will interpret ''agency employee'' in accordance with the common law definition of employee. This guidance is utilized for payroll and accounting purposes for issuance of W–2 forms for the HHA. One commenter asked that CMS define the term ''professional employment organization.''

Response: The regulation does not include the term ''agency employee;'' therefore we are not defining it. Where the term ''employee'' is used, CMS generally considers an employee someone for whom the facility issues a W–2. The regulation does not include the term ''professional employment organization''; therefore it is unnecessary to set forth a definition for this term.

Comment: A commenter asked that CMS include the definition of ''caregiver'' in the final rule. They asked for CMS to clarify what the term ''caregiver'' is meant to encompass and how the term differs from ''family.'' They suggest CMS use the term ''family caregivers,'' which refers to any relative, partner, friend or neighbor of the patient who has a significant relationship with, and who provides a broad range of assistance to, the patient.

Response: The term ''caregiver'' refers to any individual who renders uncompensated care to a patient, whereas the term ''family'' refers to legal and/or blood relationships. We do not believe that it is necessary to define the term because it is not an HHA-specific term of art, nor is it being used to have a special meaning in this rule. Furthermore, we believe that adding a definition would run the risk of inadventently excluding a type of caregiver, which would be detrimental to patients, caregivers, and HHAs alike. Many times ''caregivers'' are ''family'' members, but this is not a requirement. For example, a patient's child may live out of state and be considered a ''family'' member, but would not render care to the patient as distance would

preclude such an arrangement. Therefore, the daughter would be a ''family'' member, but not a ''caregiver.'' We do not believe that using the term ''family caregivers'' would bring greater clarity to our meaning, as such a term would inappropriately imply that only family members can be caregivers. Rather than being inclusive of neighbors, friends, church members, etc., the term ''family caregivers'' would imply that these individuals are not included in the broad category of ''caregivers.''

Release of Patient Identifiable Outcome and Assessment Information Set (OASIS) Information and Reporting OASIS Information

Comment: We received many supportive comments regarding the proposed OASIS data reporting requirements. Several of the commenters believe the changes are more consistent with electronic reporting technology and software that is currently being utilized for data transmission. One commenter stated they believe the proposed OASIS changes combine most of the current requirements and the language reflects current technological terms.

Response: We appreciate the support of the commenters, and are finalizing these sections as proposed, with one change. We originally proposed to change the transmission requirements for test OASIS data in a manner that would bring the regulation in line with current transmission guidelines that existed at the time when the proposed rule was published. Specifically, at § 484.45 we proposed to require that an HHA must, ''Successfully transmit test data to the state agency or CMS OASIS contractor.'' On January 1, 2015 CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the Quality Improvement and Evaluation System, Assessment Submission and Processing, (QIES ASAP) System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements.

Comment: One commenter encouraged CMS to address the potential implications and to coordinate its policies concerning data collection with the requirements of the IMPACT Act. They specifically mentioned the call for standardized post-acute care assessment data for quality, payment, discharge planning and other purposes.

Response: We agree that data collection should be coordinated, and have undertaken numerous efforts to align data elements across data sets, where appropriate. On November 5, 2015, we finalized the CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements rule (80 FR 68623) that discusses implementation of the requirements of the IMPACT Act for HHAs. We will be taking steps to implement the IMPACT act over the next several years, in accordance with its statutory deadlines.

Comment: Several commenters cautioned CMS on over-reliance on OASIS to assess home health agency performance and for CMS to address shortcomings with the OASIS data collection tool. They recommended that CMS advise home health agencies to utilize available resources that provide guidance in managing complex health conditions.

Response: While we appreciate these suggestions related to the OASIS, the content of the OASIS and its use by CMS to assess the quality of care provided by HHAs are not within the scope of this rule. HHAs are encouraged to use all appropriate available resources to manage patient care, such as those available on the CMS OASIS Web site (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/index.html?redirect=/OASIS/01_Overview.asp*).

Patient Rights

Comment: Many commenters supported the proposed patient rights requirements, highlighting the patient-centered focus of the proposed requirements, and stating that such requirements will help achieve better health and better health outcomes. Conversely, a few commenters questioned the need for an expanded set of patient rights and stated that the new requirements would require too many forms. Others stated that the proposed requirements were repetitive.

Response: We appreciate the support for this requirement, and agree that it is a useful part of the overall goal to achieve better outcomes for patients. We do not agree that the new requirement will result in a greater number of forms per patient, as these changes can be incorporated into the current patient rights process that HHAs are already required to have. We also do not agree that the requirements are repetitive in that each standard addresses a distinct aspect of patient rights.

Comment: A few commenters suggested that CMS take an active role in assisting HHAs in complying with the patient rights requirements by requiring states to develop ombudsman services for home health care patients to help patients resolve complaints and assist patients who wish to appeal an HHA's decision to transfer or discharge them. Commenters also suggested that CMS should create a consumer Web site to provide information about patient rights in layperson's terms, and that this Web site should be available in multiple languages.

Response: We appreciate these suggestions; however, they are beyond the scope of this regulation. Therefore, we are precluded from acting upon them in this rule. We will retain this suggestion for future consideration.

Comment: A few commenters suggested that CMS develop standardized patient rights materials, translated into the languages most commonly used by Medicare beneficiaries. Commenters also suggested that CMS should provide the OASIS privacy notice in languages other than English and Spanish, and that the notice should be written in a way that is understandable to persons who have limited English proficiency.

Response: The content and format of the OASIS privacy notice are not within the scope of this rule; however we will retain this suggestion for future consideration. We do not agree that requiring a specific patient rights form would benefit HHAs or HHA patients, as the use of a specific form would reduce HHA flexibility to include additional HHA-specific information that may be relevant. In addition, mandating a specific form may interfere with or duplicate the patient rights information requirements established by states and accrediting organizations. Therefore, this rule does not require the use of a specific patient rights form. Rather, HHAs may use a means of their choosing that conveys the required information. We remind HHAs that where several regulatory bodies have established standards governing the same subject matter, we expect HHAs to adhere to the most stringent requirement. Absent a single mandated notice of patient rights, it is not possible for CMS to provide translations.

Comment: A commenter requested clarification regarding the provision of the notice of patient rights. The commenter asked whether the HHA would be required to deliver notices to (1) both the patient and the patient's representative, or (2) either the patient or the patient's representative.

Response: We proposed, and are finalizing a requirement that the notice of patient rights must be provided to both the patient and his or her representative. This is particularly

necessary in situations where the representative legally possesses health care decision making authority. In situations where the representative is patient-selected and does not possess legal health care decision making authority, a patient may choose to decline the provision of the notice of rights to the patient-selected representative because the definition of the term ''representative'' explicitly states that the patient determines the role of the representative, to the extent possible. The patient may choose to involve or not involve the patient-selected representative regarding every interaction with the HHA. We would expect an HHA to document in the patient's record that a patient declined to have a copy of the notice of rights provided to the representative. We believe that explicitly allowing patients to choose whether or not the information is provided to the patient-selected representative will give patients greater control over their care.

Comment: A few commenters referenced existing statutes and regulations that relate to the proposed requirements. One commenter stated that it would be helpful if CMS expressly stated that these requirements are identical to the requirements under Title VI of the Civil Rights Act to ensure that there is no discrepancy related to the standard that will be applied. Another commenter referenced the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS standards, *https://www.thinkculturalhealth.hhs.gov/content/clas.asp*), and stated that, under these standards, an agency may identify the dominant languages in its patient population and prepare written materials in the most frequently spoken languages. Individuals who speak less commonly encountered languages receive a description of the contents of the patient rights notice from an interpreter. The commenter asked whether adherence to the National CLAS standards will meet the intent of the proposed regulation. The commenter also suggested that we should revise the regulation requirements at § 484.50(a)(1)(ii) to specifically allow interpreters to be used to help individuals who speak a language not commonly found in the agency's service area to understand the notice of patient rights. Yet another commenter referenced the Office for Civil Rights (OCR) Guidance at *http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/hhslepguidancepdf.pdf,* which states, ''. . . the starting point is an individualized assessment that balances the following four factors: (1) The number or proportion of limited English proficiency (LEP) persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs.'' The commenter suggested that this guidance should be used as the basis for the regulations.

Response: We appreciate the comments on this subject, but as stated in the proposed rule, the regulation requirements on this subject are already consistent with Department of Health and Human Services guidance regarding Title VI of the Civil Rights Act. We agree that the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS) is a good reference, but we are unable to say with certainty that adherence to CLAS guarantees full compliance with this rule because each situation is evaluated on its own merits. In addition, we would like to clarify that regulation requirements that state documents must be ''understandable'' does not require or suggest that documents must be written in every language.

Comment: While commenters expressed general support for the concept of effective communication with patients, a large number of commenters posed questions regarding the proposed requirement to communicate with patients in a language and manner that they understand. Commenters wanted to know if all patient rights documents would be required to be translated into the patient's preferred language both orally and in writing. Commenters also requested clarification regarding the responsibility of each HHA to have written notices in each possible language the agency may encounter in the community, and asked that CMS provide a more limited and nationally standardized set of languages in which such notice must be conveyed. Additionally, commenters suggested that we should differentiate between ''vital'' and ''non-vital'' patient rights information that would need to be provided, in writing, in a language and manner that a patient understands, limiting required written information to what is vital and permitting the communication of non-vital information to an oral translation. Commenters further noted the challenges associated with providing a written copy of the notice of rights in the preferred language at the time of the initial visit because there are times when an HHA is not aware of the referred patient's language preference until the visit is initiated. The commenter suggested that, in such situations, the HHA should be required to provide the written notice in a reasonable amount of time (for example, 72 hours). Similarly, a commenter questioned whether an unforeseen inability to orally inform a patient of his or her rights in understandable language and manner ''in advance of providing care'' would mean that the clinician performing the initial patient visit would be prohibited from admitting the patient to services.

Response: We appreciate these comments and realize the task of requiring agencies to communicate with patients in a language and manner in which they understand may cause confusion when trying to meet the regulations in a consistent manner to remain compliant. We do not have the expectation that HHAs will be presenting a translated patient rights document to every single patient in their native language when they are admitted and before they begin receiving care. We want to emphasize that the term ''understandable'' does not mean it is expected to be written in every language. A general understanding means that patients achieve a grasp of the explanation of something and not necessarily a verbatim written translation. We expect HHAs to utilize technology, such as telephonic interpreting services and any other available resources for oral communication in the patient's primary or preferred language prior to the completion of the second skilled visit. The flexibility that is built into this requirement, allowing the use of technology, remote interpretation services, and patient-selected interpreters should accommodate most situations, alleviating potential concerns regarding an ''unforeseen inability'' to communicate with patients in advance of furnishing services. Based on the HHA location, language needs will vary and often times a document will only have to be translated once and then can be utilized again as needed without extra translation burden. In addition, we have revised the requirements to allow additional time for HHAs to provide oral notification of rights, removing the requirement that oral notification be provided in advance of providing care. We believe that this change will also alleviate concerns regarding an unforeseen inability to orally inform a

patient of his or her rights in understandable language and manner preventing the clinician performing the initial patient visit from admitting the patient to services.

Comment: A commenter requested clarification of the term ''preferred language.''

Response: The Department of Health and Human Services 2013 Language Access Plan described ''Preferred Language'' as the language that a limited English proficiency (LEP) individual identifies as the preferred language that he or she uses to communicate effectively.

Comment: Several commenters submitted comments regarding the role of patient-selected, rather than professional, interpreters. Specifically, commenters supported statements in the preamble that would permit a patient to select his or her own interpreter in lieu of a professional interpreter. Commenters noted that, even if a patient or representative does offer to provide an interpreter, she or he should still be informed of the availability of professional interpretation services. A commenter requested clarification of the preamble statement that an HHA ''may wish to document'' the refusal of a professional interpreter, stating that some surveyors may interpret this suggestion as a regulatory requirement.

Response: We appreciate these comments of support. We agree that a patient should be informed of the availability of professional interpretation services, regardless of whether the patient offers to provide an interpreter. Section 484.50(c)(12) requires HHAs to provide written notice, prior to the initiation of care, informing patients that they have the right to access auxiliary aids and language services, and how to access these services. Title VI of the Civil Rights Act does not require documentation, and we do not intend to require anything above and beyond what is currently required in Title VI. HHAs have the flexibility to document more information, but it is not a regulatory requirement.

Comment: A commenter disagreed with the idea that an HHA may communicate patient rights information to the patient's representative ''if a patient is unable to effectively communicate directly with HHA staff.'' The commenter asserted that this should only be true in situations where the patient is unable to participate, to any degree, in decision making regarding her or his health care. The commenter stated that if a patient can participate in health care decision making, it is essential that HHAs offer auxiliary aids, professional interpretation services, and translated materials directly to the patient, rather than relying on the representative to serve as an interpreter.

Response: Our intent is to assure that HHAs communicate directly with the patient in all situations where the patient has the mental capacity to participate in and understand such communications. However, if a patient is unable to effectively communicate and participate in their care due to a compromised mental capacity as identified through information provided by referral sources, clinical observations, and/or clinical assessment, then the HHA is permitted to communicate with the patient's representative.

Comment: A commenter disagreed with the way we characterized the role of an interpreter in the preamble of the proposed rule. The commenter stated that, in addition to our original description, it is also an interpreter's role to facilitate two-way communication, so that the patient can describe changes in his or her condition or experience of care, ask questions, and articulate preferences and concerns.

Response: We agree that an interpreter's role also includes facilitating two-way communication and patient participation in his or her care. We encourage communication that will help the patient be an active participant in his or her care. We emphasize the interpreter's role in communications from the facility because the facility has a legal obligation to communicate effectively with the patient or his/her representative.

Comment: Some commenters agreed, while other commenters disagreed, with the requirement that the HHA must ensure that the communication via the interpreter of choice is effective. A commenter stated that this requirement is impracticable, as by nature of the fact that the HHA staff is using an interpreter means that staff member is unable to communicate in the patient's language, rendering the staff member incapable of ensuring the effectiveness of the communication. Another commenter recommended that minors should be prohibited from acting as patient-selected interpreters. This commenter stated that minors lack clinical knowledge to be effective interpreters, and that performing interpreter duties may result in minors being exposed to information that is confusing or frightening to them, especially if they are interpreting for a parent.

Response: The most reliable way to assure that communication is effective is to use the services of a professional interpreter who possesses appropriate training and certifications to perform his or her job duties as an interpreter. Even so, patients have the right to choose someone other than a professional interpreter. Absent a professional interpreter, either because the patient has expressly declined the use of one or the patient's language is so rare that an interpreter, whether in person or by communication device such as the telephone, cannot be located, the HHA may use a patient-selected interpreter, such as the patient's representative. The patient's representative, who could be a family member or friend, may act as a liaison between the patient and the HHA to help the patient communicate, understand, remember and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the HHA staff. The HHA would be responsible for verifying that communication to the representative was effective and accurate communication, which could be accomplished by having the patient representative repeat back instructions. An HHA would be expected to observe the interactions between the patient-selected interpreter and the patient to determine whether the communication appears to be effective. For example, if a patient continues to look confused after the information is presented, then the HHA clinician may conclude that the communication was not effective in conveying the necessary information. This regulation is consistent with the current HHS guidance (''Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' 68 FR 47311, August 8, 2003, (*https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/*), and the HHA should respect patient preference to use someone other than a professional interpreter (even after being offered and denied). If the competency or accuracy of the patient-selected interpreter is in serious question, for example, the clinician speaks a paragraph of specific instructions and the interpreter ''interprets'' in a single sentence, the expectation would be to then bring in the services of a professional interpreter. We agree that the use of minors to serve as interpreters should be a last resort and only used in emergency circumstances.

Comment: Several commenters raised concerns about translators, particularly

in relationship to less common languages. Commenters requested guidance on handling situations when an interpreter is not available in the community. Other commenters requested guidance on the appropriate use of available technologies that could be used to achieve compliance with the accessibility requirements in this rule.

Response: We understand these concerns and agree that it is occasionally difficult to locate an interpreter for certain less common languages. Compliance with this requirement is achievable if the HHA takes all reasonable steps and actions to provide meaningful access to an interpreter as set forth by the HHA guidelines. HHAs are expected to exhaust all avenues of technology such as telephone translation, video conferencing, or online translation of written documents. All of those choices are acceptable options when a local interpreter cannot be located, provided that the chosen option meets the patient's communication needs.

Comment: A commenter asked whether the regulation requires HHA personnel to read the entire content of the notice of patient rights to the patient or whether it is acceptable to explain the overall intent and general content of the notice of patient rights without reviewing the rights verbatim.

Response: The intent of this requirement is for HHAs to thoroughly discuss the content of the notice of patient rights with the patient and representative, and to allow patients and representatives an opportunity to ask questions and otherwise seek clarification regarding the notice of patient rights. HHA staff members are not required to read the notice word-for-word to the patient. Rather HHA staff members have the flexibility to provide comprehensive and accurate summaries of each right in conversational language and tone in order to engage patients and representatives in this discussion.

Comment: A large number of commenters submitted comments regarding the proposed requirement to provide the notice of patient rights prior to the initiation of care. Commenters expressed concern about providing a large amount of information (both in paper form and in oral explanation) at a single visit, and all prior to initiating care. Commenters stated that this can be overwhelming for patients, and can result in patients not retaining important information (for example, how to make a complaint). The commenters suggested a multi-visit approach to providing information regarding patient rights. Some commenters suggested spreading the communications regarding patient rights across two visits, while others suggested a more extended approach. Commenters suggested that the first visit should include the information deemed to be essential prior to the initiation of care, with important, but not essential, information being reviewed during a subsequent visit. A commenter also suggested that HHAs should be required to provide the notice of rights whenever the plan of care is revised or updated, and should be required to obtain the patient's signature each time this is done.

Response: In accordance with the requirements of section 1891(a)(1)(F) of the Act, HHAs must provide notice in writing to each patient regarding his or her rights in advance of providing care. We agree that providing both written and oral notice in advance of providing care may not be in the best interest of all HHA patients. Therefore, we are revising the requirements at § 484.50(a) to require written notice in advance of providing care and oral notice by the end of the second skilled visit. HHAs must obtain the signature of the patient or the patient's legal representative to confirm that written information was received. HHAs may conduct a thorough conversation with the patient and representative regarding the content and meaning of the notice of patient rights over the first two visits by a skilled professional (nurse, therapist, and medical social worker). We believe that extending the time frame for the oral explanation of the notice of patient rights and responsibilities will foster greater patient understanding of those rights, as well as assure that the conversation does not inappropriately impede the delivery of patient care. HHAs would still need to document in the patient's clinical record that they have provided a complete oral explanation of the notice of patient rights, in addition to the written notice provided in advance of furnishing care. Documenting oral notice may be done by obtaining the patient's or representative's signature, or by a clinical note.

Comment: A commenter expressed concern with the proposed requirement that the HHA must provide the patient and the patient's representative (if any) with written and verbal notice of the patient's rights and responsibilities during the initial evaluation visit, in advance of care being provided to the patient. The commenter noted that a patient-selected representative may not be available or identified at the initial visit. Furthermore, the commenter stated that requiring the provision of written and verbal notice of patient rights to the representative in situations where a patient is competent may serve to postpone the initiation of patient care, and negatively impact patient health and safety. The commenter suggested that the requirements of § 484.50(a) should be clarified to allow for a patient's representative to receive a written notice of the patient's rights upon admission or as soon thereafter in situations when the patient is competent to make his or her own decisions.

Response: If a patient has a legally appointed or designated representative that has health care decision making authority, the HHA must provide notice of the patient's rights prior to initiating care. Notifying the individual with legal health care authority cannot be postponed. However, we agree that providing notice to patient-selected representatives that do not have legal health care decision making authority is not always necessary prior to the initiation of care. As stated previously, a patient may choose to decline the provision of the notice of rights to the patient-selected representative. We believe that HHAs would choose to document this in the patient's record in order to demonstrate compliance upon survey. If the patient does not decline to have the patient-selected representative be informed, and such representative is not present at the time of care initiation, an HHA may provide a copy to the patient-selected representative within 4 business days of initiating care. This information can be provided by mail or electronic means. We have revised the regulatory text at § 484.50(a) accordingly.

Comment: Some commenters strongly supported the proposed requirement to provide each patient with contact information for the HHA's administrator. A commenter stated that it would be appropriate to provide contact information for the administrator, as well as the administrator's designee, to meet the requirement. The administrator is not always available, so naming an alternate contact at the agency would facilitate more efficient and timely response to patient complaints or questions. However, a commenter suggested that an administrator should be responsible for receiving complaints, but not for answering routine patient questions that may be more appropriate for clinical staff and clinical managers. Other commenters suggested that it would be more appropriate to provide contact information for the HHA's 24-hour on-call service number or the HHA's general contact information.

Response: We agree that routine patient questions may be more appropriate for clinical staff and clinical managers; therefore at § 484.50(a) we have removed from the regulation text the requirement for the administrator to receive questions. The requirement that the administrator receive complaints remains in the regulation because we believe this is an essential leadership function. We also agree that providing contact information for the 24 hour call line would be appropriate for answering patient questions; however we do not believe that this is necessary to require in regulation. HHAs may choose to incorporate this information, but would not be required to do so. Similarly, HHAs may choose to include contact information for the administrator's designee, but would not be required to do so.

Comment: A commenter questioned the necessity of requiring an HHA to provide each patient with a copy of the OASIS privacy notice, given that patients are also provided the Health Insurance Portability and Accountability Act (HIPAA) privacy statement. The commenter stated that, if the point of the OASIS privacy notice is to advise the patient why the OASIS is being collected, this information can be more simply stated and incorporated elsewhere.

Response: As stated in the June 18, 1999 notice related to the implementation of the OASIS data set (64 FR 32984 through 32989), HHA patients whose data will be collected and used by the federal government must receive a notice of their privacy rights. These rights include: (1) The right to be informed that OASIS information will be collected and the purpose of collection; (2) the right to have the information kept confidential and secure; (3) the right to be informed that OASIS information will not be disclosed except for legitimate purposes allowed by the Federal Privacy Act; (4) the right to refuse to answer questions; and (5) the right to see, review, and request changes on their assessment. The statements of patient privacy rights with regard to the OASIS collection (one for Medicare/Medicaid patients, one for all other patients served by the HHA) are included in the OASIS privacy notice. Many of the topics addressed in the OASIS privacy notice are not included in the HIPAA (Pub. L. 104–191, 110 Stat. 1936, enacted August 21, 1996) privacy statement. Therefore, we do not believe that the HIPAA privacy statement is an appropriate substitution for the OASIS privacy notice, and we are maintaining the requirement that HHAs must provide patients with both the HIPAA privacy statement and the OASIS privacy notice.

Furthermore, we believe that the content of the OASIS privacy notice is understandable to patients. As explained in the June 1999 notice, consumer testing was undertaken to determine whether Medicare beneficiaries understood the overall message of the proposed Medicare notice. The findings indicated that beneficiaries understood that the notice was informing them about their rights relating to their personal health care information and that these protections were good. In addition, the majority of the beneficiaries found the notice's language to be clear and easy to understand.

Comment: Most commenters supported the patient-centered, patient-directed approach used in relationship to the role of the patient representative, and several commenters offered suggestions for ways to implement or clarify this role. A commenter suggested that HHAs should build a conversation focused specifically on patient representation into every admission visit. This conversation would allow the patient to identify those person(s) with whom the agency may discuss their care, or not discuss their care. The agency would document this in whatever format is most appropriate for them (for example, the electronic medical record (EMR)) and that would guide future conversations. In addition, the commenter suggested that HHAs should provide patients with written information, as part of the patient rights information, that would inform the patient that he or she can choose representatives, and make changes to that choice at any time by contacting HHA staff. Another commenter suggested that, in order to comply with the proposed requirement to allow patients to select their representatives, HHAs would need to create timeframes for contacting representatives, maintain documentation of patient preferences, maintain documentation of contacts with representatives, and actually involve representatives in care planning. Another commenter suggested that HHAs should be required to establish a primary contact to which all communication will be directed concerning the patient. That person would receive all information regarding the patient's rights, plan of care, and discharge plan updates.

Response: We appreciate all of the suggestions, and believe that they are examples of best practices that an HHA may consider adopting in order to facilitate compliance with the written regulations and spirit of the rule.

Comment: A few commenters suggested changes to the wording used to describe competency as it relates to rulings under state law. Commenters stated that the regulation should include other designations made under state law short of adjudication of ''incompetence.'' In place of the term ''incompetence,'' commenters suggested that we use the phrase ''lack legal capacity.'' Commenters also suggested that, if a state court has not adjudged a patient to lack legal capacity, the patient's representative should be permitted to exercise the patient's rights, but doing so must be in accordance with state law and with the patient's permission.

Response: While we believe that ''incompetence'' is a legally appropriate term, we agree that there are degrees of competence and incompetence, and that the term ''incompetence'' may not adequately express the exact degree that we originally intended to convey. For this reason, at § 484.50(b) we have replaced the term ''incompetence'' with the more precise phrase ''lack legal capacity to make health care decisions as defined by state law.'' The extent to which patients who possess legal capacity to make their own health care decisions choose to delegate that decision making authority to others would be established by the patient, as recognized in the definition of the term ''representative.'' The definition at § 484.3 states that, ''the patient determines the role of the representative, to the extent possible.'' HHAs are encouraged to engage patients in a thoughtful discussion about the representative role that the patient desires. HHAs may find resources related to supported health care decision making agreements helpful in creating a framework for and documenting the results of these discussions. (See *http://autisticadvocacy.org/wp-content/uploads/2014/07/ASAN-Supported-Decisionmaking-Model-Legislature.pdf* for one example of a supported health care decision making agreement.)

Comment: A commenter suggested that the patient or his or her representative should have the right, upon an oral or written request, to inspect all records pertaining to himself or herself including current clinical records within 48 hours (excluding weekends and holidays); and to receive copies of electronic records free of charge or to purchase, at a cost not to exceed the community standard, photocopies of the records or any portions of those records with 2 working days of the HHA receiving the request.

Response: We agree that patients and/or representative have the right to request a copy of their clinical record. Patients may access their records in accordance with § 484.110(e), which requires that a patient's clinical record (whether hard copy or electronic form) must be made available to the patient upon request, free of charge, at the next home visit, or within 4 business days (whichever comes first).

Comment: A commenter stated that it is redundant to require that HHAs must assure that patients receive services in a manner that is free from illegal actions, such as sexual abuse or physical abuse.

Response: We do not agree that it is redundant because the enforcement mechanisms for criminal statutes and these CoPs are very different. While certain actions, such as misappropriation of patient property (theft) are illegal, HHA surveyors do not enforce criminal statutes. However, we do believe that the HHA has a responsibility to ensure that no illegal activity takes place, and should be penalized if it does not take all necessary precautions to prevent its staff from engaging in criminal activity. If this requirement at § 484.50(c) were removed, an HHA surveyor would have no mechanism to cite an HHA for criminal acts committed by its staff. Therefore, we believe that it is in the best interest of HHA patients to include this requirement and enable an HHA surveyor to issue a deficiency citation for non-compliance.

Comment: A commenter stated that the patient's right to participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to factors that could impact treatment effectiveness is not a reasonable expectation in all cases.

Response: We disagree with this comment. A patient's right to be informed about care, and to consent or refuse any element of that care, is fundamental. Furthermore, where internal or external factors exist that may impact the effectiveness of a given treatment option, we believe that it is a reasonable expectation that they would be discussed with a patient in advance so that the patient can make an informed decision about the care they are set to receive.

Comment: A commenter opposed the proposed requirement that a patient has the right to participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate. The commenter opposed the phrase ''where appropriate,'' stating that there are no circumstances where it would not be appropriate for a patient to participate in, be informed about, and consent or refuse care in advance of and during treatment. The commenter also stated that the term ''appropriate'' is subjective and would be defined by the HHA, possibly resulting in limiting or even eliminating a patient's right to be involved in his or her care.

Response: While we agree that patients have these fundamental rights, and that those rights should be guaranteed in regulation, the phrase ''where appropriate'' is necessary. The patient has the right to determine the degree to which he or she wants to be involved in his or her care, and the use of this phrase reflects the fact that each patient will determine what is or is not appropriate in his or her own way. We believe that most patients will not want to be involved in every specific detail of care (for example, the type of supplies used). Thus, these decisions would likely not require full explanation to, and discussion with, the patient. To mandate the right to participate in, be informed about, and consent or refuse care in advance of and during treatment, for every single decision made by an HHA would be burdensome to patients that have no interest in such a degree of participation, and contrary to the goal of delivering care efficiently.

Comment: A commenter suggested that patients should have the right to participate in, be informed about, and consent or refuse care in advance of and during treatment with respect to the timing of visits and who provides services.

Response: These concepts are already included in § 484.55(c)(2), which requires the HHA to assess each patient's care preferences, and § 484.60, which requires that the individualized plan of care be based on the assessment of the patient.

Comment: A commenter suggested that, rather than requiring that a patient has the right to be informed about the patient-specific comprehensive assessment, the regulation should require that a patient has the right to be informed about all assessments throughout the course of care. The commenter stated that patients and caregivers may want to know the findings of any given assessment, rather than just the comprehensive assessment, which is performed at specified periods of time.

Response: We agree that the HHA's patients should be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to all patient assessments, rather than just the ''comprehensive assessment.'' We have revised the regulation text at § 484.50(c)(4)(i) to reflect this change.

Comment: A commenter recommended that a patient's right to be involved in establishing and revising the plan of care should be limited to involvement in major revisions to the plan of care, such as a change in the goal of care, the number of visits, or discharge date.

Response: The intent of this requirement is to assure that HHA patients can be informed about and involved in establishing and revising their plan of care as a whole. We believe the patient has a right to be involved with all facets of the care they receive. It is the HHA's responsibility to discuss the level of involvement that patients and their representatives want to have in the plan of care. This would include factors such as how much the patient is capable of understanding and the extent they wish to be involved with the development and updates to the plan of care. HHAs should make all reasonable attempts to respect patient wishes.

Comment: The majority of commenters expressed concern regarding the proposed requirement that an HHA must provide a patient with a copy of his or her plan of care. While some commenters agreed with our position that providing a patient with information about his or her plan of care would improve patient understanding and compliance, most stated that, as a clinically oriented document for use by medical personnel, the plan of care is not created in a manner that would make sense to a patient. Some commenters stated that patients would not want information about their plan of care, and noted that all patients already have a right to request copies of medical records, while other commenters stated that patients would prefer to receive this information. A few of these commenters suggested that the plan of care should be required to be provided if the patient desires it or specifically requests it. A single commenter sought reassurance that the copy of the plan of care would be provided at no charge to the patient. Still other commenters requested additional clarification regarding the meaning of the term ''plan of care'' as it is used in this section. These commenters stated that ''plan of care'' could mean general items the patient, home health clinicians, and physician agree the patient will be working on, or, it could mean all the physician orders, medications, etc. Some commenters suggested that HHAs should be required to provide each patient with an abbreviated plan of care, also referred to as a care plan summary, as a distinctive product specifically designed to engage

patients, their caregivers, and representatives as partners in treatment and care. Commenters suggested the following elements for this product: Patient condition, goals of care and measurable outcomes that the agency and patient have identified, a list of homecare services to be provided, specific training and interventions designed to prevent the need for emergency department care and hospitalization, a visit calendar for each discipline involved in the patient's care, and any other information that is necessary to improve the patient's health.

Response: We appreciate the many thoughtful comments that were submitted on this subject. We agree with the large majority of commenters that the plan of care (as set forth in § 484.60(a)) is a clinically oriented document that is written in medical terminology and in a manner that may not be comprehensible to the majority of HHA patients. For this reason, we agree that it is not appropriate to require HHAs to routinely provide each patient with a copy of his or her plan of care and we have removed this requirement from the regulation at § 484.50(c). However, HHAs are still required to provide any information contained in the clinical record, including the plan of care, free of charge, upon request from the patient, in accordance with the requirements of § 484.110(e). While we see the potential benefit of requiring HHAs to prepare and provide a plan of care summary to each patient, and believe that patients should be able to easily access information pertinent to their care, we do not believe that the significant burden that would be imposed with such a requirement is justified at this time. Currently many HHAs do not possess the technology, such as electronic medical records with secure patient portals, to make implementation of a plan of care summary requirement feasible. We will consider a plan of care summary requirement in the future based on the evolving use of technology in the HHA environment. While the plan of care described in this rule is focused on services delivered by the HHA, we also note that the concept of a ''plan of care'' continues to evolve, and future ''plans of care'' are likely to be more comprehensive documents that reflect the care patients receive across settings. As plans of care become more comprehensive, the importance of ensuring patients have access to this document will also increase. It is important to note that HHAs are still required to involve patients in the actual development and updating of the plan of care as required by § 484.50(c) and § 484.60(c).

In addition, in response to comments requesting that CMS require that written clinical and educational information be made available to HHA patients and caregivers, we have added a new standard at § 484.60(e), ''Written information to the patient.'' The new provision, which partially replaces other requirements previously placed elsewhere, requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. We believe that these requirements will ensure that patients are actively engaged in their own care. In addition, HHAs may use any form of communication (for example, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, or orientation videos) to facilitate patient knowledge and understanding of the care being provided. Providing patients and caregivers written instructions that they may refer to between visits is critical to both the quality and safety of patient care.

Comment: Many commenters sought clarification regarding the format for providing a copy of the plan of care to each patient. Specifically, commenters questioned whether the plan of care could be provided via electronic means, such as a secure patient portal. A few commenters suggested that the regulations should only require information to be communicated to patients orally, rather than in written form. Commenters also sought clarification regarding the timing for providing a copy of the plan of care. Commenters questioned whether the plan of care needed to be signed by the physician before being provided to the patient. Commenters also stated that requiring that patients be immediately provided with a hard copy of their plan of care would be extremely difficult in the current system of electronic medical record (EMR) reliance, and urged that HHAs be allowed to mail a copy of the plan of care within 24 hours of any actions that necessitate the copy to be shared. Commenters also suggested that HHAs be permitted to deliver the copy of the plan of care either to the patient or to the patient's representative. Numerous commenters requested additional information about the proposed requirement to provide each updated version of the plan of care to each patient. Commenters questioned whether updates could be delivered electronically by email or other secure electronic means to the patient or to the patient's representative. Other commenters sought clarification about the types of updates that would be required to be communicated to patients. Specifically, one commenter stated that in the preamble to the proposed rule, we explained that an HHA would need to notify a patient when the individualized plan of care is updated due to a significant change in the patient's health status. However, the text of the proposed regulation did not include the word ''significant,'' making it appear as if slight changes in patient status that result in tweaks to the plan would require notice. The commenter stated that we should include the word ''significant'' in the final regulation. Commenters offered suggestions regarding changes that would be significant, such as a change in therapy from physical to occupational therapy, with new caregivers coming to the home, or a change in medication, versus changes that would not, in the commenter's opinion, be significant, such as a change in visit frequencies or a change in medication dose. Commenters also requested flexibility in the format for providing notice, such as providing updates to the plan of care orally, with a notation in the patient's clinical record to document this oral communication. In addition to providing oral communication of changes to the plan of care, one commenter suggested that, if the change of plan of care involves teaching the patient skills to improve their medical treatment, the HHA should provide written information, such as flyers, that would help the patient remember and follow what they were taught. Another commenter suggested that HHAs should be required to manually update the copy of the first plan of care whenever there is a change or new order, and then furnish a clean, current copy of the plan of care upon request by the patient or representative, or whenever it is apparent that the patient's copy is missing, incomplete, inconsistent, or difficult to clearly read or follow.

Response: For the reasons set forth above, as well as in light of the many logistical concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHAs must involve patients in the development and

updating of the plan of care to the degree that a patient chooses to be involved in this process. HHAs are permitted to use any form of communication (for example, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, or orientation videos) to facilitate patient knowledge and understanding of the care being provided.

Comment: A few commenters expressed concern regarding the information security of leaving a copy of a patient's plan of care in the home. The commenters were concerned that potentially sensitive information, such as substance use-related diagnoses, may be included on the plan of care, and potentially disclosed in the act of leaving a copy of the plan of care in the patient's home. A commenter also stated that it would be burdensome to require HHAs to educate patients and caregivers regarding the proper handling of sensitive information. The commenter stated that patients and caregivers, not HHAs, are in the best position to determine where this information should be kept and who sees it.

Response: We appreciate the thoughtful comments regarding sensitive patient information. For the reasons set forth above, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHA patients retain the right to request a copy of any information contained in the patient's clinical record, including the plan of care. It is the HHA's responsibility to ensure proper and appropriate education is provided to the patient regarding protecting their own healthcare information. We do not agree that patient education regarding protection of the plan of care is any different than the patient education that is already provided regarding protection of other information that HHAs routinely leave in the patient's home (for example, aide visit calendars and patient rights information); therefore there would not be an additional burden for this activity. Rather, it is part of the cost of doing business. Teaching patients to secure their personal healthcare information is basic information that can be shared when giving the HHA contact information, policies and procedures and plan of care in the initial phase of care. Patients and their representatives have the ultimate responsibility to decide how and where information will be kept in the home.

Comment: Many commenters were concerned with the burden that would be placed upon HHAs in providing each patient with a copy of his or her plan of care, as well as updates to that plan of care.

Response: For the reasons set forth above, as well as in light of the many logistical and burden-related concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient.

Comment: A few commenters asked for clarification about providing a copy of the plan of care in relation to the requirement to communicate with patients in a manner that they understand. Specifically, commenters wanted to know whether the plan of care would need to be provided in the language the patient is most comfortable with, whether it would need to be understood at a 6th grade level, and whether it would need to be provided in a format that accommodates individuals with disabilities.

Response: For the reasons set forth above, as well as in light of the many logistical concerns raised by commenters, we have revised the regulation at § 484.50(c) to remove the requirement that HHAs must routinely provide a copy of the plan of care to each patient. HHAs are permitted to use any form of communication (including, but not limited to, typed summaries, checklists, calendars, handwritten notes, secure electronic communications, and orientation videos) to facilitate patient knowledge and understanding of the care being provided. Should an HHA provide a written document to a patient, we would expect that document to be understandable to the patient in accordance with the requirements of § 484.50(f). As clarified above, the term ''understandable'' means that patients achieve a grasp of the explanation of something and not necessarily a verbatim written translation. We expect HHAs to utilize technology, such as telephonic interpreting services and any other available resources for timely oral communication in the patient's primary or preferred language.

Comment: While some commenters agreed with the proposed requirement that a patient would have the right to participate in establishing the goals of care, other commenters identified some concerns with this concept. Commenters observed that patients may not understand the concept of establishing measurable goals of care, may have unrealistic goals, or may have goals that are inconsistent with other goals of care. One commenter requested guidance on how to comply with this proposed requirement when the patient-identified goals are unclear or unrealistic, while another commenter suggested that in these cases an HHA should document the reason that the patient's goal cannot or should not be accommodated.

Response: We appreciate the thoughtful comments. Regardless of whether a patient can verbalize their goals, all patients have goals even if it is as basic as feeling better today than they did yesterday. It is part of the HHA's responsibility to help patients form and shape achievable goals that are relevant to the delivery of the HHA care they receive. There may be times when a patient's goal may be contrary to the HHA healthcare goals. For example, a patient may wish to walk outside unattended, but if the patient has serious cognitive impairment, they may be at risk for wandering. We believe the HHA is capable of discussing realistic goals with their patients and documenting why a specific goal may not be appropriate. As part of the re-directing process with the patient, the HHA is able to identify more appropriate goals that are achievable.

Comment: A few commenters sought clarification regarding the proposed patient right to refuse services. Commenters sought to understand the scope of this right, asking questions such as whether this right is meant to cover minor situations, such as refusing to have their hair washed on a particular day because of feeling ill, or more significant refusals such as the refusal of all services. Commenters stated that, if a patient's refusal relates to a significant part of the recommended care, the home health agency is faced with determining whether continued home care is reasonable and necessary for claims billing purposes or whether the home health patient should be discharged. Commenters stated that further guidance in this area would be appreciated.

Response: Patients have always had the right to refuse services. Although this is the first time that we are including such a right within the regulations, it is not a new concept. We expect HHAs to already have policies and procedures in place to address these situations. If a patient refuses something minor, such as declining a bath due to fatigue that day, we would expect the HHA to document this in the clinical record. If the patient or patient representative refuses large aspects of care (such as dressing changes or essential medications), then the HHA has the responsibility to document this in the clinical record and communicate with the patient regarding implications of the refusal. The HHA would also

need to communicate with the physician(s) responsible for the plan of care regarding the refusal of one or more large aspects of care that have the potential to compromise the HHA's ability to safely and effectively deliver care to the extent that the HHA can no longer meet the patient's needs, and discuss the options with the physician(s). The HHA may need to consider discharge if the patient's refusal of services compromises the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs. We would expect HHAs to advise the patient, the representative (if any), the physician(s) responsible for issuing orders related to the element(s) of the plan of care that are refused, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge is being considered. HHAs should also provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care in a manner that is consistent with the patient's preferences.

Comment: A commenter suggested that the regulation should clearly state that representatives and caregivers have a right to be involved in establishing the goals of care and care preferences.

Response: This is an enumeration of the patient's rights. Legal representatives with health care decision making authority make decisions on behalf of the patient, and would therefore already have the right to establish the goals of care and care preferences on the patient's behalf. Additionally, if a patient has authorized a patient-selected representative to make decisions on his or her behalf, this individual would have the authority to establish the goals of care and care preferences. We believe that these flexibilities are sufficient to assure that representatives are able to represent the interests of patients. As an enumeration of the rights of the patient, we do not believe that it would be appropriate to set forth the distinct rights of the caregiver. It is a best practice for HHAs to take caregiver goals and preferences into account, but it is not a regulatory requirement.

Comment: A few commenters questioned the need for regulations that would enforce a patient's right to receive all of the services included in the plan of care. Additionally, a commenter expressed concern with this requirement in relation to specific service coverage limitations that may be imposed by payment sources.

Response: We believe it is absolutely necessary to include in regulations the right for the patient to receive all services outlined in the plan of care. Since HHAs and physicians are responsible for the items and services included in the plan of care, we presume they will only include those items and services that are covered by the patient's payment source or that the patient is willing to pay for.

Comment: A commenter suggested that HHAs should not be required to inform patients regarding the health hotline and patient liability for payment.

Response: These are statutory requirements for HHAs set forth at 1891(a)(1)(G) and (E), respectively, of the Act. Thus, it is appropriate and necessary to include these requirements in the HHA regulations.

Comment: Many commenters requested clarification regarding the proposed requirement that an HHA include contact information for local federally-funded and state-funded consumer information, protection, and advocacy agencies. Many of these commenters requested flexibility to determine, based on their patient population, which organizations would be most appropriate to meet this requirement. Commenters also stated that HHAs should not be required to assure that this list is exhaustive. Other commenters suggested that CMS should provide a set list of agencies to be included in the notice that is provided to patients. A commenter suggested that any organizations or agencies that are included on any list should be capable of substantive initial and follow-up services. Another commenter suggested that the list should include the local Center for Independent Living, transportation broker, and housing authority. Some commenters noted potential difficulties with this requirement, stating that it could be difficult to maintain the list as organizations and agencies continue and discontinue operations, relocate, etc. A commenter suggested that HHAs should be required to prepare and update the list annually. Furthermore, commenters noted that a universal list may not meet the needs of different patient populations. Commenters also stated that not all communities may be able to provide these types of services. Still other commenters stated that the requirement was unnecessary because nurses and social workers are available in HHAs to direct patients to the resources that suit their needs. Instead, commenters suggested that CMS should require that HHAs maintain accurate and up-to-date lists of local, state, and federal support and services agencies available to agency patients in the area where they reside.

Response: We agree that HHAs should have flexibility to include, at their discretion, those national, state and local resources that would appropriately meet the needs of their patient population. At the same time, we also agree that there needs to be a minimum set list of organizations and entities that all patients will receive. Therefore, we are finalizing a requirement at § 484.50(c) that an HHA must provide the names, addresses, and telephone numbers for the regional Agency on Aging (defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002), *http://aoa.acl.gov/AoA_Programs/OAA/How_To_Find/Agencies/find_agencies.aspx*), Center for Independent Living (as defined in section 702 of the Rehabilitation Act of 1973 (29 U.S.C. 796a), *http://www.ilru.org/projects/cil-net/cil-center-and-association-directory*), Protection and Advocacy Agency (*http://www.ndrn.org/en/ndrn-member-agencies.html*), Aging and Disability Resource Center (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002), *http://www.adrc-tae.acl.gov/tiki-index.php?page=ADRCLocator*), and Quality Improvement Organization (as set forth at sections 1152 through 1154 of the Social Security Act, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/QualityImprovementOrgs/*) that serves the area where the patient resides. These federally- and state-funded community-based services and organizations provide care for patients who are returning home or who want to avoid institutionalization entities, and are required by federal statute to help connect individuals to community services and supports. HHAs that choose to provide the names, addresses, and telephone numbers of additional organizations and entities may find the Eldercare Locator at *http://eldercare.gov/Eldercare.NET/Public/Index.aspx* to be useful, both as a reference for HHAs and as a reference to be provided to patients and their representatives.

Comment: A commenter stated that patients should be counseled on their right to access auxiliary aids and language services, and how to access those services.

Response: Section 484.50(c)(12) of the final rule states that patients have the

right to be informed of the right to access auxiliary aids and language services, and of how to access these services. We believe that this information would be included in the written notice of patient rights that is understandable to the patient. Additionally, HHAs are required to orally discuss the content of the notice of rights, and we believe that this oral discussion is sufficient to meet patient needs.

Comment: Some commenters requested clarification regarding the proposed requirement that an HHA provide a patient with information regarding the HHA's admission, transfer, and discharge policies. Specifically, commenters wanted to know whether the proposed requirement means that the policies must be provided to the patient, or that the HHA must notify the patient that such policies exist and are available upon request. Commenters also wanted to know if this information would be required to be provided orally or in writing. Finally, commenters requested clarification regarding how this requirement would be enforced in the survey process.

Response: HHAs are required to provide physical or electronic documents for the patient's keeping that outline the acceptable reasons for discharge or transfer, as set forth in 42 CFR 484.50(d)(1) through (7). We agree that disclosure of admission policies is not necessary as the patient would already be admitted to the HHA before any such disclosure would take place, rendering the disclosure unnecessary. Therefore, we have revised the regulation at § 484.50(d) to clarify that only those discharge policies set forth in this rule need to be included in the notice. We expect that verification of distribution of this notice would be incorporated into a home visit made by a state surveyor.

Comment: A commenter suggested that we should add the following requirement to the patient rights CoP: An HHA must ensure that a patient is transferred or discharged to a setting in which he or she will receive the level and type of care needed and make every effort to honor a patient's preferences and choices. A transfer or discharge may not occur until care in an appropriate setting is obtained. The HHA must provide sufficient preparation and orientation to patients to provide for a safe and orderly transfer or discharge from the HHA.

Response: HHAs have the responsibility of coordinating the discharge and transfer plan to the greatest degree possible to assure a smooth transition in accordance with patient preferences. We agree that proper planning and thorough patient preparation is an important part of a smooth transfer and discharge process. The patient, representative, caregivers, follow-up care practitioner, etc. are required to be informed of changes to the transfer or discharge plans in accordance with the requirements of § 484.60(c)(3)(ii), and we believe this would be an appropriate time for HHAs to prepare patients for a transfer and discharge. However, we note that HHAs cannot control the availability and quality of post-discharge or post-transfer care and should not be held responsible for those elements that are beyond their control.

Comment: A few commenters submitted comments related to patient involvement in the discharge or transfer process. Some commenters suggested that the HHA should be required to provide written notice of potential discharge or transfer to the patient, as well as the caregiver or representative (as appropriate), at least 30 days in advance of discharge or transfer. Furthermore, a commenter suggested that the written notice should be required to include the following:

- The reason for transfer or discharge;
- The effective date of transfer or discharge;
- The location to which the patient will be transferred or discharged;
- A statement that the patient has the right to appeal the HHA's decision to transfer or discharge him or her; and
- The address and telephone number of any agency/program that can represent the patient at a hearing, including but not limited to, the local office of the Legal Services Corporation; the state protection and advocacy system; and the local long-term care ombudsman if the state long-term care ombudsman program is authorized to serve home care clients.

Additionally, a commenter suggested that HHAs should be required to notify the State Survey Agency and Medicare contractor of its intention to discharge for cause. Another commenter requested clarification regarding whether patient consent is required for transfer. A commenter suggested that the regulation should include a specific process for patients to follow if they disagree with the HHA's decision to discharge or transfer.

Response: We believe the commenters' concerns are sufficiently addressed by § 484.60(c)(3)(ii), which requires that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, and caregiver(s). This is sufficient to assure appropriate communications between the HHA and the patient, representative, and caregiver(s) regarding transfer or discharge plans. Specifically, we do not believe a thirty day notice of transfer or discharge is a practical requirement for HHAs at this time. HHA discharges can occur in much shorter timeframes for a variety of unavoidable reasons ranging from a patient's decision to transfer to another HHA to a patient's transfer to an acute care provider to a situation in which HHA personnel are unable to deliver care due to an unsafe home environment.

Comment: A few commenters suggested additional circumstances under which HHAs should be permitted to discharge a patient. The commenters suggested the following additions:

- The HHA experiences a staffing change (unexpected staffing shortage); and
- The coverage requirements (that is, the face-to-face encounter) have not been met.

Response: We do not agree that staffing changes would be an appropriate reason for patient discharge. HHAs are responsible for assuring adequate staffing at all times to consistently meet the needs of all patients under their care. Likewise, we do not agree that it is necessary to add a reason for discharge specifically related to coverage requirements. In the event that coverage requirements are not met, an HHA would be permitted to discharge a patient because the patient or payer will no longer pay for the care (§ 484.50(d)(2)). We believe that situations where an HHA patient does not meet Medicare coverage requirements due to a failure to complete the face-to-face encounter requirements should be exceptionally rare, as we have made considerable efforts to streamline the requirements related to the face-to-face encounter coverage requirement and there is ample time (a 120 day period) to complete this coverage requirement. We expect HHAs to facilitate and coordinate efforts of the patient and physician to ensure that the face-to-face encounter occurs timely. In the case where the face-to-face encounter requirement is not met, an HHA cannot hold a patient financially liable for services provided. Failure to meet a condition for payment is not one of the criteria where an HHA can hold a patient financially liable. Once a patient is admitted, an HHA cannot abruptly discharge a patient unless the patient is properly notified and there is a valid reason for discharge. Ideally, a face-to-face encounter, as part of the

certification process, would occur before the patient received services.

Comment: A few commenters made suggestions regarding the entities to which patients are discharged. One commenter suggested that, in addition to requiring an HHA to discharge a patient to a suitable source of care, the regulation should also address situations where the patient refuses further placement or care from another entity. The commenter stated that patients have the right to refuse follow-up services. Another commenter suggested that HHAs should not be required to ''ensure'' a safe and appropriate transfer to another care entity because HHAs are not in control of other healthcare providers and cannot guarantee that another agency will take a patient under care.

Response: We appreciate these comments. All HHAs are required to ensure that appropriate arrangements for transfer are made for those patients whose acute care needs cannot be met by the HHA, and we have revised the final regulation at § 484.50(d)(1) to clarify this responsibility. The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) requires HHAs to take into account patient goals and preferences in discharge and transfer planning. On November 3, 2015, we published a proposed rule, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' (80 FR 68126), that would implement this section of the IMPACT Act. The HHA patient has the right to refuse a transfer to any provider or supplier, and the HHA would be expected to document the refusal and communicate with the patient and representative/care giver to help meet their healthcare needs to the best of the HHA's ability.

Comment: A commenter disagreed with the proposed regulation that an HHA would be permitted to discharge a patient when the patient or payer will no longer pay for the services provided by the HHA. The commenter stated that this regulation would conflict with the regulation in one state. Another commenter suggested that the regulation should be clarified with regard to what it means for a patient to no longer pay for services. Specifically, the commenter stated that discharge for non-payment should not be allowed in situations when a patient has submitted to a third party payer the paperwork necessary for the bill to be paid, and the bill is still pending.

Response: For those instances where state and federal laws overlap, the stricter regulation would prevail. For example, if a state regulation did not allow HHAs to discharge a patient due to a lack of payment, then the HHA would have to comply with state law, since state law prohibits discharge while federal regulations permit it. We agree that a discharge for non-payment is not to be considered until all payment source options have been fully explored and payment from a third party is no longer considered pending.

Comment: Some commenters opposed the proposal that an HHA be permitted to discharge a patient when the physician and HHA agreed that the patient no longer needed HHA services because the patient's health and safety had improved or stabilized sufficiently. The commenters stated that this regulation would, in certain cases, violate Medicare coverage law and regulations, as well as the settlement agreement in *Jimmo* v. *Sebelius (see Jimmo et al.* v. *Sebelius, D.Vt, No. 11–cv–17, October 25, 2011, 2011 WL 5104355).*

Response: The proposed rule stated that discharge or transfer would be permitted if it is appropriate because the patient's health and safety have improved or stabilized sufficiently, and the HHA and the physician who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services. Our intent was that, if the physician responsible for issuing orders related to the reason that HHA care was initiated and the HHA both agree that a patient has achieved the goals set forth in the plan of care (see § 484.60(a)(2)(xiv)), then discharge would be appropriate because the goals of care have been achieved. We have clarified this original intent in the regulation to assure that it is appropriately implemented. If the patient disagrees with a discharge or transfer, he or she has the right to appeal the decision. As set forth in § 484.50(c)(8), each patient has the right to receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204. This written notice includes information related to patient appeals. Finally, the *Jimmo* settlement agreement pertains only to guidance, not to regulations, and does not prevent implementation of new regulations.

Comment: A few commenters submitted suggestions to clarify the proposed discharge requirements for situations when patients refuse HHA services. One commenter noted that there are various degrees of which a patient may refuse services. For example, a patient may refuse an IV antibiotic, but accept therapy services in lieu of such treatment. The commenter suggested that only a refusal of all HHA services would warrant discharge. Other commenters suggested that it is not the refusal of services in and of itself that would necessitate a discharge. Rather, it is the effect of that refusal that may make discharge appropriate. These commenters stated that HHAs should be allowed to discharge or transfer a patient at any time when the refusal of services or the refusal to follow the agreed upon plan of care results in the HHA being unable to effectively deliver care.

Response: As stated previously, patients have the right to decline services. If a patient declines something minor, such as declining a bath due to fatigue that day, we would expect the HHA to document this in the clinical record. If the patient or patient representative declines large aspects of care (such as dressing changes or essential medications) then the HHA has the responsibility to document this in the clinical record and communicate with the patient regarding implications of the decline. We would expect HHAs to explore alternative options for providing care that is both consistent with patient preferences that continues to meet the patient specific needs as identified in the comprehensive assessment, and the measurable outcomes and goals identified by the HHA and the patient. The HHA would also need to communicate with the physician regarding the decline of services that have the potential to compromise the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs, and discuss the options. The HHA may consider discharge if the patient's decline of services compromises the HHA's ability to safely and effectively deliver care to the extent that that the HHA can no longer meet the patient's needs. We would expect HHAs to advise the patient, the representative (if any), the physician(s) issuing orders for the home health plan of care, and the patient's follow-up care professional (if any) that a discharge is being considered because the HHA can no longer meet the patient's needs. HHAs should also provide the patient and representative (if any) with contact information for other agencies or providers who may be able to provide care following discharge from the HHA.

Comment: Many commenters stated that HHAs should be explicitly permitted to discharge a patient for cause if the safety of the HHA's staff is threatened. In such situations, commenters suggested that reporting the danger to the proper authorities, such as law enforcement, protective services, etc., should suffice for documentation of the significant safety hazard that warranted a discharge. Other commenters suggested a broader list of reasons related to staff well-being that they believed would warrant discharging a patient from services, such as sexual harassment or verbal abuse. A commenter also suggested that, if a patient is discharged for reasons related to HHA staff safety and well-being, the HHA should be permitted to conduct the discharge process via alternative means, such as by phone, mail or electronic communication.

Response: The proposed regulation text states that if ''the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired,'' then the HHA may discharge the patient after following certain intermediary steps to attempt to resolve the issue(s). We believe this requirement already includes situations where the HHA's staff feels threatened, as such situations would seriously impair the HHA's ability to operate effectively in the delivery of care. We also believe the proposed requirement for documenting the problem and efforts made to resolve the problem will be sufficient for documentation purposes. If HHA staff felt that re-entry to the patient's residence was unsafe for them, the discharge process could be handled by way of an alternative method (for example, phone or electronic mail) rather than face-to-face communication.

Comment: While many commenters suggested that HHAs should be permitted to discharge patients for cause at the discretion of the HHA, without any regulatory limitations, other commenters strongly opposed the concept of discharge for cause in its entirety, suggesting that a discharge for cause provision would be used to ''dump'' patients (or patients who have caregivers) who they could claim were being ''difficult.''

Response: While we acknowledge that the discharge for cause provision may be subject to misuse in rare cases, we do not believe that the potential for abuse is appropriately counteracted by the complete removal of all discharge for cause options. Likewise, while we acknowledge that the discharge for cause provisions impose significant limits upon an HHA's ability to discharge patients who may be perceived as being ''difficult,'' we believe that these restrictions are essential in order to minimize the potential for inappropriate discharges. As part of the survey monitoring process, HHA's may be asked if there have been patients who have been discharged for cause. The surveyor may also request the patient(s) record as part of the clinical record review process during the survey. We believe that this type of monitoring may mitigate potential negative behaviors in an HHA.

Comment: A commenter opposed a statement in the preamble of the proposed rule that ''it would be incumbent upon the HHA to take all reasonable steps to resolve safety and noncompliance issues prior to taking steps to discharge a patient.'' The commenter stated that the word ''all'' is overly broad and implies that corrective action is entirely up to the agency.

Response: It appears that the intent of the statement was misunderstood. Rather that requiring that ''all'' steps be taken, this statement was intended to convey the message that ''all reasonable'' steps must be taken prior to discharging a patient for cause. HHAs would be expected to take every reasonable step that is available to them in order to resolve the issue(s) at hand prior to initiating a discharge for cause.

Comment: A few commenters requested clarification regarding the proposed requirement that HHAs investigate injuries of unknown source. Commenters sought guidance on how and to what extent HHAs should conduct such investigations. The commenters noted that patients are in the presence of HHA personnel for a very limited amount of time, and that HHAs should not be held responsible for minor injuries that occur in the course of everyday life, such as bruises and cuts.

Response: We appreciate the commenters' views and the opportunity to clarify the parameters an HHA should use when investigating an injury of an unknown source. An injury should be classified as an ''injury of unknown source'' when both of the following conditions are met: (1) The source of the injury was not observed by any person or the source of the injury could not be explained by the patient; and (2) The injury is suspicious because of the extent of the injury, or the location of the injury (for example, the injury is located in an area not generally vulnerable to trauma), or the number of injuries observed at one particular point in time, or the recurring incidence of injuries over time. The type, extent, process, and personnel involved for investigations would be left to the discretion of the HHA. HHAs are responsible for asking the questions necessary to determine whether minor injuries are indicative of more significant concerns. Furthermore, HHAs are responsible for complying with applicable state-specific reporting laws, in accordance with the requirements of § 484.50(e)(2).

Comment: While several commenters expressed strong support for the proposed requirement to investigate patient complaints regarding potential violations of patient rights, several other commenters offered suggested revisions to this requirement. While one commenter stated that CMS should recognize that investigations necessarily must vary in terms of intensity and duration, depending on the complaint alleged, and as such, any required investigation process should be flexible enough to allow for calibration to the circumstances, other commenters disagreed with the open-ended manner in which the standard was written, calling it ''too vague.'' Some commenters sought specific parameters for what constitutes appropriate reporting and documentation. Others suggested that the regulation should include examples of authorities to whom patient rights violations should be reported, such as adult protective services, law enforcement, and the state licensure agency. Additionally, others suggested that the regulation should identify and delineate complaints into different categories by level of severity, and implement a clear process for investigation for each different level. Still another commenter suggested that we should create a robust and detailed complaint investigation standard that requires the following:

- HHAs must have a complaint process, complete with policies and procedures, that is provided, in writing, to the patient, the patient's representative, and the patient's caregivers at the time of admission and each time the plan of care is updated.
- HHAs must provide a written report to the patient, documenting the findings of the investigation and resolution of the complaint within 14 calendar days of its receipt.
- If the patient is not satisfied with the HHA's response, the patient should be permitted to request another review, and the HHA would be responsible for responding, in writing, within 30 days from the date it received the patient's request for review.
- The HHA's response to this second review would be required to include the

telephone number and address of all agencies and programs with which a complaint may be filed, and the telephone number of the state home health hotline.

Response: We believe the proposed general language establishing an expectation for patient complaint investigation and reporting, without specifying details, is the most appropriate regulatory approach given the wide variety of situations that HHAs will likely encounter. We agree that HHAs will experience varying levels of intensity and duration when investigating patient complaints. These investigation and reporting suggestions from the commenters are all appropriate elements for HHAs to include in their internal policies and procedures for implementing this general requirement.

Comment: A few commenters sought clarification on the relationship between the proposed patient rights violation reporting requirements and existing state laws and regulations. One commenter stated that its state law requires HHAs, rather than HHA staff, to report misappropriation of patient property. Another commenter suggested that the reporting requirement should be qualified by the phrase ''in accordance with state law'' to assure that reporting meets current state requirements. A commenter also suggested that any HHA staff member who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, should be required to report said incidences or circumstances directly to law enforcement, in addition to reporting to the HHA management.

Response: We agree with the commenter that reporting should occur in accordance with state law, and have amended the regulations at § 484.50(e) to include this requirement. We note that, where these federal requirements are more stringent, HHAs are expected to comply with the more stringent federal requirement. We believe allowing each HHA to establish its own policies and precise chain of command for reporting incidents will give them the flexibility to meet the various levels of incidents and behavior, and to respond appropriately.

Comment: A commenter suggested that the regulation should state that a patient complaint may not be investigated by any HHA staff involved in the complaint.

Response: We agree that this is the appropriate policy for all HHAs, and would expect HHAs to exercise appropriate discretion in their investigations. However, we do not believe that this needs to be incorporated into the regulatory text, which establishes the broad goals for investigations rather than the specific mechanisms for them.

Comment: A commenter suggested that the regulation should clarify that complaints by a patient, representative, or caregiver may include, but are not limited to, complaints regarding treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately. Another commenter suggested that the regulation should state that the patient has the right to make complaints ''without discrimination, retaliation or fear of retaliation to the HHA and the state survey and certification agency.''

Response: We agree that the topics set forth in the proposed rule are not the only issues that a patient may make complaints about, and have revised regulatory text at § 484.50(e) accordingly. We also agree that patients have the right to exercise their right to complain without discrimination, retaliation or fear of retaliation. This concept is reflected in § 484.50(c)(11), which states that the patient has the right to be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity. This would include the right set forth in § 484.50(c)(3) to ''Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA.''

Comment: A commenter suggested that the regulation should specifically state that an HHA must take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

Response: We agree that HHAs should take all appropriate steps to prevent retaliation, and have incorporated this requirement into the regulatory text at § 484.50(e)(1)(iii).

Comment: A few commenters expressed concern regarding the proposed requirement to provide auxiliary aids to patients for the purpose of facilitating communication, citing the potentially large expense of certain auxiliary aids. Commenters stated that HHAs should be expected to make efforts to facilitate acquisition of auxiliary aids for patients, but not be required to provide more expensive equipment directly. Commenters also sought clarification of the proposed requirement to provide patient rights information in alternate formats. Specifically, the commenters stated that the term ''alternate formats'' is unclear.

Response: The provisions of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act require facilities to provide equal access to individuals with disabilities. If the provision of auxiliary aids becomes an ''undue burden,'' the HHA may seek protection that is available under section 504 of the Rehabilitation Act. As we noted in the preamble of the proposed regulation, the alternate formats expectation includes, but is not limited to, the provision of qualified interpreters, large print documents, Braille, digital versions of documents, and audio recording.

Comment: Several commenters made suggestions regarding ways that CMS and HHAs could address the issue of health disparities. Comments ranged from providing a standardized notice of patient rights in multiple languages to requiring HHAs to employ personnel who are similar in age, gender, and background to the HHA's patient population to formulating a CMS-wide response to the results of the vulnerable care study mandated by the Affordable Care Act.

Response: We appreciate these suggestions that commenters submitted; however, they are beyond the scope of this rule. We will retain these suggestions for future consideration.

Comprehensive Assessment of Patients

Comment: A commenter stated that the requirement for each patient to have an initial and comprehensive assessment should only apply to those patients who are receiving skilled care. Another commenter asked whether the proposed content elements of the comprehensive assessment applied to patients from all payer sources, or only to a subset of patients with certain specified payer sources, such as Medicare and Medicaid.

Response: We do not believe that limiting the assessment requirements solely to those patients set to receive skilled care services or to those patients who have Medicare or Medicaid as a payment source would be in the best interest of patients. The patient assessment is designed to identify patient needs, and all patients will have needs to be assessed. Therefore we are maintaining the requirement that all patients must be assessed; otherwise they would not be receiving HHA services in the first place.

Comment: The majority of commenters who submitted comments on this section made suggestions regarding the professionals who are permitted to complete the initial and

comprehensive patient assessments under various circumstances. Suggestions included allowing a therapy discipline to complete the assessments as long as that therapy is ordered, and allowing therapists to complete all assessments in all situations to allowing occupational therapists to complete the assessments in therapy-only, but not necessarily occupational therapy-only, situations.

Response: The suggestions made by commenters go far beyond our original intent to maintain the long-standing requirements that was proposed in the October 2014 rule. Since this would be a significant change to what was originally proposed, we believe that the most appropriate course of action would be to address this issue in separate notice and comment rulemaking at a future date. Therefore, we are finalizing the proposed requirements, which is a continuation of longstanding CMS policy.

Comment: A commenter stated that the 5 day time frame within which HHAs must complete the comprehensive assessment may not be sufficient to capture the full extent of some of these proposed factors in the comprehensive assessment, such as psychosocial and cognitive status, for certain patients. The commenter stated that this is due, in part, to the nature of certain conditions—especially psychosocial conditions—and, in part, to the focus on stabilization that consumes much of the initial visit(s). The commenter recommended that CMS should acknowledge this limitation, and should provide for additional time to complete the comprehensive assessment in limited, necessary circumstances.

Response: We do not agree that a period of greater than 5 days is necessary to gather information regarding all elements of the patient assessment. HHAs are already accustomed to completing the current assessment requirements within 5 days, and there is no evidence that patient care has suffered because of the failure of additional conditions to manifest themselves within that timeframe. While we acknowledge that this rule will expand the content of the assessment, such expansion is in keeping with current best practices and can be incorporated into HHA assessment timelines without undue burden. We note that hospice care providers, who operate under similar conditions, and who are also required to complete a patient assessment of very similar content, have developed ways to successfully assess things such as psychosocial condition within the same 5 day period as we are finalizing in this rule. Given the success of another very similar provider type in meeting this timeline, we believe that it is appropriate to maintain the 5 day timeline for HHAs. The 5 day timeline to complete the comprehensive assessment begins upon the physician ordered start of care date. If an HHA is unable to begin care on that date for any reason, we would expect the HHA to decline the referral because it is unable to meet the patient's needs in a timely manner. It is not acceptable for an HHA to seek a new referral with a new start of care date that is more convenient for the HHA.

Comment: Several commenters expressed support for the proposed requirement that, when occupational therapy is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the occupational therapist. The commenters interpreted this requirement to mean that occupational therapy in now permitted to establish eligibility for the Medicare home health benefit.

Response: We appreciate the commenters' support. However, we did not propose to change the requirements for establishing eligibility for the Medicare home health benefit. Rather, we proposed that if occupational therapy established eligibility, which may occur for a non-Medicare home health benefit such as private insurance or for a subsequent episode of home health care when the continuing need for occupational therapy establishes Medicare eligibility for the home health benefit, then the occupational therapist may perform the assessment.

Comment: A commenter noted that the new requirements related to the content of the comprehensive assessment will require revisions to forms and electronic medical records in order to assure that all information is documented appropriately.

Response: Neither the proposed rule nor the final rule mandate the use of a specific assessment form or electronic medical records (EMRs), which may also be referred to as electronic health records (EHRs). The extent to which HHAs choose to revise their forms or EMRs is entirely left to their discretion.

Comment: A commenter suggested that information about caregivers should be gathered as part of the comprehensive assessment. The commenter noted that oftentimes caregivers play a significant role in care delivery, as indicated by the proposed rule's inclusion of specific requirements related to caregiver education and training. Given their important role in care delivery, the commenter suggested that the patient assessment should include the following additional elements: caregiver willingness and ability to provide care; caregiver availability and schedules (for example, hours worked outside the home); the caregiver's current level of comfort in carrying out medical/nursing tasks or assisting with activities of daily living; and a brief screen for caregiver strain or depression. The commenter suggested that these elements are necessary in developing an understanding of a caregiver's particular situation in order to best provide appropriate and effective caregiver education and training.

Response: We agree that gathering certain key information about caregivers is essential for effective HHA care planning activities. HHAs cannot develop a schedule for turning a bed-bound patient, for example, without knowing the times when a caregiver would be available to perform the task. Thus, we are adding a requirement in this final rule that, as part of assessing patient caregivers (proposed and finalized at § 484.55(c)(6)), HHAs will be required to gather information regarding caregiver willingness, ability, availability, and schedules. We believe that the concept of ''willingness and ability'' adequately covers a caregiver's level of comfort in carrying out tasks. We believe that these concepts fit well with the finalized requirement at § 484.60(d)(5) that an HHA must ensure that each patient, and his or her caregiver(s), receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. However, screening for caregiver strain/depression is beyond the scope of HHA services as set forth in the Act. While these screenings are certainly a best practice that we encourage HHAs to incorporate on their own, we do not have the authority to expand the unit of care beyond the patient.

Comment: A commenter recommended that the comprehensive assessment regulation should address the use of standardized tests and measures by home health clinicians. The commenter stated that the use of standardized tests and measures early in an episode of care establishes the baseline status of the patient, assists in the development of the plan of care, and provides a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information

about whether predicted outcomes are being realized.

Response: We fully support the use of standardized data elements, tools, and measures by HHAs. To that end, the OASIS already provides standardized data elements that HHAs may use to establish the baseline status of the patient, assist in the development of the plan of care, and provide a means to quantify change in the patient's functioning. For those aspects of the patient assessment that are not captured via OASIS data elements, we encourage HHAs to use standardized data elements, tools, and measures that are available from national sources. This may include measurement scales such as the Functional Independence Measure and Functional Assessment Measure (*http://www.dementia-assessment.com.au/symptoms/fim_manual.pdf*) and the Chedoke-McMaster Stroke Assessment (*http://www.rehabmeasures.org/pdf%20library/cmsa%20manual%20and%20score%20form.pdf*) to name a few.

Comment: While most commenters expressed general support for our proposal to expand the required elements of the comprehensive assessment, several commenters requested additional clarification regarding specific proposed elements of the comprehensive assessment as follows: Psychosocial status, and cognitive status. Specifically, commenters sought more information regarding the extent to which these proposed elements may or may not differ from similar OASIS items (M1700–M1750), the meaning and intent of the term ''psychosocial,'' and the goals that CMS wants to achieve as a result of requiring an HHA to assess psychosocial and cognitive status.

Response: We appreciate the opportunity to clarify the intent of these requirements. Assessing a patient's psychosocial status refers to an evaluation of his or her mental health, social status, and functional capacity within the community by looking at issues surrounding both a patient's psychological and social condition (for example, education and marital history). This provision is intended to be a screening for potential issues that may complicate or interfere with the delivery of HHA services and the patient's ability to participate in his or her own care. Based on the results of this screening, an HHA may need to make referrals to additional care sources and other outside entities. Assessing a patient's ''cognitive status'' refers to an evaluation of the degree of his or her ability to understand, remember, and participate in developing and implementing the plan of care. Numerous screening tools are available that HHAs may choose to use in order to implement this requirement (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2117747/*). We are not requiring the use of any particular tool, nor are we prescribing the extent of the cognitive status assessment. Our goal is to make cognitive assessment a routine practice in HHAs so that HHAs can use this information in developing and implementing the patient-specific plan of care, and so that HHAs identify potentially unmet patient needs that warrant follow-up care with another health care provider, with the HHA making appropriate referrals as needed. We agree that there is crossover between these assessment elements and those items already included in the OASIS. However, those items included in the OASIS may not be sufficient for all patients. That is to say, some patients may require additional assessment beyond what is required in the OASIS, and we expect HHAs to revise or expand their patient assessment, as needed, to assure that each patient's psychosocial and cognitive status are assessed. The goal of this requirement is to enable HHAs to develop a more complete and person-centered understanding of the patient.

Comment: A commenter requested additional information regarding the intent and meaning of the proposed requirement that an HHA would identify a patient's strengths and care preferences. Another commenter requested guidance on honoring patient care preferences in case-by-case situations, such as when a patient prefers a shower bath on a day that they are feeling well versus the bed bath that is scheduled for that day.

Response: Traditionally the home health plan of care has been developed with a focus on patient deficits that require treatment. The physician and the HHA decide how to treat these deficits, and patients are told what is going to be done. This model of care places patients in a passive recipient role that does not optimize the achievement of positive patient outcomes. First, this model does not take into account those patient-strengths that can be harnessed by the HHA staff and plan of care to facilitate patient well-being. Examples of patient strengths that HHAs may identify, through observation and directly asking the patient to identify his or her own strengths, may include things such as knowledge of medications, motivation and readiness for change, vocational interests/hobbies, interpersonal relationships and supports, and financial stability. HHAs need to look at a patient's deficits as well as their strengths in order to develop a complete understanding of the patient, and we believe that this requirement will facilitate this practice.

Second, the traditional model of home care tells patients what is going to be done rather than asking patients what their care preferences are. The requirement to gather information regarding patient care preferences and take them into account when developing and implementing the home health plan of care seeks to revise this approach. We would expect patients to be engaged as active participants in their own care, and this begins with gathering and taking into account patient preferences regarding their care. For example, if a patient prefers a shower on a day when a bed bath is scheduled, or, conversely, if a patient prefers a bed bath on a day when a shower is scheduled, we would expect the HHA to take this preference into account and accommodate it to the greatest degree possible. Patient care preferences may go beyond basic daily decisions. Some patients may prefer to have a greater degree of pain control requiring medications that impair the ability to safely function independently while other patients may prefer to take less medication, even if that means a higher level of pain, to allow a greater degree of independence to safely function. Each patient has their own set of care preferences, and we would require HHAs to both identify and respect these care preferences to the greatest degree possible. Our goal is to assure that HHAs plan for and provide care that is both patient-directed and in accordance with the physician-ordered plan of care.

Comment: A few commenters requested clarification regarding proposed § 484.55(c)(8), which would require the comprehensive assessment to include data items collected at inpatient facility admission or discharge only. The commenters wanted to know what data items were being referred to in this requirement. The commenters asked if this requirement was in reference to the inpatient facility discharge/home health agency referral paperwork, or if there were other data items that we had in mind when developing this proposed requirement.

Response: The phrase ''data items collected at inpatient facility admission or discharge only'' is included in the regulations that HHAs have been required to comply with for more than a decade. This phrase refers to specific OASIS data elements (see *https://www.cms.gov/Medicare/Quality-*

Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-C1-DataSets.html). Specifically, in OASIS-C1/ICD 10, ''data items collected at inpatient facility admission'' is equivalent to those items that must be collected for ''Transfer to an Inpatient Facility.'' The data items collected at ''discharge only'' are equivalent to those items that must be collected for ''Discharge from Agency—Not to an Inpatient Facility Death at home,'' and ''Discharge from agency.'' No change to these data set items is being made at this time.

Comment: A commenter requested clarification on the criteria HHAs should use to determine when a change in a patient's condition warrants an update to the comprehensive assessment. The commenter interpreted this requirement to mean that an update to the comprehensive assessment is required only in situations where the change in a patient's condition is significant enough that it warrants close monitoring by HHA staff or results in a revision to the plan of care.

Response: The proposed provisions do not reflect a change in our policy. Current policy requires each HHA to have a policy defining a significant change in condition that would trigger an update to the assessment. For example, an initiation or discontinuation of a service, or a significant improvement or worsening of a patient's condition not anticipated in the plan of care. It will be up to each individual HHA to determine how a significant change in condition is to be defined.

Comment: All commenters who submitted comments regarding the proposed allowance for a physician-ordered resumption of care date fully supported this proposed change. One commenter suggested that the requirement to update the comprehensive assessment within 48 hours of the patient's return to the home from a hospital admission should be reconsidered because a hospital stay is not the only marker of a change in condition that would warrant an update to the comprehensive assessment. The commenter noted that patients with extended emergency room stays, patients who are in the hospital on observation status, and patients who are accessing urgent care may all be appropriate candidates for a physician-ordered re-assessment.

Response: We agree that extended patients who experience extended emergency room stays, being kept in the hospital on observation status, and utilizing urgent care services for urgent concerns may be in need of an update to the comprehensive assessment. These situations are all examples of a ''significant change in condition.'' The regulation at § 484.55(d) requires that the comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than the last 5 days of every 60 days beginning with the start-of-care date, unless there is a significant change in condition. Consistent with current CMS policy, HHAs are expected to develop policies and procedures that establish the parameters for what constitutes a ''significant change in condition.'' We believe that extended emergency room stays, patients who are in the hospital on observation status, and patients who are accessing urgent care are all experiencing a ''significant change in condition'' that would warrant a patient assessment. Therefore, we do not believe that it is necessary to explicitly incorporate these circumstances into the regulation because they are already captured under the broader heading of ''significant change in condition.''

Care Planning, Coordination of Services, and Quality of Care

Comment: A commenter suggested that the requirement to develop an individualized plan of care should only apply to patients receiving skilled services. In other words, the plan of care requirements should not apply to those patients that only receive non-skilled (that is, homemaker) services.

Response: All patient care, regardless of the level of clinical skill involved, should be delivered in accordance with a plan of care. To do otherwise would create opportunities for uncoordinated care, duplication of services, and missing services.

Comment: A commenter stated that the use of the terms ''plan of care'' and ''care plan'' throughout the rule is confusing because some may interpret these two terms as being two separate documents. The commenter suggested that a single term be used consistently in order to avoid potential confusion.

Response: The use of ''care plan'' and ''plan of care'' were intended to mean the same thing. However, in order to avoid the potential for any confusion, we are using the term ''plan of care'' throughout to express this concept.

Comment: Most commenters expressed strong support for the overall concept of an HHA developing a patient-specific, patient-centered plan of care for each patient. The commenters stated that the revised requirement would better ensure that the patient will, indeed, receive all the services and education called for in the plan of care. One commenter suggested that the requirement should specify that each plan of care be individualized to the patient's needs, as reflected in the comprehensive assessment.

Response: We agree that the plan of care should be based on the assessment and that it is important for the plan to specify patient education and training. We understand that is standard of practice for the patient to receive written care information based off the individualize plan of care, from the HHA outlining the medication schedule/instructions, visit schedule and any other pertinent instruction related to the patients care and treatments that the HHA will provide. We believe that this is critical information to improve the patient and caregiver comprehension of diagnosis and treatment, improve compliance with medications and treatment schedules and promote high quality care for the patient. Therefore, in response to comments, we have revised our proposed rule to create a new standard at § 484.60(e), ''Written information to the patient.'' The new provision requires the HHA to provide written instructions to the patient and care giver outlining visit schedule, including frequency of visits; medication schedule/instructions; treatments administered by HHA personnel and personnel acting on the behalf of the HHA; pertinent instructions related to patient care; and the name and contact information of the HHA clinical manager.

Comment: A commenter requested examples of effective interdisciplinary teams.

Response: Interdisciplinary teams work together, each member contributing their knowledge and skills, interacting with and building upon each other, to enhance patient care. The interdisciplinary team model is the foundation of care in other health care providers, such as hospices and complex chronic care management practices. HHAs may choose to develop interdisciplinary team models based on the experiences and knowledge developed by these similar care providers, or may develop their own strategies and structures to create effective interdisciplinary teams.

Comment: A commenter requested clarification of the term ''social needs'' in the context of the proposed requirement that patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing,

rehabilitative, and social needs in his or her place of residence.

Response: Patients come from a variety of backgrounds and settings, each with their own social needs. Some patients require a more intense level of services based on their social needs, and not all HHAs have the staff (for example, social workers) or other capabilities to meet the needs of all patients. Patient social needs may include intrapersonal and interpersonal relationships in the immediate family, financial status, homemaker/household needs, vocational rehabilitation needs, family social problems, transportation needs, and recreational needs. This requirement assures that, if a patient has social needs that go beyond the capabilities of the HHA and/or they would interfere with the HHA's ability to safely and effectively deliver patient care, the HHA would not be expected to accept that patient for care.

Comment: A few commenters suggested that licensed practitioners, such as nurse practitioners and physician assistants, should be permitted to review, sign and order home health services for patients served by Medicare certified HHAs. Other commenters suggested that ''physician extenders'' should be authorized to provide verbal orders. The commenter stated that, as necessary, their orders could be co-signed by the physicians to whom they report for the purposes of billing.

Response: Section 1861(m) of the Act requires that the home health plan of care be established and maintained by a physician. Section 1861(r) of the Act defines ''physician'' in a manner that does not include other licensed practitioners, such as nurse practitioners and physician assistants. Therefore, pursuant to statute, other licensed practitioners may not establish and maintain the home health plan of care, including reviewing, signing, and ordering home health services.

Comment: A commenter suggested that the individualized plan of care should be required to identify caregiver needs.

Response: While the needs of caregivers are important, they are beyond the scope of the home health benefit as set forth in the Social Security Act. It would be inappropriate to require HHAs to identify caregiver needs in the home health plan of care, as HHAs would then be obligated to deliver care to meet those needs and such an obligation is beyond the scope of covered HHA services.

Comment: A commenter stated that the regulation should include more specificity regarding the proposed requirement that the plan of care would include safety requirements, functional limitations and nutritional requirements. The commenter stated that the regulation should specify the data elements and level of detail for these aspects of the plan of care because there are no industry standards for them.

Response: The intent of this final rule is to allow HHAs flexibility, where appropriate, to tailor their practices to the needs and preferences of their patients and staff, to the extent possible. Thus, specifying the data elements and exact level of detail for these aspects of the plan of care would not be in keeping with the intent of this rule. HHAs may identify data elements at a level of detail that meets the needs of patients and clinicians.

Comment: A small number of commenters requested clarification of the proposed requirement that each patient's plan of care be required to include the frequency and duration of visits to be made. One commenter stated that HHAs currently indicate visit frequency and duration in their plans of care, and questioned whether the proposed requirement is different from this current practice. Another commenter stated that some HHAs prescribe visit frequencies that span the entire 60 day certification period, while other HHAs prescribe visit frequencies and durations based on the patient's condition and best practices. The commenter wanted to know if the proposal would require HHAs to assure that visit frequencies and durations are based on assessment and plan of care findings, rather than on general episodes of care.

Response: The term ''frequency'' is used to refer to the frequency of services that are ordered by the physician (for example, nursing 2 to 4 times per week). Likewise, the term ''duration'' refers to the amount of time for a given frequency (for example, 5 weeks of nursing services, with nursing 2 to 4 times per week for the first 3 weeks, and 1 to 3 times per week for the last 2 weeks) and may, in the case of therapy services, also refer to visit lengths and/or intervention lengths (for example, 90 minute visit, 70 minutes therapeutic interventions and 20 minutes heat application). We expect the plan of care to contain visit frequencies and durations based on the patient-specific needs as assessed in the patient assessment. This may or may not mean that visit frequencies and durations will account for the entire 60 day certification period.

Comment: A small number of commenters suggested that HHAs should not be required to include a patient's rehabilitation potential in the plan of care because some patients receive home health services for skilled maintenance therapy and, therefore, this element may be unnecessary. Commenters also expressed concern regarding the presence of this element in the plan of care in relationship to the medical review process that is related to HHA payment policy. These commenters believe that including information related to rehabilitation potential in the plan of care may create problems for HHAs during medical review.

Response: We believe that including ''rehabilitation potential'' on the plan of care is appropriate for all patients, including those patients receiving skilled maintenance therapy. Assuming all other eligibility and coverage requirements are met, skilled maintenance therapy services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of a safe and effective maintenance program. ''Rehabilitation potential'' in the plan of care should include expected outcomes and the plan of care must also list measureable goals. The ''rehabilitation potential'' or the expected outcome of maintenance therapy can be to preserve and maintain the patient's current condition or to prevent or slow further deterioration. In addition, the home health record must specify the purpose of the skilled service required.

We remind the commenters that HHAs are required to report all services provided to the beneficiary during each episode, this includes reporting each visit in line-item detail. Therefore, it is expected that the home health records for every visit will reflect the need for the skilled care provided. In accordance with Chapter 7 of the Medicare Benefit Policy Manual (Pub. 100–02, section 40.2.1, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf*) these clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. Taken as a whole then, the clinical notes are expected to tell the story of the patient's achievement towards his or her goals as outlined in the plan of care. In this way, the notes will serve to demonstrate why a skilled service is needed. Therefore, in accordance with Chapter 7 of the Medicare Benefit Policy Manual, the

home health clinical notes must document as appropriate:

- The history and physical exam pertinent to the day's visit, (including the response or changes in behavior to previously administered skilled services) and
- The skilled services applied on the current visit, and
- The patient/caregiver's immediate response to the skilled services provided, and
- The plan for the next visit based on the rationale of prior results.

Clinical notes should be written such that they adequately describe the reaction of a patient to his or her skilled care. Clinical notes should also provide a clear picture of the treatment, as well as ''next steps'' to be taken. When the skilled service is being provided to either maintain the patient's condition or prevent or slow further deterioration, Chapter 7 of the Medicare Benefit Policy Manual requires that the clinical notes must also:

- Include a detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- Describe the complexity of the service to be performed, and
- Describe any other pertinent characteristics of the beneficiary or home.

Finally, CMS requires the therapist to initially assess (and reassess at least every 30 calendar days) the patient using a method which allows for objective measurement of function and successive comparison of measurements. The therapist must document the measurement results in the clinical record.

Comment: All commenters who commented on the proposed requirement that each patient's plan of care must include patient and caregiver education and training to facilitate timely discharge expressed full support for this proposal. One commenter highlighted resources for caregiver education and training that are available from the Alzheimer's Association. The Association provides a wide variety of caregiver resources, which can be found at *www.alz.org,* as well as through a 24/7 Helpline at 800–272–3900. A commenter also highlighted the Chronic Disease Self-Management Program (CDSMP) based at Stanford University's School of Medicine and the Skills2Care program, which helps caregivers to manage the challenges of dementia in the home.

Response: We appreciate the support from commenters, and agree that the resources noted in comments may be helpful to HHAs.

Comment: A single commenter requested guidance for handling situations in which it has been determined by clinical assessment that a patient is able to learn how to self-administer insulin but simply refuses to learn, and there is no able, willing and available caregiver to teach.

Response: Section 40.1.2.4 in Chapter 7 of the Medicare Benefit Policy Manual (Pub. 100–02) states that where a patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service covered by the Medicare home health benefit. However, Medicare would not cover this service for a patient who is capable of learning and self-administering insulin, but refuses to do so, in which case the HHA may choose to discharge a patient because the payment source will no longer pay (see § 484.50(d)(2)). However, we believe that these situations are very rare. We would expect an HHA to explore all possible avenues to identify one or more individuals who could administer insulin to the patient as well as all possible options for convincing a patient to learn the proper self-administration techniques. We would also expect an HHA to thoroughly document all steps taken to resolve this issue, converse with the patient regarding the implications of this decision, communicate with the physician(s) involved in the patient's home health care and the practitioner who will be providing follow-up care, and provide the patient with information regarding other possible sources of care that may meet the patient's care preferences. For patients with other sources of payment that would continue to pay for insulin administration to a patient who is capable of learning self-administration, but refuses to do so, HHAs are permitted to continue providing services until such time as the patient is no longer in need of the HHA's services.

Comment: Several commenters supported the proposed requirement that the plan of care would be required to include measurable outcomes and goals identified by the HHA and the patient. One commenter stated that patients and caregivers need to feel their concerns matter in order to ensure their engagement. However, other commenters expressed concern and requested additional clarification regarding this proposed requirement. Commenters sought specific guidance regarding how to document patient goals, comply with patient-identified goals, and reconcile potential conflicts between patient-identified goals and the physician-ordered plan of care. One commenter suggested that HHAs should be required to establish the plan of care ''in collaboration'' with the patient, rather than ''in partnership'' because acting ''in partnership'' would increase the burden to HHAs. A single commenter asserted that patients don't know how to identify quantifiable, measurable goals.

Response: We appreciate the support of the commenters who submitted comments on this issue. We did not propose, nor are we finalizing, specific documentation or implementation requirements for this provision, as such requirements may impose unnecessary restrictions on HHAs in achieving the ultimate goal of delivering goal-concordant care. We acknowledge that patient established goals of care may be verbalized in a different fashion than those that are established by the physician(s) involved in the HHA plan of care. Nonetheless, we believe that patients are capable of establishing goals and that these goals can be successfully aligned with the goals established by the physician(s). Where there is direct conflict between a patient-established goal and a physician-established goal, we would expect the HHA to educate the patient about why the physician-established goal must be used to guide the care planning and delivery process. Patients should also be encouraged to discuss concerns regarding their care goals with their physician(s). We are finalizing this requirement as proposed, including use of the phrase ''in partnership.'' We believe that the phrase ''in partnership'' is equivalent to the suggested phrase ''in collaboration'', and that there is no difference in burden based on the use of one phrase over another.

Comment: Some commenters agreed with the proposed requirement that the plan of care would include measurable outcomes, even suggesting that such outcomes should be supported by evidence based measures through the use of standardized test and measures when possible. However, a single commenter contested the necessity of including measurable outcomes in a patient's plan of care, stating that there is not sufficient evidence to support the requirement. Other commenters expressed concern with the potential implications of the proposed requirement. These commenters stated that requiring measurable outcomes may imply that the goal of helping patients safely and effectively manage their health conditions in a community setting is not sufficient in itself, and that

home health services should be available to clients only so long as they demonstrate continued, quantifiable improvement from those services. Additionally, commenters expressed concern that working with the physician to establish such goals would be burdensome.

Response: The concept of measurable outcomes is well established in health care. For example, measurable outcomes are used in physical therapy to assess the effectiveness of interventions and are used in medical social work to assess patient progress in mental health therapy. Measurable outcomes can be used in home health care to measure these elements, as well as outcomes related to nursing, patient safety, and effective self-management, to name just a few. Measurable outcomes jointly established by the patient, HHA, and physician(s) may include measures related to self-medication management, avoidance of unnecessary emergent care visits and hospital admissions, and more. We do not agree that the phrase ''measurable outcomes'' would in any way convey the message that the goal of helping patients safely and effectively manage their health conditions in a community setting is not sufficient of itself, and that home health services should be available to clients only so long as they demonstrate continued, quantifiable improvement from those services, as the commenter asserted. Furthermore, we do not agree that establishing measurable outcomes would be burdensome, as this should already be part of standard care planning activities. Without the pre-establishment of outcomes, it would be difficult to measure when a patient with a goal of rehabilitation (the primary population currently served by HHAs) has made sufficient progress to warrant discharge. Likewise, it would be difficult to assess whether maintenance services have, in fact, achieved their maintenance goals.

Comment: A commenter requested clarification of a statement in the preamble related to the development of measurable outcomes and goals. The preamble stated, ''An evidence and outcome based approach to patient care that can be understood by the patient and caregivers, with specificity of orders, and adherence to best practice interventions to provide the basis for the development of an optimal plan of care and goals.'' The commenter requested further explanation regarding evidence and outcome based approaches, as well as how adherence to best practices will be measured.

Response: The concept of evidence-based care, an approach to decision-making in which the clinician uses the best evidence available, in consultation with the patient, to decide upon the option which suits that patient best, is well established. For example, in 1997 the Agency for Healthcare Research and Quality launched an initiative to promote evidence-based patient care through its Evidence-based Practice Center Program. Among other things, the Program develops evidence reports on clinical topics and publishes those reports for public use (see *http://www.ahrq.gov/research/findings/evidence-based-reports/overview/* for more details). We expect HHAs to use evidence-based care, often done through the implementation of best practices, to improve the experience of care and outcomes of individual patients and entire patient populations within an HHA's care.

Comment: One commenter requested examples of measurable outcomes, while another commenter noted that the National Quality Forum recently released recommendations on quality measurement and dementia that could be considered by HHAs as they develop outcomes for persons with dementia and their caregivers. This commenter also urged that patient- or representative/caregiver-reported outcomes be included as measurable outcomes in the plan of care, stating that patient and caregiver perspective is often overlooked in favor of more quantifiable measures.

Response: Measurable outcomes may include anything from an improvement in ambulation to a stabilizing of blood pressure to an improvement in self-management. Measurable outcomes must be tailored to the specific patient, including his or her circumstances, goals, and condition. We believe that leaving the term as broad as possible is the most appropriate way to account for this high degree of variability. We believe that the suggestions provided by the commenter related to available resources are appropriate and may be of value to HHAs in implementing this requirement.

Comment: A commenter stated that, in addition to permitting the HHA and physician to add additional items to the plan of care, the patient should also be permitted to add items to the plan of care.

Response: HHAs are paid for their services based on a set of covered services and items that is established by each payment source, whether Medicare, a Medicaid state plan, private insurance, or the patient him/herself. While we agree that patients have the right to state their care preferences and goals (see § 484.50) and that those preferences and goals should be incorporated into the individualized plan of care (see § 484.60), we do not agree that patients should be permitted to add items to the plan of care. Because we require HHAs to provide all services set out in the plan of care, such additions could possibly place HHAs in the position of being required to deliver services and items that are not covered by the payment source. This would be an unreasonable burden on HHAs.

Comment: Commenters supported the concept of assessing a patient's risk for re-hospitalization, and several even suggested that the requirement should apply to all patients rather than be limited to those patients that are admitted to HHA services following a hospitalization. One commenter requested clarification regarding the exact patient population to which the requirement would apply, noting that not all home care begins immediately following a post-acute discharge. Commenters stated that identifying a patient's risk for re-hospitalization and emergency department visits will help improve patient care and reduce unnecessary and avoidable hospitalizations.

Response: We agree that, for the sake of patient safety and for the sake of establishing a requirement that can be clearly and equally applied by all HHAs, this requirement should be applied to all patients, as all patients have some level of risk for a hospital admission or emergency department visit. Therefore, we have made a change to the regulatory text at § 484.60(a)(2)(xii) to apply this requirement to all HHA admissions. This requirement is consistent with CMS's focus on reducing preventable re-admissions through a variety of efforts such as HHA quality measures and CMS payment reforms.

Comment: Commenters identified opportunities for improved clarity regarding the re-hospitalization risk assessment proposal. Commenters noted that using ''low, medium, and high'' to rank each patient's risk may result in significant variation among HHAs because these terms are subjective and are not defined. One commenter suggested that CMS should provide additional resources and training to facilitate compliance. A few commenters suggested that, in order to achieve consistency, there should be an instrument that has been validated for agencies to use. Another commenter suggested that this risk assessment should be based on a Patient Activation Measurement (PAM) score. The commenter stated that peer-reviewed studies, have identified a strong link

between patient activation or having the knowledge, skills, and confidence needed to manage one's health and hospital readmissions. A study conducted at Boston Medical Center (Journal of Internal Medicine. February 2014; 29(2): 349–355. *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912296/*) found that patients with the lowest levels of activation had nearly twice the risk of returning to the hospital within 30 days, compared with patients with the highest levels of activation. Systematic assessment of a beneficiary's level of activation and self-management capability can guide more effective approaches to provider interactions with beneficiaries during in-home visits by skilled home healthcare professionals. Patients in the lower two levels of activation are often overwhelmed by their medical condition and struggle with health-related self-management tasks. Knowing a beneficiary's level of activation allows home health providers to tailor information, goals, and action steps to the abilities of the patient.

Response: We agree that the terms ''low, medium, high'' are not useful without further definition and standardized measurement tools that all HHAs would use. Our goal is to bring this issue to the forefront of patient care, and to assure that, within an HHA, it is consistently examined and addressed for each patient. While there may be benefits to establishing more inter-HHA consistency in the application of this requirement, we do not believe that those benefits would outweigh the cost of reducing HHA flexibility and innovation to determine the best possible way to achieve the overall goal of reducing unnecessary emergent care visits and hospital admissions. Therefore, at § 484.60(a)(2)(xii) we have removed the terms ''low, medium, high'', and are not suggesting a specific tool or process at this time.

Comment: The proposed rule included a requirement that all patient care orders, including verbal orders, must be recorded in the plan of care. A commenter requested clarification regarding the need for, and benefit of, including ALL orders (including verbal orders) in the patient's plan of care. The commenter stated that including all orders may cause confusion in cases where orders have changed several times over the course of an episode.

Response: The plan of care is an evolving document that outlines the patient's journey throughout HHA care and treatment. It is essential that the plan of care be reflective of past orders and current orders that are actively ongoing. As new orders are given to initiate or discontinue an intervention, the plan of care is updated to reflect those changes. New versions of the plan of care are created as needed to assure that each clinician is working on the most recent plan of care, with older versions being filed away in the clinical record in any manner that meets the needs of the HHA.

Comment: Several commenters expressed concern with the proposed requirement that drugs, services, and treatments are administered only as ordered by the physician who is responsible for the home health plan of care. Commenters stated that patients often have multiple physicians who order treatments and medications, and that the physician responsible for the home health plan of care is often not the ordering physician for every drug and treatment included on the home health plan of care. According to commenters, the standard practice is that the HHA informs the physician responsible for the home health plan of care of all treatments, drugs and services that the patient is receiving, and if applicable, who the ordering physician is, without requiring that this physician actually orders all of them himself or herself. Another commenter stated that in certain situations one physician will not take responsibility for the orders of another. One commenter stated that the regulation should be revised to allow communication from the HHA to a physician group practice, noting that some HHAs provide services patients who receive care from a group of physicians, and these patients do not necessarily have a single physician who is responsible for the plan of care. Commenters suggested that the regulation should be revised to reflect that drugs, services, and treatments be administered only as directed by a physician who is responsible for the care of the patient, and that the physician responsible for the home health plan of care is made aware of all treatments that the patient is receiving from the HHA.

Response: We agree that situations may exist in which multiple physicians are directly involved in providing care for a patient at the same time, and would thus be in a position to give orders to the HHA related to the care of a single patient. Furthermore, we agree that it is appropriate to revise the regulations to permit this arrangement. To that end, we have revised the requirement specifically related to physician orders to allow HHAs to accept orders directly from multiple physicians who are involved in a patient's care at that point in time, regardless of whether those physicians are part of the same group practice or not. The physician that is responsible for care of the condition that led to the initiation of home health care, and is thus the main physician responsible for the home health plan of care would have the opportunity to review all orders because all orders from all physicians must be included in the plan of care (§ 484.60(a)(3)) and the plan of care must be reviewed and signed by the physician responsible for the HHA plan of care (§ 484.60(a)). We have also added new requirements within § 484.60(d), Coordination of care, to specifically address the role and responsibility of the HHA when it chooses to accept orders from more than one physician. Specifically, in addition to the proposed requirements that HHAs would be responsible for coordinating HHA services and ensuring patient education and training, we have added new requirements within § 484.60(d) that HHAs that choose to accept orders from multiple physicians are responsible for:

(1) Assuring communication with all physicians involved in the plan of care.

(2) Integrating orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

The purpose of assuring communication and integrating orders is to avoid duplicate or contradictory physician orders and to assure that all patient needs are being met (whether directly by the HHA or by the physicians). We would expect HHAs to have appropriate systems and processes in place to both identify and resolve conflicting or duplicative orders. We believe that these expectations are consistent with the role of the clinical manager at § 484.105(c). In particular, the clinical manager is responsible for assuring the development, implementation, and updates of the individualized plan of care. We believe that, in order to effectively assure the development, implementation, and updates of the individualized plan of care, there would have to be communication with all physicians involved in the plan of care and integration of orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient. The requirement to integrate orders from all physicians would include those orders related to medications. Medication orders may be for long-term maintenance issues (for example, cholesterol management medications) as well as shorter-term medications for temporary issues that may or may not be directly related to the reason that home

health care was initiated (for example, pain management medications that may be used in the process of surgical recovery or may be used as part of a treatment plan for a strained back that the patient just happened to experience during the time that he or she receives HHA care). We would continue to expect that all services or interventions that are ordered are medically necessary, as supported by documentation in the patient's record, in accordance with the requirements of 42 CFR 409.44 and 409.45.

Comment: One commenter requested clarification regarding the proposed requirements permitting HHAs to offer vaccinations to patients in accordance with HHA policy without obtaining a separate physician order for each patient. The commenter requested that CMS define what steps in the vaccination process it will hold providers accountable for, and how CMS will reimburse providers for the vaccine.

Response: The proposed provisions do not reflect a change in our policy. HHAs are permitted to, in consultation with a physician, develop a policy for the administration of influenza and pneumococcal vaccinations without a patient-specific physician order, such as in the form of a standing order. We would expect that this policy would address topics such as obtaining patient consent and assuring that it is safe to administer a vaccination to a given patient prior to administration. As a medical treatment, this rule would require that any administered vaccines be documented in the patient's clinical record in accordance with the requirements of § 484.110(a).

Comment: A few commenters expressed confusion regarding the relationship between the concept of ''verbal orders'' and orders that are faxed or otherwise transmitted through other electronic methods. The commenters were unclear as to whether faxed or other HIPAA-compliant electronic orders are considered to be ''verbal orders.'' One commenter suggested that emailed and faxed orders would be followed up by a written order signed by the physician.

Response: In accordance with the definitions set forth in § 484.2, a verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care. Faxed and other electronic orders are not considered verbal orders because they do not meet this definition. However, all orders need to be appropriately authenticated.

Comment: The proposed rule stated that, when services are provided on the basis of a physician's verbal orders, the clinician receiving the order(s) must document it in the patient's clinical record, and sign, date, and time the order(s). While a single commenter supported this proposal, the vast majority of commenters who submitted comments regarding this proposal disagreed with the requirement that verbal orders must be timed, questioning the relevancy and necessity of a requirement in the home health care setting. A commenter also stated that it is unclear whether the ''timed'' requirement applies to the time that the care was provided or activity occurred; when the verbal order was documented; or when the verbal order was signed by the physician.

Response: While we acknowledge that most HHA patients do not typically require rapidly changing orders, we nonetheless believe that timing the receipt of verbal orders is necessary for those infrequent occasions when such situations do arise. There are times when a patient's condition rapidly changes, and clinicians are not necessarily able to effectively predict when such situations are about to occur. Therefore, we believe that it is necessary and appropriate to proactively record the time of day that each verbal order is received by an HHA clinician from a physician. This requirement corresponds with the clinical record authentication requirements at § 484.110(b), which requires all entries in the clinical record to be timed.

Comment: The proposed rule stated that verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. Several commenters understood this provision to also require timing of the physician signature, and disagreed with that idea. One commenter suggested that the regulation should include a timeframe for physician signature, while other commenters strongly supported the proposed deferral to applicable state laws and regulations. One commenter cautioned states and HHAs against imposing 48 hour timeframes for physician countersignature of verbal orders, stating that strict deadlines could impose constraints on physicians' time and patient care schedules, and could also negatively impact patients and Medicare expenditures by leading to delays in receiving treatments.

Response: We appreciate the opportunity to clarify the proposed requirement. We believe that there was some confusion among commenters, and want to be clear that we did not propose, nor are we finalizing, a requirement related to a physician timing the signature for a verbal order. Rather, all verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. We do not believe that it is necessary to require a specific timeframe for completing the authentication process, as in general, this is already effectively governed by existing state requirements. States and HHAs are permitted to establish timeframes that meet their needs. We remind HHAs that authentication must be completed in accordance with established billing requirements for those patients for whom Medicare is a payment source.

Comment: A commenter expressed concern about the requirement in § 484.60(b)(4) that a registered nurse or qualified therapist must document verbal orders. The commenter stated that state law allows others to receive verbal orders, and that the requirement included in the proposed regulation would limit an HHA's ability to employ licensed practical nurses (LPNs).

Response: We agree that there is no health and safety-related reason to prohibit a LPN from receiving and documenting verbal orders because LPNs have the necessary training and skill to perform this function. Therefore, we agree that it is appropriate to allow LPNs to receive verbal orders as long as the LPN is acting within his or her state licensure requirements and permitted in accordance with state scope of practice. This policy is consistent with the regulations for other providers, such as hospitals and hospice inpatient care facilities, both of which permit LPNs to receive verbal orders in accordance with state regulations and the organizations own policies and procedures. We have revised the regulation text at § 484.60(b)(4) to reflect this change.

Comment: A commenter requested clarification regarding the relationship between the requirements for care plan reviews and the timeframes for verbal order countersignature.

Response: All verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies. This requirement applies to verbal orders that occur at any time during the plan of care development, implementation, and update cycle.

Comment: Commenters supported the proposed level of physician involvement in updating the plan of care, as well as the proposed

requirement for an HHA to communicate with the physician as frequently as the patient's condition or needs require, when any significant changes in the patient's health care status occur, and at the time of discharge from the HHA.

Response: We appreciate the support of these provisions, and are finalizing these requirements at § 484.60(c) with minor changes to reflect situations where more than one physician issues orders for patient care.

Comment: A few commenters suggested that the timeframes for updating the plan of care should be modified. Commenters suggested that the regulation should require a plan of care update when there is a significant change in patient condition, and upon the request of the patient or representative (if any), but no less frequently than once every 60 days, beginning with the start of care date.

Response: The HHA should be in regular communication with the patient and caregiver(s), and must assure that the plan of care is achieving the goals established by the patient and physician(s). However, we do not see a reason to explicitly state that the plan of care should be updated at the request of the patient or representative. The plan of care is not updated as long as it is meeting the goals established by the physician(s) and the patient.

Comment: A small number of commenters disagreed with the proposed requirement that a revised plan of care must reflect current information from the patient's updated comprehensive assessment. Commenters stated that a new assessment is not needed when there is a revised plan of care. Commenters also stated that the proposed requirement implies that any change in the plan of care, such as a ''minor'' change in orders that does not constitute a ''significant change in condition'' (for example adjusted medication dose, revised wound care procedure), requires an updated comprehensive assessment.

Response: The proposed provisions do not reflect a change in our policy. Current policy requires each HHA to have a policy defining a significant change in condition that would trigger an update to the assessment (for example, an initiation or discontinuation of a service, or a significant improvement or worsening of patient condition not anticipated in the plan of care). It will be up to each individual HHA to determine how a significant change in condition is be defined.

Comment: A few commenters sought clarification regarding communications related to changes in the plan of care and the discharge plan. We proposed that, if the plan of care is revised due to a change in patient health status, an HHA must communicate the revisions to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care. We also proposed that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, the physician who is responsible for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any). Commenters asked the following questions:

- Does this mean that the care plan and discharge summary must be communicated to a specific provider or can be communicated to the patient's physicians' practice?
- What are the timeframes for when communication regarding revisions to the plan of care, including discharge planning, need to be completed and documented?
- Can these changes be communicated to the patient and the physician physically by mail or electronically by email or other secure electronic means?

Response: In the majority of cases where there is a specific physician or practitioner with whom to communicate, we would expect HHAs to communicate directly with that individual. In the small minority of cases where there is no designated practitioner, HHAs may communicate with the practitioner group. We are refraining from specifying timeframes and formats in order to afford HHAs flexibility in complying with these rules. Patient acuity and patient needs should drive the timeframes for various communications, with critical and/or time sensitive information being communicated as quickly as possible and less critical or time sensitive information being communicated on an as-needed basis. Likewise, the needs of the recipients should drive the format of the information and any associated documentation. We do not believe that it is necessary or appropriate to specify how information is communicated, provided that the patient's right to a confidential record is assured in accordance with § 484.50(c)(6).

Comment: Many commenters supported the proposed requirement that an HHA communicate changes in the plan of care to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care, stating that, in order to successfully implement the plan of care, everyone involved must be aware of its contents. A few commenters suggested that the regulation should clarify that such communications must occur only when there is a significant change to the plan of care, such as when new orders are needed from the physician.

Response: We appreciate the support of the commenters for the requirement that an HHA communicate changes in the plan of care to the patient, representative (if any), caregiver, and the physician. HHAs are strongly encouraged to engage patients, representatives, and caregivers in a conversation about the level of involvement that these individuals prefer to have in developing and updating the plan of care, and to act in accordance with those preferences. Some individuals may prefer to have more involvement, desiring communication regarding every change, while others may prefer communications regarding changes to focus only on certain topics or occur no more than once a week. HHAs would document these preferences and structure their communications accordingly to meet them. In the absence of such patient-directed guidelines for communication of changes, the default expectation from CMS would be that all changes in the plan of care are communicated, even ''minor'' ones, such as visit frequencies. We remind HHAs that communications regarding updates to the plan of care to the patient, representative, or caregivers can be done via telephone or secure electronic means, with associated documentation in clinical record.

Comment: A commenter requested additional guidance regarding the manner in which HHAs should document that they communicated changes to the plan of care to patients, representatives, caregivers, and physicians. The commenter requested that CMS clarify whether all changes to the plan of care require the plan of care to be re-signed by the physician, and if not, explicitly when that would and would not be required. The commenter also suggested clarifying whether the HHA would also need the patient and/or the patient's representative to sign the plan of care to indicate that the HHA has communicated this information. If a patient signature is not required, the commenter requested information regarding how HHAs should provide evidence that the communication occurred.

Response: The signature of the physician who is responsible for issuing

orders related to the condition(s) that led to the initiation of home health services should be on all iterations of the individualized plan of care for each patient in accordance with the requirements of § 484.60(a). We did not propose, nor are we finalizing, patient signature requirements for the plan of care. HHAs may document communications with the patient in regards to the patient's plan of care in any manner that demonstrates compliance with the communication requirements of § 484.60. This could include documentation in clinical notes, a specific section of the clinical record developed for this purpose, printouts or .pdf versions of secure electronic communications that are linked to or maintained within the clinical record, or any other method that could be used to demonstrate compliance.

Comment: Several commenters submitted comments regarding the proposed care coordination requirements. Commenters supported the goals of care coordination, stating that communication between the HHA and other physicians and practitioners is essential for producing the best possible outcome of care. This is especially true with respect to issues that are not directly connected to the issues being addressed by the HHA. Commenters also stated that it was important to coordinate care with those managing the patient's care after the patient is discharged from the HHA. Commenters suggested that care coordination should be led by a clinician, and should be patient centered, goal oriented, and outcome based. Within the context of this broad support, a few commenters raised specific concerns and points for additional clarification. A commenter noted that carrying out these activities is growing increasingly complex with the emergence of new models of care. As managed care penetration grows, and new accountable care models gain traction, patients with complex needs are experiencing care management and care coordination on a number of fronts. There is a risk of duplication of effort, and confusing or inconsistent communications to patients and health care professionals. The commenter suggested that the regulations should support efforts to streamline requirements among various health care sources and increase flexibility in implementing them. Another commenter cautioned that, while it is important to involve family caregivers, as appropriate, in care coordination and provide needed training, the coordination of care should also include appropriate continuity of care and referrals to accessible home and community-based services in the community, as needed. The commenter sought to assure that care coordination activities would not be delegated by an HHA to the caregiver.

Response: We agree with commenters that well implemented care coordination within an HHA has the potential to improve patient care and outcomes, and are finalizing this requirement. We note that the proposed care coordination requirements were specifically referring to coordinating care within an HHA. We expect HHAs to coordinate the nursing, therapy, aide, and medical social work services that they offer, whether these services are provided directly or under arrangement. In addition to these expectations, as discussed previously, in response to public comments we are finalizing a new requirement for HHAs to be in communication with all physicians who are writing orders related to the HHA plan of care. These activities are the inherent responsibility of the HHA, and it would not be appropriate for the HHA to delegate these tasks to a patient or caregiver under any circumstances. We do not expect HHAs to coordinate the care being provided by other entities beyond what is included in the HHA plan of care. For example, we would expect the HHA to coordinate all services and orders related to wound care for a patient receiving post-operative hip replacement HHA care. We would not expect the HHA to coordinate that patient's cardiac care with the patient's cardiologist and other specialists if this care coordination is already performed by the physician who is issuing the wound care orders, and if all orders for all care (wound and otherwise) are issued by that single physician who assumes the care coordinator role. It is only when HHAs choose to accept orders from multiple physicians to be included in the plan of care for a single patient that we would expect HHAs to coordinate the orders of those physicians. If an HHA chooses place itself in the role of a direct recipient of orders from multiple physicians, it is incumbent upon the HHA (as required by § 484.60(d)(2)) to assume the role of a care coordinator in order to assure that patient needs are continuously met and that there is no duplication or contradiction of services. While there may be HHAs that participate in care coordination programs where the HHA coordinates all aspects of a patient's care, care coordination programs are separate programs that have their own requirements, separate from the home health care requirements set forth in this rule. In these situations, HHAs would be expected to assume a care coordination role that meets the standards of the care coordination program in which it is participating, as well as meeting these HHA CoPs.

Comment: A commenter requested additional guidance on what constitutes an ''adequate'' level of coordination across all disciplines and the mechanism to conduct coordination. Another commenter suggested that the regulation should require HHAs to specifically document care coordination activities.

Response: Coordination of patient care entails assuring that patient needs are continually assessed, addressed in the plan of care, that care is delivered in a timely and effective manner, and that goals of care are achieved. HHAs may document these activities in a manner that suits their needs to demonstrate compliance.

Comment: Most commenters who submitted comments related to the ''Care planning, coordination of services, and quality of care'' requirement focused their comments on the proposed discharge summary requirements. Many of these commenters stated that the regulations should not include any requirements related to the discharge summary. Other commenters suggested a pared down list of content elements focused on the status of the patient at the time of discharge, such as a current reconciled medication list, a copy of the most recent plan of care, and recommendations for follow-up care.

Response: We appreciate the many suggestions that commenters submitted on this topic. Two days prior to publication of the proposed HHA CoPs, the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) was signed into law. Section 2(a), which added new section 1899B(i) to the Act, requires hospitals of various types and HHAs to take into account quality measures, resource use measures, and other measures to assist patients and their families during the discharge planning process. We believe that this provision will encourage hospital patients and their families to become active participants in the planning of their transition to post-acute care settings (or between post-acute care settings). This requirement will allow patients and their families' access to information that will help them to make informed decisions about their post-acute care, while addressing their goals of care and treatment preferences. Due to the very

close timing of this legislation in reference to publication of the HHA rule, the proposed HHA rule did not take into account the requirements of the IMPACT Act. In order to meet the requirements of the IMPACT Act for HHAs, we have decided to withdraw our proposals related to the content of the discharge summary. In its place, we are proposing a separate rule (''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies,'' November 3, 2015 (80 FR 68126)) that would implement the discharge planning provisions of the IMPACT Act and would address the content of the HHA discharge summary.

Comment: Many commenters responded to the request for additional ways to increase and improve HHA-physician communication. Comments ranged from statements that it is not necessary or desirable to increase communications between HHAs and physicians to suggestions that HHAs should be required to have medical directors overseeing clinical operations. Additional suggestions included: The implementation of interoperable health records to facilitate timely information exchange; establishing a demonstration to test the use of licensed practitioners, such as nurse practitioners, to oversee the home health plan of care; and aligning physician financial incentives with the goal of reducing hospital admissions and re-admissions while improving patient outcomes.

Response: The only commenter suggestion that could be implemented through the CoPs is the suggestion that the regulations should require each HHA to have a physician medical director. This concept was not included in any manner in the proposed rule, and its inclusion would be a significant change. We believe that, should this policy be considered for implementation, it would be most appropriate to pursue separate notice and comment rulemaking at a future date. All other suggestions are beyond the scope of this rule.

Quality Assessment and Performance Improvement (QAPI)

Comment: We received many comments regarding the proposed Quality Assessment and Performance Improvement (QAPI) requirements. The comments supported our understanding of data collection as a driving force in implementing evidence-based healthcare. The commenters stated that HHAs that are using data to drive organizational change can expect to improve the quality of care they provide to their patients. Many commenters appreciated the flexibility of the proposed requirement that allows HHAs to proactively identify risk areas and performance problems through the QAPI program. The commenters also supported the concept that each HHA would be expected to conduct its QAPI program in a way that best met its needs and the needs of the HHA's patients. However, we also received several comments that were not supportive of the QAPI CoP. One commenter stated that QAPI might not be appropriate for a home-based provider because the type of information collected through QAPI is geared toward facility-based patients and facility-based providers. In addition, this commenter stated that QAPI was too burdensome and too costly relative to any increased benefit it will provide. One commenter stated that the impact analysis for this provision was far under their perceived estimate to implement a QAPI program and the cost proposed by CMS would not allow the HHAs to produce any credible results that would represent any fundamental quality improvement change.

Response: We appreciate the support of this proposed requirement, as it confirms our understanding of current HHA quality practices. We do not agree with the assertion that QAPI is not appropriate for home-based providers. Hospices and dialysis providers, both of which include home-based services within their scope of services, have been successfully complying with QAPI requirements since 2008. HHAs have an abundance of standardized data elements and quality measures to select from in order to facilitate compliance with this requirement. We note that the impact analysis is neither a minimum nor a maximum level of effort. It is merely an estimate of the time and associated costs for a statistically typical HHA to develop and implement a basic QAPI program. Each HHA, depending on its needs and circumstances, may need more or less resources than estimated in the impact analysis.

Comment: Several commenters asked for a phased-in implementation time frame beyond the other HHA regulations. The reasons for the increased implementation time frame were because many states align their licensure requirements with some of the federal CoP requirements and the fact many HHAs do not currently have a comprehensive QAPI program that meets the standards of the proposed CoP.

Response: We agree that a phased-in implementation time frame is appropriate for the requirement that HHAs must conduct performance improvement projects because it will take additional time to collect the data necessary to identify areas for improvement that are appropriate for performance improvement. We have added a phase-in to allow HHAs the time necessary to collect data prior to implementing performance improvement projects. This allows for a full 12 month time period between the time that this final rule is published and the time that HHAs must begin conducting performance improvement projects. All other QAPI requirements can be implemented within the standard time frame for implementation of the CoPs as a whole (by July 13, 2017).

Comment: One commenter suggested that CMS utilize the Patient Activation Measure (PAM) as part of the requirements for HHAs under the QAPI CoP. The commenter explained that PAM is a 10- or 13-item questionnaire that assesses an individual's knowledge, skill and confidence for managing their health and healthcare. They stated the measure has strong psychometric properties and is being used in clinical settings around the globe. In a related comment, a commenter suggested that HHAs should use the ASHA Functional Communication Measures, and should collect patient-level data related to speech, language, cognition, and swallowing as areas of focus within their QAPI programs.

Response: HHAs may choose to use data elements and measures that meet their quality needs and goals, provided that those data elements and measures meet the requirements of this final rule.

Comment: One commenter suggested it would be a good idea to have families or patients participate in a survey about the quality of service they are receiving from the HHA. They stated that having a survey like this would allow for CMS and HHAs to understand and receive feedback on the care they are providing.

Response: We agree that obtaining patient feedback is an important aspect of assessing the quality of care provided by an HHA. For this reason, in October 2009 HHAs began participating, on a voluntary basis, in collecting this information through the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey (HH CAHPS). The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies. HHA participation in the survey became mandatory in late 2010. (*https://homehealthcahps.org/*) Information from the survey is publicly reported on Home Health Compare on the *Medicare.gov* Web site as of April

2012. (*https://www.medicare.gov/homehealthcompare/search.html*)

Comment: Several commenters urged CMS to consider the development and use of tools that can be utilized by HHAs and shared with surveyors to provide additional guidance. Some suggested that OASIS data be used for QAPI, while others voiced concern over potential problems with Private Duty Nursing (PDN) patients versus traditional home health patients when utilizing OASIS data to measure HHA quality. Some commenters suggested incorporating information from HHA surveys by State Survey Agencies, and that quality measures should be differentiated by HHA size (small, large and more complex HHAs).

Response: Accreditation organizations, industry associations, universities, and other independent entities are all sources of quality measures, tools, guides, and other resources that HHAs may use to aid in the implementation of QAPI requirements. OASIS data and survey data may or may not be an appropriate source of information for specific quality measures, depending on the data needed. We believe that these various sources of quality measures and tools make it unnecessary for us to develop separate tools.

Comment: We received several comments that expressed concern over the QAPI requirements, suggesting that CMS was providing too much latitude to HHAs in designing and implementing their QAPI programs. The commenters stated that such flexibility would allow some HHAs to evade scrutiny or conveniently brush problems and violations under the rug. They stated that in the absence of clear expectations, parameters and standards for enforcement, less scrupulous providers will pay lip service to QAPI requirements without making a meaningful effort to address problem areas.

Response: While there may be a subset of providers that attempt to do the bare minimum to comply with all of the requirements in this rule, we do not believe that creating a more prescriptive requirement will enhance overall patient care. Indeed, a prescriptive requirement would likely lead to rote behaviors that lack the introspective analysis that QAPI is based on. HHAs would be more likely to just do something for the sake of compliance, rather than to think about ways to continually improve. We believe that the HHA survey process, which includes HHA surveys by State Survey Agencies or accreditation organizations at least every 36 months, is effective in identifying substandard providers and prompting the necessary corrections.

Comment: We received several general questions regarding the QAPI requirements. One commenter asked if an HHA could fulfill the QAPI requirements if it participated in a larger, system-based improvement program that was implemented by their parent hospital/health system. A second commenter asked about what would be considered to be an ''effective'' program. A third commenter stated they believed the requirements should hold HHAs accountable for complying with the requirement and not just require that the QAPI program be ''capable of showing measurable improvement.'' A fourth commenter asked if HHAs would be considered out of compliance if it chose an area that did not meet the criteria of high risk, high volume or problem-prone. A fifth commenter asked about what happens if improvements are not sustained.

Response: A QAPI program must be individualized to the HHA and must be designed in a manner that will result in improving patient care and HHA operations. We require that a program be ''capable of showing measurable improvement'' because, despite an HHA's best efforts, not all endeavors will result in actual improvements being made. Parts of quality improvement are trial and error, figuring out which interventions do and do not improve processes and outcomes. HHAs are responsible for making all reasonable efforts to collect and analyze data from a wide variety of sources (including, but not limited to, patient care records, administrative records, and procurement records) to assess its operations and care delivery, and for using that data to develop and analyze performance improvement projects. For this reason, we believe that it remains appropriate to require that an HHA QAPI program be ''capable of showing measurable improvement.'' As stated previously, this rule requires the QAPI program to be individualized to the HHA. Participation in a larger, system-based improvement program may or may not satisfy the requirements of this rule, depending on whether the larger, system-based improvement program addresses the specific areas of concern or weakness within the HHA component of the system. HHAs are required to include, at a minimum, those areas that are high risk, high volume, or problem-prone, and that reflect the scope, complexity, and past performance of the HHA's services and operations. If, for example, a system-based program focused on infection prevention and control, while the HHA's historical area of weakness is the effectiveness of occupational therapy in achieving desired outcomes, then participation in the larger, system-based improvement program would not be considered sufficient to meet the requirements of this rule. Conversely, if an HHA chose to participate in the system-based program that focuses on infection prevention and control in addition to its own separate focus on occupational therapy, then it could be considered to be in compliance. HHAs may choose to focus on areas that are not high-risk, high-volume, or problem-prone in addition to their efforts related to areas that are high-risk, high-volume, or problem-prone. Regardless of the chosen focus areas, HHAs are required to implement performance improvement projects, to monitor their implementation, revise the projects as necessary to achieve success, and assure that improvements are sustained over time. If improvements are not sustained over time, we would expect HHAs to continue to revise their approach as needed until improvements are sustained.

Comment: We received several comments that suggested we remove or revise language in the regulations. Several comments asked that CMS remove or revise the language that used the term ''medical errors.'' They stated ''medical errors'' appears more applicable to hospitals and there is a legal definition of ''medical error'' now associated with liability insurance, so they cautioned CMS to use the term carefully. One commenter suggested the removal of ''hospital admissions/re-admissions'' and replace it with the terms ''emergent care/re-hospitalization'' because they pertain more to home health care. One commenter suggested we revise the requirement ''immediate correction of any identified problem that directly or potentially threaten the health and safety of patients'' because these types of situations indicate ''immediate jeopardy'' or emergency and should be corrected immediately and not necessarily as a result of data collection.

Response: We appreciate the suggestions related to ''medical errors'' and hospital admissions/re-admissions. In regards to the term ''medical errors'', we are not associating this term with HHA liability insurance. While there may be liability insurance implications that may occur as a result of identifying a ''medical error,'' such insurance issues are not within the scope of this rule. Recognizing and responding to ''medical errors'' is an essential responsibility of all HHAs because medical errors are a significant quality

and safety concern. As for hospital admission/re-admissions, we agree that using the term emergent/re-hospitalization is acceptable, however, all three of these areas (hospital admissions, re-admissions and emergent care) need to be considered by the HHA. We have revised the regulation at § 484.65 to include emergent care, in addition to admissions and re-admissions. Lastly, we agree that any immediate jeopardy situations that are identified, whether through an incident report, patient complaint, staff observation, or data collection should be corrected immediately. However, we do not agree that it is appropriate to revise the regulatory requirement that there must be an immediate correction of any problem that directly or potentially threatens the health and safety of patients. A problem that directly or potentially threatens the health and safety of patients should be immediately corrected, and we see no reason to change this requirement.

Comment: We received several comments that asked who should work on QAPI. One commenter stated the preamble mentioned physician participation but did not include physicians specifically in the regulatory language. One commenter pointed out that patients, their representatives and caregivers are not included in the QAPI CoP requirements.

Response: We do not agree that it is necessary or appropriate to specify the persons that should be involved in QAPI. Each HHA may choose different individuals representing different areas of knowledge and experience in order to achieve their specific QAPI goals. HHAs may choose to solicit specific information from physicians, patients, representatives, and caregivers beyond the data that is already gathered from them to use in QAPI efforts.

Comment: One commenter asked if the elimination of the ''Group of Professional Personnel'' will eliminate physician involvement. The commenter stated that the current group of professional personnel requirement is the only factor that insures a physician has involvement with the operations of the agency. On the other hand, another commenter stated that maintaining the group of professional personnel ''was more a troublesome administrative burden than a mechanism that yielded demonstrable benefits for patient care.'' This commenter further stated the QAPI program, based on the concepts articulated in the proposed rules and prevailing QAPI accreditation standards, provides a better basis for achievement of patient-focused, performance-based outcomes. Another commenter stated that the previously-required 60 day summary of care statement should be part of an HHA's evidence-based program of quality improvement.

Response: HHAs may choose to involve physicians in their QAPI efforts, and may benefit from seeking the input of a variety of physicians, such as those who refer to home health care, those who manage HHA plans of care, and those who have expertise in quality measurement and improvement. However, we do not believe that it is necessary to mandate physician involvement, because this would be a significant cost to HHAs. Furthermore, HHAs may choose to assess the timeliness and completeness of HHA-physician communications, in their many forms, as part of their QAPI programs. We agree that this measurement and subsequent analysis may be valuable. However, we do not believe that it is appropriate to mandate such measures because they may not meet the specific needs of all HHAs.

Comment: One commenter suggested that CMS add a CoP that requires that every HHA receiving public dollars from Medicare and Medicaid programs must implement an electronic visit verification mechanism. They stated they believe this would provide electronic proof and record accountability that a visit had taken place. In addition, they stated this would be a common sense best practice approach to prevent fraud, waste and abuse that all HHAs must comply with in order to participate in the Medicare programs.

Response: While we agree that electronic visit verification software may be a helpful tool for HHAs to use, there are no uniform standards for the implementation of electronic visit verification. In the absence of these standards, we do not believe that it is appropriate to mandate the use of electronic visit verification software.

Comment: We received several comments asking for clarification and justification for the performance improvement projects. Several commenters asked that CMS be more specific in the requirement for performance improvement projects, specifically asking for a prescribed level of detail regarding their content and frequency. Commenters suggested that performance improvement projects may be warranted in response to a deficiency cited by a survey. In addition, commenters voiced concerns regarding the potential for inconsistent survey processes and outcomes related to this requirement because the requirement for QAPI is not prescriptive. One commenter asked why performance improvement projects are required and expressed concern that conducting performance improvement projects could distract and take away from program activities that address critical problems. Additionally, a commenter observed that the proposed requirement does not call for the HHA to sustain these improvements. Absent such requirements, the commenter stated that the time and resources would be wasted on a short-lived effort whose effect does not last.

Response: The regulation already requires that performance improvement projects, as part of the overall QAPI program, be focused on indicators related to improved health outcomes, patient safety, and quality of care; focused on high risk, high volume, or problem-prone areas; and that the number and scope of distinct improvement projects conducted annually be reflective of the scope, complexity, and past performance of the HHA's services and operations. To be more specific than these requirements would restrict the flexibility that HHAs need in order to effectively and efficiently comply with these requirements. Of particular note, we believe that the requirement to focus on high-risk, high-volume, and problem-prone areas is the same as focusing on program activities that address critical problems. Rather than detracting from such efforts, the rule would require that they receive the data and resources necessary to develop effective solutions. Furthermore, the regulation at § 484.65(c)(3) requires that ''The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.'' We believe that this requirement will assure that HHAs sustain improvements over time.

Comment: We received various comments on the role of the governing body in the QAPI CoP. A few commenters stated that they supported the concept of ''leadership from the top,'' and that the approval of data collection should be the role of the HHA leaders, not the governing body. We received comments that asked for clarification regarding the role of the QAPI Committee, the Professional Advisory Committee, the Interdisciplinary Record Review Committee and whether one takes the place of another, whether they could be combined, if there were expectations as to who served on what committee, how often each committee would need to meet, whether or not HHAs would need

a medical director, and what role they would serve in meeting the QAPI CoPs.

Response: The HHA governing body is responsible for approving data collection, leaving HHA management responsible for all of the research and decisions leading up to final approval by the governing body. Furthermore, these regulations do not require any particular committees to be used, so we are unable to clarify the roles, schedules, or compositions of committees that HHAs may choose to develop or maintain. Additionally, this regulation does not require an HHA to employ a medical director. If an HHA chooses to employ a medical director, the HHA would be allowed to incorporate the medical director into the QAPI program in a manner that it sees fit.

Infection Prevention and Control

Comment: We received many positive comments that supported our new infection control program requirements. Previously, the home health regulations only briefly addressed infection control procedures. One commenter stated they believed incorporating preventive care of infectious diseases is the best addition to the CoPs. Other commenters also agreed that infection control requirements will bring the focus of care back to the patient, and that it will promote and help to improve quality of care.

Response: We agree with commenters that the infection prevention and control requirements are an important addition to the HHA CoPs, and appreciate the support of the commenters.

Comment: Several commenters asked that CMS utilize a phased-in approach for the infection control program. The rationale for a phased-in approach was based on the fact that variation exists among home health agencies with regard to the infection control elements required, and will require additional resources for the agencies.

Response: This rule will be effective July 13, 2017. We believe that this time period will be sufficient for HHAs to develop and implement an infection prevention and control program that complies with these requirements.

Comment: One commenter suggested that CMS consider the requirement of an infectious disease specialist in implementing and maintaining such a program. The commenter believed that having an infectious disease specialist would help align the infection control efforts within the broader, integrated network and could be relied upon to lead the education programs for staff, patients and caregivers.

Response: The services of an infectious disease specialist may be valuable for HHAs in the development and refinement of infection prevention and control. However, we do not agree that the services of an infectious disease specialist are necessary for establishing a program that is capable of meeting the requirements of this rule. We believe that non-specialist physicians, advanced practitioners, nurses, and others have sufficient knowledge and training to create effective programs without the added cost and logistics of consulting an infectious disease specialist.

Comment: One commenter asked CMS to clarify the role of the Infection Control Committee. They asked if it was part of the QAPI or is it a separate committee.

Response: This rule does not require the use of an infection control committee. HHAs are permitted to create an infection prevention and control program using the expertise of all appropriate individuals.

Comment: Several commenters requested clarification on the method, plan and use of ''standards of practice'' when implementing an infection control program. They specifically asked for examples of surveillance activities, which guidelines or current standards of practice to use, and guidance on the type and amount of education and whether or not it can be provided verbally or if it must be in writing.

Response: Federal and state agencies such as the Centers for Disease Control and Prevention and state departments of health, as well as accreditation organizations and national professional organizations, have all developed infection prevention and control standards of practice. There is a wide variety of information on this subject available for HHAs to choose from in creating their own programs, and we do not believe that it is appropriate to specify which standards HHAs must use. We would expect an HHA to be able to identify the source of the standards it selects and be capable of explaining why those standards were chosen for incorporation into the HHA's infection prevention and control program. Similarly, we do not believe that it is appropriate to specify the form or content of patient and caregiver education regarding infection prevention and control. The education, both in content and format, must meet the needs of the patient and caregivers. This means different things for different individuals. Some understand better with written instructions while others understand better with in person demonstrations and still others understand better with video instructions. The form and content of the education efforts need to meet the needs of the individual being educated. We would expect HHAs to document these efforts in a manner that suits the workflow of the HHA and successfully demonstrate upon survey that the requirement was met.

Skilled Professional Services

Comment: One commenter suggested that this requirement should be renamed ''Professional Services'' because use of the term ''skilled'' may be confusing in relationship to coverage requirements. Additionally, the commenter recommended that CMS develop a more comprehensive title for § 484.75(b) by combining the language for a more inclusive responsibility.

Response: The professions included in this section are all ''skilled''; therefore we believe that it is appropriate to maintain this element of the title. Furthermore, we do not agree that standard (b) should be re-named, as the content of the standard is directly related to the responsibilities of skilled professionals.

Comment: While several commenters supported the grouping of discipline-specific regulations under a single CoP, a small number of commenters disagreed with this regulatory text organizational structure. These commenters recommended retaining all of the current provisions as separate CoPs, and adding new regulatory requirements within each of those separate CoPs to support interdisciplinary participation. One commenter was concerned that grouping discipline-specific regulations under a single CoP would impede interdisciplinary care by diluting the roles of professionals within the team. One commenter also asked that ''physician extenders'' be recognized as part of the interdisciplinary team, while another suggested that physician services include those services provided by interns and residents.

Response: We appreciate the support for the reorganization of skilled professional services. We believe it is in the best interest of the HHA staff that each discipline be held to the same high standard, and that combining all discipline-specific requirements into a single standard will help assure that all disciplines are being equally held to the same expectations. Furthermore, applying the same expectations to all disciplines will facilitate HHA compliance with the regulations as well as facilitate survey consistency. We do not agree that holding all disciplines to the same expectations will dilute the roles of each discipline. In regard to the

use of physician extenders, section 1861(m) of the Act specifically defines HHA services as skilled nursing, PT, OT, SLP, medical social services, and medical supplies. However, the Act does not include physician extenders. Therefore, we do not think that it is appropriate to include these professionals in the ''skilled professional services'' section. Lastly, there is only one place in section 1861(m)(6) of the Act that refers to HHA physician services. The Act states that ''in the case of a home health agency which is affiliated or under common control of a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital'' are part of HHA services. Since we do not have a specific requirement for physician services in any part of this rule, they are otherwise not part of HHA services, and are exceedingly rare. Therefore, we do not believe that regulatory language is needed beyond what is already included in the Act to govern these situations.

Home Health Aide Services

Comment: Several commenters offered support for the home health aide proposed requirements. One commenter states they are pleased CMS is proposing to enhance the current regulations to require HHAs to take action when there is a potential or verified deficiency in aide services. This new monitoring and oversight of aide performance would help ensure ongoing quality care. Another commenter strongly supports the incorporation of home health aides into the health care team process and supports the proposal to add a new home health aide skill requirement related to recognizing and reporting changes in skin condition, including pressure ulcers. Lastly, commenters strongly support the recognition of additional skilled professionals within the interdisciplinary team and urges CMS to adopt an immediate effective date for therapists and other appropriate skilled professionals to determine home health aide assignments.

Response: We appreciate the support of commenters in moving forward with these changes. While we acknowledge that some HHAs may wish to implement select changes as soon as possible, most commenters requested a significant period of time to implement the requirements of this final rule. To accommodate commenter concerns, we are finalizing a July 13, 2017 effective date. Therefore, the provision permitting therapists to determine home health aide assignments will be effective July 13, 2017.

We also appreciate the commenters' support for the new home health aide skill requirement related to recognizing and reporting changes in skin condition, including pressure ulcers. We believe that it is important for home health aides to be taught to recognize and report changes in skin condition; however, it has been brought to our attention that the skills involved in reporting changes in the condition of pressure ulcers are beyond the home health aide's normal scope of practice. Therefore, in light of this information, we are withdrawing our proposal to require home health aides to be taught to recognize and report changes in pressure ulcers. The revision will require only recognizing and reporting changes in skin condition.

Comment: One commenter stated that the regulations for education, training, competency evaluations, certification and supervisory requirements for certified home health aides are different in their state than what is proposed.

Response: We acknowledge that states often have more stringent aide requirements. In situations where a state has more stringent requirements for aide education, training, competency evaluations, certification and supervision, those state requirements would take precedence over these federal requirements. Likewise, in situations where the federal requirements are more stringent, those would take precedence over the more lenient requirements.

Comment: Several commenters expressed concern that the regulation's attention to home health aide service is excessive. Several other commenters suggested that the regulations should allow state nursing boards to set the standards.

Response: Many of the home health aide requirements, such as those for aide training and entities prohibited from offering training, are set forth in the Act and, as such, must be included in the regulation. We have streamlined the home health aide requirements to the greatest degree possible while still implementing the requirements of the Act and assuring that all essential components of aide services that lead to safe and effective patient care are addressed.

Comment: One commenter requested CMS to consider either not requiring home health aides to obtain CNA certification, or change the requirements to maintain CNA certification so a home health aide could maintain CNA certification without undue burden.

Response: To clarify, the proposed regulation does not require CNA training. Rather, the regulation proposed that CNA training (as opposed to home health aide training) may be considered as an appropriate qualification for an individual to be a home health aide.

Comment: A commenter disagreed with the proposed requirement that the individual complete another aide training program before providing services if, since the individual's most recent completion of the aide training program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual were for compensation. Similarly another commenter recommended that flexibility be incorporated into this requirement. Another commenter stated that the aide 24-month lapse was not necessary.

Response: This regulatory requirement directly implements section 1891(a)(3)(A) of the Act and cannot be altered via regulation.

Comment: We received many comments requesting clarification on several different issues related to home health aides. A few commenters specifically requested clarification on home health aide employment/training. One commenter asked if a home health aide who had worked for an HHA for 10 years and then stopped working for the agency for 2 years to care for an aging parent, would then be required to complete a new aide training program prior to returning to work for the agency? Another commenter asked CMS to clarify what happens if an HHA aide completed another training program but had not furnished home health aide services for 24 months. This same commenter also requested a definition of the term ''compensation.''

Response: We appreciate the opportunity to clarify the requirement related to home health aides. Part of our requirements for home health aides states, ''A home health aide or nurse aide is not considered to have completed a training and competency evaluation program if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which no aide services (personal care services, simple dressing changes, assistance with medications that are ordinarily self-administered, assistance with activities that are directly supportive of skilled therapy services, and routine care of prosthetic and orthotic devices) were furnished for compensation.'' In the examples from the commenters there was a 24-month lapse in furnishing services for compensation. This means the

individual must complete another training and competency evaluation program, or a competency evaluation program, before providing services. If an individual has a 24 consecutive month lapse in furnishing aide services for compensation, regardless of the circumstances surrounding the lapse, he or she will be required to complete a new training and competency evaluation program, or a competency evaluation program, prior to providing aide services on behalf of the HHA. Compensation as it relates to home health aide means monetary compensation, as set forth in section 1891(a)(3)(A) of the Act.

Comment: A commenter cautions CMS against using the word ''clinical'' in the standard relating to communication skills. It created a higher standard of clinical qualifications than may be required by the state. Instead of ''verbally report clinical information,'' the commenter suggested, ''verbally reporting information relevant to the patient's clinical condition.'' In addition, a commenter expressed concern about the possibility of increased expectation regarding the aide's capability in preparing documentation for the clinical record. The commenter asserted that HHA aides are not ''certified'' and so their level of documentation skills are not standardized. The commenter asked how a surveyor would assess the documentation developed by an aide when documentation standards do not exist for the aide. The commenter also stated that, unlike nurses, who must meet documentation standards by virtue of licensure, aides do not have such standards.

Response: We appreciate the opportunity to clarify the requirements related to HHA aide documentation. We do not agree that the language change to ''verbally reporting information relevant to the patient's clinical condition . . .'' is any clearer than what was proposed. Therefore, no changes will be made. The commenter also stated that HHA aides are not ''certified'' and so their level of documentation skills is not ''standard.'' To clarify, aides are expected to function within their existing state licensure requirements to the extent applicable, so no higher level of skill is expected than what is already established under a state's laws and regulations. As for documentation, this standard is related to the content of the aide training program. By including ''documentation'' as an element of the basic aide training program, training in documentation would become standardized, and both HHAs and surveyors would be able to assess the accuracy and effectiveness of aide documentation that is produced as a result of this training. HHAs will be held responsible for the accuracy of information in the clinical record that is created by HHA aides, in accordance with the requirements of § 484.110. HHAs will also be held responsible for assuring that each aide completes, at a minimum, a competency evaluation to assure that an aide's documentation skills are sufficient.

Comment: We received several comments regarding HHA aide training. A few commenters requested clarification on currently employed HHA aides who have already been through basic training and competency assessment. Specifically the commenter asked if agencies will need to implement training regarding skin care, decubitus ulcers and communication and if that could be met through in-service training. Other commenters asked CMS to provide greater clarification as to the requirements regarding home health aide communication skills, including the required ability to read, write and verbally report clinical information to patients, representatives and caregivers as well as HHA staff. Several commenters suggested that the effective date for compliance be phased in to accommodate those aides currently employed by the agency to receive updated training in new areas through in-service training. A few commenters proposed that a certified nurse aide must successfully complete supplemental training in order to qualify as a home health aide. One of the commenters went on to suggest that the content of this training should be set by CMS and approved by the state.

Response: This rule will be effective on July 13, 2017. We do not believe that additional time for this provision is necessary because current HHA aides would only require training on new skills (for example, recognizing skin changes), which may be done through routine in-service training. In accordance with the requirements of § 484.80(a), individuals trained as nurse aides are already required to complete a competency evaluation to assure that they have the skills appropriate to furnish home health aide services to home health patients. In accordance with the requirements of § 484.80(c)(4), any skills for which a HHA aide is evaluated as unsatisfactory may only be done under the direct supervision of a registered nurse until such time as he or she successfully completes a subsequent evaluation. Retraining would be done as needed to assure competency in all required skill areas. We believe that this competency evaluation process will assure that nurse aides possess all necessary skills to furnish safe and appropriate care to home health patients.

Comment: A commenter requested clarification as to whether HHAs could use in-service education provided by another organization such as the HHQI national campaign, accompanied by a post test, adding that the HHA would still provide any educational needs or questions the aide may have.

Response: We appreciate the opportunity to clarify the requirements related to HHA aide in-service education. It would be permissible for HHAs to use in-service education through another organization, as long as it is under the supervision of an RN.

Comment: A commenter stated that the roles and responsibilities of the home health aide should be clarified. For example, the proposed language may be interpreted as allowing home health aides to provide clinical information to the patient, which the commenter did not support. In addition, the commenter recommends that this requirement provide specific direction as to how home health aides are to be involved on the interdisciplinary team.

Response: We appreciate the opportunity to clarify the requirements related to home health aide roles and responsibilities. The role of the aide is governed by the state licensure requirements. Therefore, CMS believes aides should be able to communicate clinical information to patients that is within the aide's licensure requirements (for example, blood pressure). While we understand the request for clarification related to the home health aide's involvement in the interdisciplinary team, we believe that being prescriptive on how aides should be involved in the team could limit the HHA's own creativity, flexibility and innovation. It is up to the HHA to decide how it would like its aides to be involved in the interdisciplinary team.

Comment: A commenter stated that § 484.80(g)(3) could be misinterpreted to imply that the physician-signed plan of care must specifically identify each individual who would perform all of the duties set out in subparagraphs (g)(3)(i) through (iv).

Response: We appreciate the opportunity to clarify these requirements. We would expect the physician-established plan of care to authorize aide services in general. However, the aide-specific plan of care would be established by the RN or qualified professional, and would be expected to contain the level of detail

set out at subparagraphs (g)(3)(i) through (iv).

Comment: A commenter requested clarification on which professionals may give written instructions to aides. This commenter stated that many times OT is involved in preparing the plan of care, but is not involved for the duration of the care, and thus would not be supervising the aide.

Response: While written patient care instructions for the aide must be prepared by a licensed professional, preparing the written care instructions includes overseeing the contributions from all disciplines involved in the plan of care and synthesizing those contributions. As a result, a discipline that is involved in the patient's care for a portion of their time on service would contribute its information to the clinician responsible for developing the written instructions.

Comment: We received several comments related to HHA supervision. One commenter requested clarification on § 484.80, stating ''please clarify 'professional'. Does this mean the actual professional (person) who completes the home health aide plan of care, or can any professional by discipline (for example, RN) perform the supervision?'' A commenter suggested that an RN, PT, or OT should be permitted to supervise home health aides. One commenter requested clarification on the requirements for supervision of aides caring for skilled care and non-skilled care, specifically the 14-day versus the 60-day minimum supervision timeframe requirement. Another commenter asked CMS to clarify that the CoP requires the aide supervisor make at least one home visit for each non-skilled case every 60 days rather than one home visit per home health aide every 60 days. Some commenters were opposed to the 14-day supervisory aide visit, requesting that we remove the timeframe entirely, while others stated that phrasing the time frame as ''every 2 weeks'' provides the agency with more flexibility. Other commenters stated that it is more practical to allow home health aide supervision to be performed during a regularly scheduled skilled visit and/or to occur when the home health aide is actually present in the patient's home, while another commenter noted that skilled visits may occur on an infrequent basis, such as every 3 weeks. Some commenters stated that requiring the aide supervision to occur onsite, as opposed to being completed via a phone call, adds undue burden on the HHA in the form of non-billable nursing visits.

Response: We appreciate the opportunity to clarify the requirements related to home health aide supervision. As originally proposed, the requirement expected that written patient care instructions for the aide would be prepared by the same clinician who would supervise the aide. However, the proposed requirement generated significant confusion, and we believe that it should be revised to be simpler. To that end, we have removed the requirement that written patient care instructions for the aide would be prepared by the same clinician who would supervise the aide. In its place, we are finalizing a requirement that the skilled professional who supervises aide services must be familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g). This revision accomplishes the same goal of assuring that the skilled professional responsible for supervision has all of the information necessary to effectively supervise the aide's services while removing the confusing regulatory language that was originally proposed.

We also appreciate the opportunity to clarify the aide supervision timeframes. If the patient is receiving skilled visits by an RN, PT, OT, SLP, then a supervisory visit is required at least once every 14 days. If the patient is receiving non skilled visits, meaning that RN, PT, OT, or SLP services are not being provided to that patient during that episode of care, then a supervisory visit is required every 60 days for each patient. While we acknowledge the request to change the ''every 14 days'' to ''every 2 weeks,'' we disagree that this is an appropriate substitute. The 14-day requirement provides a more reliably frequent supervision schedule, whereas ''every 2 weeks'' creates the possibility for excessively long gaps between supervisory visits. Lastly, we believe that supervision by phone is not adequate. Without the supervisor actually seeing the patient in person, the onus is placed on the patient to report substandard care. The patient is not necessarily qualified to recognize when standards of practice are not followed. It is the responsibility of the HHA to ensure patient care is being delivered according to best practices, as well as agency policies and procedures. However, if a patient or representative report a problem related to the delivery of aide services, the expectation would be that the problem is noted by the supervisor and an onsite supervisory visit to observe aide serves would occur. We believe in-person supervision is in the best interest of the patient, ensuring quality health care in a safe environment.

Comment: A commenter stated that they did not agree that if an aide performed task(s) unsatisfactorily, only an RN could subsequently supervise (rather than a LPN), stating that both RNs and LPNs are qualified to supervise home health aides. The commenter proposes that CMS consider allowing for the RN or LPN to be able to assess the aide's proficiency of the task in a laboratory setting in addition to the patient's home. Another commenter recommended that remediation on the skill that was deemed deficient be required, rather than a complete competency evaluation.

Response: A registered nurse is responsible for overall aide supervision; therefore we believe that it is appropriate to require that a registered nurse must be responsible for supervising an aide in a task for which the aide's skills have been determined to be unsatisfactory. In addition to this level of supervision, a competency evaluation is necessary in situations where an aide's skill is noted to be unsatisfactory because a deficiency in one skill area may indicate higher likelihood of deficiencies in the aide's other skill areas. A competency evaluation would provide HHAs the opportunity to note any additional skill deficiencies, as well as the opportunity to reteach aides on unsatisfactory skills, thus assuring safer patient care.

Comment: One commenter requested clarification regarding the wording of § 484.80(h)(1)(iii), stating that this requirement may be interpreted as either requiring the HHA to provide an annual on-site visit to one of the home health aide's patients while the aide is working or that the HHA has to do an annual visit on each patient being seen by each home health aide. The commenter also expressed concern that in § 484.80(h)(1)(ii), the term ''potential deficiency'' is undefined and lacks a timeframe for what and when potential deficiencies would require a follow-up visit by the supervisor. They recommended that CMS change the term ''potential deficiency'' to a more solid term necessitating follow-up such as ''identified deficiency.'' The commenter also requested further clarification of this requirement by including a time frame for the supervisor's site visit and adding this time frame requirement to § 484.80(h)(3).

Response: We appreciate the opportunity to clarify the requirements related to the aide supervisory visits. To clarify, the intent of this standard is to require supervision of each aide with at least one patient every year. We agree with the comments that the term ''potential deficiency'' may be misleading. Therefore we are amending

the language to state ''area of concern'', which is also consistent with the way we express this same concept in the hospice CoPs. Lastly, we disagree with the commenters suggestion to include a time frame for the supervisor's site visit and adding this time frame requirement to § 484.80(h)(3). We want to ensure the necessary flexibility to account for variations in aide visit frequencies to the patient's home, as some patients have more frequent aide visits while others have less frequent aide visits. We also want to allow HHAs to tailor the timing of the direct supervision to the urgency of the area(s) of concern, with those that may affect patient safety or outcomes requiring a faster response time.

Comment: One commenter requested clarification on whether the supervision elements set forth in (h)(4)(i) through (vi) must be documented on each aide supervisory visit. Lastly, one commenter requested clarification on what is meant by ''demonstrate specific communication skills''?

Response: All elements set forth in paragraph (h)(4) need to be accounted for in each and every supervisory visit. In other words, each supervisory visit would need to provide for and document supervision related to: Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional; maintaining an open communication process with the patient, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights. The phrase ''demonstrate specific communication skills'' was never used in the proposed rule, so we are unable to clarify its meaning or intent.

Compliance With Federal, State, and Local Laws and Regulations Related to Health and Safety of Patients

Comment: We received several comments regarding lab services, specifically, the prohibition on substituting home health agency equipment for patient's equipment. Several commenters suggested that CMS allow HHAs the flexibility of using agency equipment based on individual patient need and with the patient's consent when assisting with self-testing. A few commenters requested clarification regarding situations when a patient could not afford equipment, or when testing would be for a short period of time. Commenters also asked if testing would be covered by a CLIA waiver, and, if an agency does not have a CLIA waiver, would they be covered to use their own equipment. Another commenter asked whether a patient's refusal to obtain equipment would be a reason to discharge for cause.

Response: We proposed and are finalizing a requirement that HHAs may not substitute HHA-owned self-administered testing equipment for patient-owned self-administered testing equipment. As stated in the preamble to the proposed rule, ''Agencies may also use their own self-administered testing equipment for a short, defined period of time when the patient has not yet obtained his or her own testing equipment, such as in the days immediately following physician orders to obtain the testing equipment when a patient may not have the time and resources immediately available to complete the process. We would expect the HHA to use available resources to assist the patient in obtaining his or her own testing equipment as quickly as possible.'' We believe that this establishes a reasonable expectation for the use of HHA owned self-administered testing equipment on a short-term basis while a patient obtains his or her own equipment. HHAs are expected to help patients identify and access existing resources that mitigate or alleviate any potential barriers to obtaining this essential equipment. We believe that enabling patients to use their own equipment will improve the quality of care management that they experience and will avoid the potential for a patient to not have access to any testing equipment in emergency situations when HHA staff may not be immediately available to provide it. In cases specifically related to the use of self-administered testing equipment for purposes of blood glucose monitoring, if, despite all HHA efforts to help patients identify and access existing resources that mitigate or alleviate any potential barriers to obtaining this essential equipment, a patient refuses to obtain his or her own testing equipment, and if the patient is receiving the Medicare home health benefit, then the refusal to obtain self-administered testing could be grounds for patient discharge. Daily, and multiple daily visits for purposes of blood glucose monitoring over a long period of time would not meet the criteria for coverage of Medicare home health services under section 1861(m) of the Act, which prohibits payment for services that are more than part-time or intermittent. Therefore, an HHA would be permitted to discharge the patient because the payment source will no longer pay (see § 484.50(d)(2)). However, we believe that these situations are very rare. We would expect an HHA to thoroughly document all steps taken to resolve this issue, converse with the patient regarding the implications of this decision, communicate with the physician responsible for the home health plan of care and the practitioner who will be providing follow-up care, and provide the patient with information regarding other possible sources of care that may meet the patient's care preferences.

If the HHA is only assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration (regardless of appliance ownership status), the testing self-administration assistance is not required to be in compliance with the applicable requirements of part 493 of this chapter. However, if the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, then the testing must be in compliance with all applicable requirements of part 493 of this chapter.

Organization and Administration of Services

Comment: While one commenter strongly supported the proposed requirement that an HHA organize, manage and administer its resources to attain and maintain the highest practicable functional capacity for each patient's medical, nursing and rehabilitative needs as indicated by the plan of care, including overcoming those deficits that led to the patient's need for home health services, another commenter disagreed with this proposal. The commenter recommended revising the requirement from ''overcoming those deficits that led to the patient's need for home health services'' to ''providing optimal care to meet patient's identified needs.''

Response: We agree that revising this statement is appropriate to reflect the broad scope of HHA services that may be provided, including maintenance services. The revised is as follows, ''The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs.''

Comment: A commenter recommended a total revision of the

organization and administration requirements in a manner that removes established roles (for example, administrator and clinical manager) in favor of a structure that focuses on parent offices, where non-patient care administrative functions are performed and service locations from which patient care functions are performed.

Response: A revision of this extent would be a significant departure from the original proposal. Thus, we believe that, should we choose to act upon this recommendation, such actions would be most appropriately undertaken in separate rulemaking to allow all interested parties the opportunity to comment on such changes.

Comment: Several commenters suggested that the regulations should require an HHA to have a physician that serves as the HHA medical director, similar to what is already required in the regulations for nursing homes and hospices. Commenters suggested that the medical director be responsible for the following:

- Implementation of patient care policies;
- Coordination of medical care within the HHA;
- Coordination and oversight of related practitioners;
- Clinical leadership regarding application of current standards of practice for patient care and new or proposed treatments, practices, and approaches to care;
- Promoting attainment of optimal patient outcomes;
- Serving as a clinical resource when attending physicians are unavailable to ensure that urgent matters are addressed;
- Diagnosing changes in patient condition;
- Linking the HHA to the physician community to improve HHA-physician relationships; and
- Providing input for the HHA's QAPI program.

Additionally, commenters requested that the relationship between the medical director and the governing body be defined.

Response: A new requirement of this magnitude, both in terms of potential effect on HHA daily operations and HHA costs, would be a significant departure from the original proposal. Thus, we believe that, should we choose to act upon this recommendation, such actions would be most appropriately undertaken in separate notice and comment rulemaking to allow all interested parties the opportunity to comment on such changes.

Comment: Commenters agreed with the proposed role of the governing body, but asked for clarification regarding the composition of the group. A commenter asked if the Professional Advisory Committee could be considered the governing body for purposes of this rule. Commenters also asked if there were specific disciplines that would be expected to be represented in the membership of the governing body and if there were specific requirements for how often the governing body would need to meet. Lastly, commenters asked for further explanation of the proposal that the governing body would assume ''full legal authority'' for the HHA.

Response: An HHA may establish a governing body composed of individuals of its choosing. The individuals that comprise the governing body are those who have the legal authority to assume responsibility for assuring that management and operation of the HHA is effective and operating within all legal bounds. Those individuals could be members of the previously-required Professional Advisory Committee, but that is not a requirement.

Comment: Many commenters submitted comments regarding the proposed requirements for HHA administrators. Of those commenters, many requested clarification on whether a single administrator would be permitted to oversee the operations of multiple HHAs. Commenters suggested that HHAs should be permitted to use this arrangement if it could be demonstrated that the administrator could fully meet the requirements of the duties set forth in the proposed rule. Commenters suggested that, in order to permit this arrangement, the regulation should be revised to clarify that the administrator be immediately available ''in person or by telecommunications.''

Response: The HHA administrator is required, among other things, to be responsible for all day to day operations of the HHA (§ 484.110) and to be available to patients, representatives, and caregivers to receive complaints (§ 484.50(c)(3)). Our expectation is that the administrator will be actively involved in the daily responsibilities of running the HHA, and that HHAs will be able to demonstrate such involvement upon survey. We do not specify the manner in which this daily involvement must occur. We did not propose, nor are we finalizing, a requirement that each HHA have a full-time administrator. Therefore, it is permissible within these regulations for an administrator to work part-time for more than one HHA. However, we believe that the expectation of active involvement in daily operations and regular availability to patients, caregivers, and representatives would be difficult, if not impossible, for an administrator to meet if he or she is responsible for operating numerous HHAs on any given day.

Comment: A commenter suggested that the role of the administrator should focus on the function of the HHA, assuring accountability to the governing body, and managing problems that cannot be resolved on a clinical level. Another commenter suggested that the role of the administrator should include responsibility for acting as liaison with the governing body, employing qualified personnel, ensuring adequate staff education, and conducting evaluations.

Response: We agree that the administrator should be accountable to and should report information to the governing body, and have added this requirement to the final rule. We also agree that assuring that the HHA employs qualified personnel is a responsibility of the HHA administrator, and have made this change. This is particularly important for the hiring and oversight of all management roles within the HHA. We believe that this concept includes assuring the proper education and training of those staff being hired. Furthermore, we agree that managing problems that cannot be resolved on a clinical level is part of the role of the administrator. However, we believe that this concept is already embodied in the requirement that the administrator must be responsible for all day-to-day operations of the HHA. We do not agree that an HHA administrator would be responsible for conducting staff evaluations, as directly evaluating all staff would be an inefficient use of administrator resources, and would likely be the appropriate responsibility of other managers within the organization.

Comment: A commenter suggested that the regulations should require an HHA to have a qualified professional clinician available to provide clinical oversight during all operating hours. The commenter noted that the current HHA regulations require a supervising physician or nurse, or equally qualified person, to be available at all times during operating hours. The proposed regulation requires the administrator (who may or may not be a clinician), or a pre-designated person who is a skilled professional, be available during operating hours. The proposed regulation did not require the clinical manager (who is a registered nurse or physician) to be available during operating hours, and did not require a designee in the clinical manager's absence. Therefore, the commenter stated that there exists the potential for

a home health agency to be operating without the direction of a clinician during operating hours. For example, when the administrator is available, the proposed rule does not specify the need for any pre-designated skilled professional to be available as well. If the administrator is not a clinician, and the clinical manager is not on duty, the home health agency would be operating without a designated clinical manager.

Response: We agree with the commenter that, as originally proposed, the regulations created the potential for a situation where a home health agency would be operating without a designated clinician serving in a manager role. This was not our intent, and we greatly appreciate the commenter's insight into this matter. We believe that a gap in clinical leadership would pose a threat to patient health and safety, as clinicians in the field would not necessarily have ready access to clinical management expertise and guidance when needed. In order to remedy this oversight, we have revised the regulatory text at § 484.105(b)(1)(iii) to require that a clinical manager, rather than a skilled professional, be available during all operating hours.

Comment: Many commenters requested additional information regarding the process for designating an individual to act on behalf of the administrator in his or her absence. Commenters asked whether the person designated to fill the role of the administrator, also referred to as the administrator designee, would need to be registered with the State Survey Agency. Commenters also asked for information regarding the timing of the designation, wanting to know whether it could be done a few days prior to the administrator being on planned leave. In addition, commenters made suggestions regarding those responsible for authorizing the administrator designee. One commenter suggested that the administrator should be permitted to authorize the designee, while another commenter suggested that any one member of the governing body should be allowed to authorize the administrator designee.

Response: Section 484.100(a)(2), which implements section 1891(a)(2) of the Act, requires disclosure of certain specified information regarding an officer, a director, an agent, or a managing employee of the HHA. This statutory authority does not extend to individuals who may act in a management capacity on an episodic basis for a short period of time in the administrator's absence (for example, 2 weeks a year while the administrator is on vacation and on an occasional basis when the administrator is ill). However, if an individual were to act in a managing employee capacity as the administrator designee on a frequent or regularly scheduled basis (for example, 1 day a week every week, a few hours each day, or 2 weeks out of each month), then that individual would be a managing employee, and the HHA would be expected to disclose the required information in accordance with § 484.100(a). The timeframe for pre-designating the individual who will be responsible for fulfilling the role of the administrator in his or her absence should be established in each HHA's own policies and procedures. We note that pre-designation needs to be by both the administrator and the governing body as a whole. The time necessary to obtain governing body approval for the designation should be factored into the HHA's timeframe as established in its policies and procedures. The goal of this requirement is to provide management continuity within the HHA to the greatest degree possible. HHA staff should know and be able to verbalize upon interview whom the pre-designated individual(s) is/are for this role.

Comment: Several commenters made suggestions related to the number of administrator designees that an HHA should be permitted to have. Commenters agreed that having one administrator and one administrator designee may not be sufficient to allow for situations of illness, planned vacations, and various other factors. Some commenters suggested that three administrator designees may be appropriate, while others suggested having no limits to the number of designees that an HHA may select. One commenter suggested that, rather than have the governing body approve a single designated back up person to function in the absence of the administrator, the regulation should allow the governing body to approve the HHA's policy outlining how administrative oversight will be transferred in the absence of the administrator.

Response: The number of administrator designees should be determined by HHA needs and set forth in each HHA's policies and procedures. As stated previously, the goal is to provide continuity within the HHA to the greatest degree possible. HHA staff should know and be able to indicate to a surveyor whom the pre-designated individual(s) is/are for this role. We are retaining the requirement that the governing body must approve the pre-designated individual(s). The governing body is responsible for the administrator's appointment, and should be similarly responsible for the designee's appointment.

Comment: A commenter suggested that the regulation should clearly permit the clinical manager to serve as the administrator designee, as long as he or she meets the qualifications for the administrator as described in § 484.115(a).

Response: The clinical manager may be the designee, as long as he or she meets the personnel qualifications to do so. However, it would not be appropriate to specify this in the regulatory text, as such an addition may inaccurately imply that others within the HHA who also meet the personnel requirements would not be permitted to be the designee.

Comment: A commenter suggested that the term ''equally qualified substitute'' be used in place of ''pre-designated person'' to describe the individual who fills the administrator role in the absence of the administrator.

Response: We believe that both the ''qualified'' and ''pre-designated'' nature of the individual should be included in the regulation, and have added ''qualified'' to the regulatory text. An individual would be considered ''qualified'' to be the ''pre-designated individual'' by meeting the personnel qualifications for the administrator role as set forth in § 484.115(a).

Comment: A commenter requested clarification of the phrase ''operating hours'' as it was used in terms of the availability of the administrator. The commenter stated that HHAs typically have a nurse available to see patients 24 hours per day, and wanted to know if this availability would also mean that the administrator must be available 24 hours a day.

Response: As currently stated in the HHA interpretive guidelines (*http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf*), the term ''operating hours'' means all hours that staff from the agency are providing services to patients. For the sake of consistency, we intend to maintain this understanding of the term.

Comment: We received many comments related to the proposed requirement that each HHA have a clinical manager who is responsible for several duties. Many of these commenters were supportive of the new requirement, stating that it more clearly articulates the responsibility of the former supervising physician or supervising nurse role, ensuring that patient needs are continually assessed, and ensuring coordination of care,

coordination of referrals, and updating of plans, etc. While some commenters suggested that the role be eliminated altogether, other commenters sought clarification regarding its function, goals, and operational implementation. A commenter asked if this role was intended to be filled by the individual who would provide hands-on care in the field, or if it could be filled by a supervisor who may not be out in the field. Another commenter expressed a similar concern, asking whether the clinical manager would be responsible for oversight of certain agency functions (for example, making patient and personnel assignments, coordinating referrals, and assuring that patient needs were continually assessed) or whether the clinical manager would have to perform the functions himself. Some commenters asked whether multiple individuals would be permitted to fulfill the clinical manager role, noting that in large HHAs it may be difficult for one single individual to perform all of the proposed duties. Some suggested that multiple people could all do the same job, each for an assigned subset of the HHA's patient population, while others suggested that multiple people could divide the duties of the clinical manager role, such as one clinical manager is responsible for oversight of personnel and another clinical manager is responsible for patient care services. Other commenters suggested that the clinical manager should be permitted to delegate to other individuals, both clinical and non-clinical, to carry out the duties for which the clinical manager has oversight responsibility. Some commenters supported the idea that the clinical manager and the administrator should be separate roles filled by separate individuals, while other commenters stated that the roles should be permitted to be combined and filled by a single person.

Response: The clinical manager requirement is set forth as a list of responsibilities, such as coordinating patient care and referrals (§ 484.105(c)), in order to allow HHAs flexibility in its implementation. In a small HHA one clinical manager may fulfill all of these roles and for all patients. In a larger HHA, multiple clinical managers may divide up the HHA's caseload, and each clinical manager takes responsibility for assuring all of these functions for his or her caseload. Alternatively an HHA may have one clinical manager that delegates different aspects of the clinical manager role to different individuals, assuring that each individual performs the necessary duties and functions. The organizational structure for each HHA will vary, as set forth in each HHA's own policies and procedures. While we believe that it would be rare for a single individual to be capable of effectively fulfilling all of the responsibilities of the administrator and the clinical manager for an entire HHA, this rule would not prohibit this arrangement, provided that the individual meets the personnel qualifications for both roles as set forth in § 484.115 and the quality of care provided to patients is not compromised. However, we believe that in the vast majority of situations, HHAs will find it necessary to have at least two individuals fulfilling the administrator and clinical manager responsibilities separately.

Comment: Numerous commenters suggested that, in addition to permitting a registered nurse or a physician to fill the clinical manager role, the regulation should also permit a physical therapist, speech-language pathologist, occupational therapist, audiologist, or social worker to fill the clinical manager role.

Response: We agree that these skilled professionals may have the appropriate qualifications to fill this role. HHAs will be responsible for assuring that any skilled professional filling the role of the clinical manager has the necessary clinical, managerial, and communication skills needed to successfully fulfill his or her responsibilities as a clinical manager. The regulatory text regarding the qualifications for a clinical manager has been revised accordingly, and has been moved to the ''Personnel Qualifications'' section of the rule at § 484.115.

Comment: A few commenters opposed the proposal that the clinical manager be responsible for assuring the development of personnel qualifications and policies. Commenters stated that this is the role of the Human Resources staff, which has specialty knowledge regarding the legal rights and obligations of professionals relative to their employment with the organization. Commenters suggested that the development of personnel qualifications and policies should be the responsibility of the administrator and the human resources director, with approval from the governing body. Commenters also suggested that clinical managers should express the needs of the clinical program to the Human Resources staff so that those needs could be reflected in personnel policies (including, but not limited to, job duties, job knowledge, expectations relating to the submission of clinical notes, productivity expectations, and hours of work). These commenters suggested that it would be more appropriate to require that the clinical manager collaborate with the administrator regarding the development of personnel qualifications and policies.

Response: We agree that assuring the development of personnel qualifications, and policies and procedures, is a task more appropriately assigned to the administrator, rather than the clinical manager. We have revised the regulatory requirement at § 484.105(b)(1)(iv) accordingly. The administrator may choose to delegate these tasks to others, including the clinical manager, as appropriate, while retaining the responsibility for assuring that tasks are completed and duties performed.

Comment: A commenter recommended that the clinical manager be responsible for ''supervision of staff.''

Response: Both the proposed and final rule require that the clinical manager provide oversight of personnel. We believe that the broad concept of ''oversight'' already includes the narrower concept of ''supervision.'' The extent to which the clinical manager directly supervises personnel or delegates such functions to others, while maintaining responsibility for assuring that supervision is done appropriately, would be left to the discretion of HHAs as established in their individual organization structures, as well as their own policies and procedures.

Comment: A few commenters suggested alternate phrasing for the clinical manager requirement in a way that avoids creating a specific management position. While the commenters supported the concept of HHA staff members performing the duties set forth in the proposed rule, they opposed establishment of a specific managerial role for those duties. Commenters suggested that the regulation should identify the functions that need to be performed without using the ''clinical manager'' title, and require that ''a designated HHA staff member'' who is a qualified licensed physician or registered nurse provide oversight. One commenter suggested that the regulation should be re-named ''Oversight of Patient Care Services and Personnel.''

Response: As stated in the preamble of the proposed rule, our goal is to consolidate under the direct responsibility and authority of HHA management those areas that receive the most frequent deficiency citations. We believe that the clinical manager role is essential for managing the complex, interdisciplinary care of home health patients. Although the current HHA rule

addresses these issues, it does so in a decentralized manner that has not consistently led to the patient care outcomes that we seek to achieve in this rule. Six of the twenty most frequently cited survey deficiencies center on the need for patient care coordination and implementation, including the most frequently cited deficiency related to ensuring that each patient has a written and updated plan of care. These frequent deficiency citations indicate that patient care, as structured under the current CoPs, is not being sufficiently planned, coordinated, and implemented to ensure the highest quality care for all HHA patients at all times. As such, we believe that a new approach is needed in order to consistently achieve improved patient outcomes, and that consolidating these frequently deficient areas under the overall responsibility of a designated management position will address this need. HHAs may choose to organize one or more clinical managers in a manner that meets their needs, but we believe that this designated position is essential.

Comment: A few commenters expressed strong support for the proposed parent-branch relationship, particularly the proposal to remove distance between locations as a consideration in the branch approval process, stating that, distance should not be a consideration as long as the parent can demonstrate administrative control over the branch. Commenters also supported the proposed requirement that the parent office has direct day-to-day control and direct supervision of all activities performed and services provided by/from the branch office, including all contracts, personnel oversight, plans of care, services, quality control, etc. However, one commenter stated that the proposed rule did not go far enough in abandoning geography as an organizational consideration. The commenter stated that advancements in technology available to HHAs, including IT enhanced functions like clinical software (including, but not limited to, assessments, plan of care, and scheduling), IT support, payroll, communications, accounting/billing and many administrative functions, such as HR administration, insurance and strategic planning, are amenable to centralized configuration for multiple service locations, as opposed to decentralized provision of services and day-to-day supervision of services.

Response: We appreciate the support of most commenters, and believe that the proposed, and finalized, requirements strike an appropriate balance between the need for HHA flexibility in management and structure, and the need to assure accountability throughout an organization and its many possible locations in a manner that assures patient safety and high quality patient care.

Comment: While some commenters supported the proposal to discontinue the use of subunits, many commenters posed logistical questions regarding the conversion of existing subunits to branches or independent HHAs. One commenter indicated that its ''branches'' currently have their own provider number or NPI, and asked whether those ''branches'' that currently do have their own NPI will be required to be registered as a separate agencies. Other commenters noted that the current CMS Manuals indicate that there is a process for the conversion of a branch to a subunit; however, those Manuals are silent on the process for the conversion of a subunit to a branch or to a parent HHA. In light of this, commenters posed the following questions:

- How will the transition need to occur for patients who span the conversion in terms of claim submission? Will agencies need to close the patient under the subunit provider number and re-open the patient's care under the parent provider number? Will that require a new start of care and associated face-to-face evaluation?
- Will a subunit converting to an independent HHA automatically be ''recognized'' as an independent parent HHA without any further application or formal conversion process? As a part of that recognition, will the subunits converting be permitted to maintain their current CMS certification numbers (''CCN'') so as not to interrupt treatment, billing and reimbursement for current patients?
- Will subunits undergoing the conversion process to branches be treated as new enrollees?
- Will subunits undergoing the conversion process be required to submit new CMS Form 855A applications?
- Will subunits undergoing the conversion process be subject to survey as a ''new'' HHA?
- Will subunits undergoing conversion be required to discharge current patients and readmit them to the parent HHA or an alternative HHA provider during the conversion process?
- Will billing and claims processing for subunits undergoing conversion to branch offices be interrupted, and how?
- How will subunits being converted to branch offices be added to their parent HHAs' CCNs?
- If an 855A is required for a subunit being converted, is there a way to streamline the process for approval if the subunit has a positive compliance record?
- How will subunits undergoing the conversion process to become a branch be held accountable for data transmission, billing, and compliance during the transition process?

Response: HHAs with subunits will need to work through a wide variety of questions and concerns. As the commenters indicated, guidance related to converting a branch to a subunit is set forth in CMS manuals in section 2182.3 of the State Operations Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*). Similarly, we believe that the logistics of converting existing subunits to branches or independent HHAs is also more appropriately addressed in CMS manuals than in this regulation. Following publication of this final rule, we intend to issue a Survey and Certification letter to the states that will explain the change in terminology and revise the guidance to reflect the new terminology. Additionally, we will revise sections of Chapter 2 of the State Operations Manual that address branches and subunits to reflect the changes finalized in this rule.

Comment: Many commenters suggested that, in order to smooth the process of converting subunits to branches or independent HHAs, CMS should reprioritize approval of new branches and new HHAs from a tier 4 priority to a tier 1 priority in the State Survey Agencies and CMS Regional Offices.

Response: Subunits are already the equivalent of stand-alone HHAs and will be able to continue functioning as such, relieving the need to change to branches. Since there would be no threat to an HHA's ability to function and serve its patients, we do not agree that it would be appropriate for CMS to allocate survey resources to those HHAs that desire to, but do not need to, convert a subunit to a branch. Thus, the current process and priority levels will remain the same.

Comment: Numerous commenters stated that the final regulation should provide ample time for HHAs to convert a subunit to either a parent or a branch. Commenters stared that HHAs converting from subunits to independent parent HHAs may need to put into place a new governing body and/or appoint a new administrator, meaning that HHAs may need time to recruit, hire, train and integrate these individuals. Commenters also stated

that time may be needed for subunits to file new or amended state licensure applications and complete the processes necessary to obtain new or amended licenses. Lastly, commenters also stated that existing subunits in some states would have to seek and obtain permission from their respective state certificate of need agencies to convert to an independent parent HHA before they could even apply for the necessary state license. For these reasons, commenters requested a transition period of 6 to 12 months to ensure that HHAs have adequate time and preparation to come into compliance with the new parent-branch requirements that eliminate the use of subunits.

Response: All requirements set forth in this rule, including the removal of the subunit organizational structure, are effective July 13, 2017. We believe that this will provide HHAs with adequate time to make any adjustments for a subunit to begin operations as a stand-alone HHA.

Comment: One commenter suggested that the regulations related to HHA structure and parent-branch relationships could be streamlined by eliminating the requirement for bordering states to have reciprocal agreements in place in order to cross state borders. The commenter stated that this would negate the necessity of the separate provider number and resulting duplicative and unnecessary administrative costs. Agencies' offices in bordering states could then function under the revised branch definition, as proposed.

Response: This suggestion regarding reciprocal agreements between State Survey Agencies is related to the survey process, and is not within the scope of this rule, which sets forth the health and safety requirements for HHAs. Therefore, we are not addressing it in the rule.

Comment: A commenter requested reassurance that HHAs with existing subunits may choose to convert the subunit to either a parent or a branch at the HHA's discretion, subject to state-specific laws and regulations and the ability of the parent to demonstrate direct support and administrative control.

Response: The commenter is correct. A subunit may choose to be a distinct HHA (a parent) or go through the current approval process to become a branch.

Comment: A commenter expressed concern with the proposal that an HHA may not contract with an entity that has been denied Medicare or Medicaid enrollment; been excluded or terminated from any federal health care program or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been debarred from participating in any government program. The commenter asked whether the entity's attestation that it meets these conditions as part of the written agreement would be sufficient to demonstrate compliance with this requirement. The commenter stated that it would be very difficult for an HHA to obtain this information directly.

Response: We appreciate the opportunity to clarify this requirement. Enforcement of these provisions will vary based on the specific provision to be verified. In order to identify whether or not an entity has been denied enrollment or had its billing privileges revoked, we agree that written and signed self-certification is the most appropriate method to assure compliance because this is not publicly available information that HHAs can check on their own. However, we expect that HHAs will routinely check the List of Excluded Individuals and Entities (*https://oig.hhs.gov/exclusions/*). HHAs should also check the Special Advisory Bulletin (*https://oig.hhs.gov/exclusions/advisories.asp*). In addition, in order to check whether or not an entity has been debarred, in accordance with the debarment regulations at 2 CFR 180.300, an HHA may check the System for Award Management (*https://www.sam.gov/portal/SAM/#content*) or obtain self-certification from the entity. HHAs are responsible for assuring a contracted entity's continued good standing, and would be expected to establish policies and procedures for doing so.

Comment: A small number of commenters suggested that the regulations should permit those individuals who are employed by a ''Professional Employer Organization'' (PEO) to be considered a direct employee for purposes of the proposed requirement that at least one HHA service must be provided directly.

Response: It is our longstanding policy to establish a ''direct'' relationship between an employer and employee through the issuance of a W–2 by an employer to an employee without intermediaries. We did not propose to revise our longstanding policy and the commenters did not provide any evidence to demonstrate that the use of PEOs would improve patient health and safety. Therefore, we are maintaining current CMS policy that providing a service ''directly'' means providing a service by employees who are issued a W–2 by the HHA.

Comment: A commenter suggested that the regulation should be clarified so that a service would be considered to be provided ''directly'' in situations when that service is temporarily provided by supplementary contracted staff. For example, an HHA may employ a large number of nurses to provide nursing services directly, but use contracted supplement nurses in situations such as a medical leave of absence of an employed nurse or to fill an employed nurse position while the HHA hires a new nurse. The commenter stated that having one or two temporarily contracted staff should not preclude the HHA from designating that service as being provide directly by the HHA.

Response: In order to assure compliance at all times with the requirement of 484.105(f), which states that a HHA ''must provide at least one of the services described in this subsection directly,'' an HHA may not use contracted individuals to provide its chosen service directly.

Comment: A commenter suggested that the services of mental health professionals (Social Workers, Psychologists, Counselors, and Therapists) should be part of home health services.

Response: Medical social services are already part of the HHA benefit, as set forth in the Act. However, mental health services beyond those provided as medical social work services are not within the scope of HHA services as set forth in section 1861(m)(3) of the Act. For this reason, it would not be appropriate to include the services of other mental health professionals in this rule.

Comment: A commenter suggested that all regulations related to HHA financial planning should be removed or replaced by a regulation that focuses on the sufficiency of the HHA's operating budget to meet its needs and provide services to the patients in its care.

Response: The financial planning requirements for HHAs are set forth in section 1861(z) of the Act and these regulations implement those statutory requirements. Therefore, we are required to retain the financial planning requirements in this rule.

Clinical Records

Comment: We received many comments on the content of the clinical record. A few commenters supported the requirement, stating that it would decrease duplication by no longer requiring certain information (for example, physician name and drug, treatment and activity orders) be included in a dedicated part of the clinical record since this information is also in the plan of care, which is a part

of the total clinical record. Other commenters requested clarification on what was meant by the term ''current'' comprehensive assessment. One commenter questioned the rationale for requiring that the home health clinical record contain the current assessment, including all of the assessments from the most recent home health admission. This commenter went on to say that assessments from prior admissions would have limited value in providing an accurate picture of a patient without all other components of the clinical record from that time frame. Furthermore, ''most recent admissions'' leaves home health agencies in the position of having to guess at the required time frame and the number of assessments needed to meet the requirement. The commenter recommended that CMS remove the requirement to include the assessments from prior admissions in the current clinical record since these assessments can be retrieved and viewed in the context of the total previous record for 5 years, in accord with record retention requirements.

Response: The current assessment would be the assessment that was completed with the most recent date. We did not propose, nor are we finalizing, that the record must include assessments from prior admissions. The patient's record is meant to provide a full history of that patient's care and status while he or she is under the care of the HHA. Therefore, it must contain all assessments ever related to the patient's current admission. HHAs may choose to keep the most current/recent assessment in a different part of the record to differentiate it from older, out of date assessments, if that would improve clarity for users of the clinical record.

Comment: One commenter urged CMS to require listing the inclusion of contact information for caregivers, not just the patient and any representative, in the patient's clinical record (§ 484.110(a)). The commenter goes on to say that while the comprehensive assessment identifies caregivers and itself is part of the clinical record, specifically including contact information for the caregivers is appropriate in light of the various responsibilities specified for HHAs with respect to a patient's caregivers throughout the CoPs.

Response: We agree that, in addition to the patient representative contact information (whether legal or patient-selected), it is important to include contact information for the primary caregiver(s) as well. We believe this would be helpful to the HHA staff as they coordinate and deliver care. Therefore, we amended the language at § 484.110(a)(4) by adding this requirement to the final rule.

Comment: One commenter expressed concern that it may be difficult for some organizations to obtain and keep contact information for the patient's primary care practitioner who will be responsible for providing the patient's care after discharge. The commenter also states that the requirement is very broad in scope, and in many cases the practitioner who will care for the patient after discharge may work within a practice in which one specific provider may not be identified for the patient. In addition, the practitioner who will care for the patient after discharge may not be the same as the physician(s) writing home health orders for the patient. The commenter continues on to say that this is often problematic for organizations to determine which practitioner will be providing care for the patient after they have completed their home health visits.

Response: We understand the commenter's concerns with obtaining contact information for the patient's follow-up care practitioner. However, we strongly believe this information benefits the patient by supporting continuity and transition of care between the HHA and the primary care or other practitioner. The practitioner(s) who will be responsible for providing post-discharge care need to be identified in the record so that HHAs know with whom to communicate regarding discharge planning, as required in § 484.60(c). We understand that the patient's practitioner(s) may be different than the physician(s) issuing orders for the HHA plan of care, which is why we strongly believe that requiring separate identification of the practitioner in the patient's clinical record is so important. Lastly, we understand it may not be possible to identify the name and contact information for a specific practitioner where the practice as a whole furnishes care to the patient. In such cases it is acceptable for the HHA to include the contact information of the health care practice.

Comment: We received many comments regarding clinical records and the proposed discharge summary requirements. Some commenters supported the transfer/discharge requirement, with one commenter stating that they wanted to reinforce their belief that CMS was correct in assuming that most agencies do develop and send a discharge summary to the physician at the time of discharge. Many commenters stated that the 7 day and 2 day proposed timeframes to send the discharge or transfer summary was not enough time. Commenters stated that transfers and discharges could occur on weekends or holidays when staffing, specifically administrative staffing, is lower. Commenters suggested numerous alternative timeframes, as follows:

- 2 business (rather than calendar) days for transfer summaries.
- 7 business days for both discharge and transfer summaries.
- Transfer summaries on the day of transfer and discharge summaries in 2 calendar days.
- 5 business days for transfer summaries and 10 business days for discharge summaries.
- 7 to 14 business days for discharge summaries
- No timeframes for any summaries

Another commenter requested that if the HHA is not able to meet the timeframe requirements, CMS should permit the HHA to document the reason(s) in the medical record.

Response: We appreciate the wide array of comments. While most commenters believed that transfer and discharge summaries are important, the time frames suggested varied greatly. We believe both transfer and discharge summaries are important for care continuity and transitions. Transfer summaries prepared and sent on the day of transfer, and discharge summaries prepared and sent in 2 calendar days after discharge are ideal, and we strongly encourage all HHAs to meet these timeframes. However, we understand that this may not be feasible in all transfer and discharge situations. The CoP requirements are meant to establish maximum timeframes. Thus, we believe that 2 business days for a transfer summary and 5 business days for discharge summary are appropriate maximum standards, and have amended the regulatory language at § 484.110(a)(6)(i) and (ii) to reflect these new timeframes.

Comment: Some commenters stated that HHAs may not know that a patient was transferred to a facility for several days after that transfer has occurred, and therefore suggest starting the 2 day clock when the HHA becomes aware of the transfer. In addition, one commenter stated that no discharge/transfer summary for urgent/emergent admissions should be required, because HHAs usually do not know about these until several days later, and providing discharge/transfer summary days after the fact is not helpful to the receiving provider. One commenter suggested that the regulation should not require HHAs to send discharge or transfer summaries to hospitals; while another commenter

requested CMS to consider allowing the HHA to develop their own policy on how to best communicate patient information at the time of transfer or discharge, which could include a verbal or written report. The commenter stated that in many cases, it is uncertain who at a hospital should receive the information. Additionally, the commenter stated that, generally, the discharge or transfer information would not be used in the diagnosis or treatment of the hospitalized individual.

Response: We understand the commenters' concerns regarding the issues surrounding an unplanned transfer to a facility, and agree that it would be difficult for the HHA to comply with the requirements if it was not aware that the transfer had occurred. Therefore, we have amended the regulatory requirement at § 484.110(a)(6)(iii) to require that the HHA sends a completed transfer summary within 2 business days of becoming aware of an unplanned transfer, only if the patient is still receiving care in the receiving health care facility at the time when the HHA becomes aware of the unplanned transfer. We believe that this revision strikes an appropriate balance between sharing information, when such sharing has the potential to be helpful because the patient is still under the care of the inpatient provider, and conserving HHA resources when the patient has been admitted and discharged from the inpatient care provider before the HHA is even aware of the situation. In the future, as the use of interoperable health records becomes widespread in the HHA industry, we may consider a shorter timeframe for sending a transfer summary in order to make the information exchange more timely and relevant to patient care.

Comment: One commenter suggested that transfers without an agency discharge, where the agency will be resuming care, should require that a transfer summary be provided only if a transfer summary was requested by the receiving facility. In addition, others stated that a transfer summary would only be needed if a patient was being discharged with no plan to return to the HHA. Another commenter suggested that an agency should be relieved of this requirement if the patient was admitted to home health from a facility and returned to that same facility.

Response: We appreciate these comments. While we understand that patients may be discharged for a period of time and then return to the HHA, we strongly believe that a transfer summary should be proactively sent, and that this information benefits the patient by supporting continuity and transition of care between the HHA and the receiving facility or practitioner. Therefore, no additional changes have been made to the transfer summary requirements at § 484.110(a)(6)(iii).

Comment: One commenter stated that CMS may want to consider including the requirement to send the discharge or transfer summary in § 484.60(e), Discharge or transfer, in addition to or instead of § 484.110(a), Contents of the clinical record. This requirement is more aligned with care coordination than clinical records, and moving its placement could make it easier to find for HHA staff working on discharge policies.

Response: While this requirement could also be grouped with those related to the content of the discharge or transfer plan, it is equally appropriate to include this requirement in the clinical record section because it addresses timeframes for distributing items that are maintained within the clinical record. In developing their own policies and procedures surrounding the discharge or transfer process, HHAs are free to gather information from all sections of the CoPs that are appropriate to inform the development of relevant HHA policies and procedures.

Comment: One commenter recommended that the regulation require the HHA to send a copy of the discharge or transfer summary to the patient, representative (if any) and the caregiver.

Response: Section 484.60(c)(3)(ii) requires that changes in the discharge plan must be communicated to the patient, representative and caregiver. We believe that this communication is appropriate and necessary for the patient, representative and caregivers. However, the discharge and transfer summary is written for medical professionals and is not necessarily appropriate for the patient's use. Therefore, we do not think that it is necessary to require HHAs to provide a copy of the discharge summary to each patient. Additionally, HHAs are required to educate patients and caregivers regarding their roles in implementing the plan of care, so patients and caregivers should already have the knowledge and skills necessary to meet any ongoing care needs following cessation of home health services.

Comment: We received a few comments regarding the proposed clinical record authentication requirements. Some commenters supported the need to document the actual time of administration of treatments and/or medication administration, but were unsure as to why each entry into the record, which is not a time sensitive issue, must be timed. In addition, one commenter requested that CMS clarify ''timed'' in the sentence ''dated and timed.'' One commenter also went on to ask if this requirement would include all records of case conferences, phone calls, interdisciplinary communications, etc. be timed and dated; and if so, what would be the supporting reasoning as to the need to time such communications. An additional commenter also supported this requirement but noted that these requirements are often part of organizational policy. This commenter went on to state that some organizations will have difficulty meeting the requirements due to failure of staff to date and time their entries and encourages CMS to provide education for all home care organizations on these requirements.

Response: There seems to be confusion related to what we mean by the term ''timed.'' To clarify, ''timed'' means the actual time that an event occurred, which is not necessarily the time when the documentation was entered into the record. The date and time requirement applies to all entries in the record. We believe it is extremely important that the clinical record accurately reflects a clear account of the patient's entire course of care. The clinical record should tell a linear story of the course of the patient's care that is managed and delivered by the HHA. Without timing entries, there is the risk for a disjointed record and a possibility for the occurrence of avoidable medical errors.

Comment: We received a few comments on authentication. One commenter requested that the regulations be more specific about what is required for electronic signature, and require electronic audit trails which show if any changes were made in a patient's electronic health record, exactly what changes were made, who made those changes, and when those changes were made in all electronic health records. The commenter stated that HHAs experience problems with vendors when HHA surveys identify documentation problems. One commenter recommended that language relating to ''signature and title'' be replaced with the broader requirement for ''authentication'' without specifying how that authentication would be accomplished. Lastly, one commenter recommended that CMS allow providers that maintain clinical records electronically to scan the ''signature'' documents and then destroy the paper copies.

Response: We appreciate the comments received on the subject of record authentication. ''Electronic signatures'' may mimic paper signatures, complete with a signature and a title (occupation), or may be a secured computer entry by an identifier that is unique to the individual creating the entry. These requirements, particularly those for a ''signature and title'' are standard practice, and we see no reason to deviate from them at this time. While we understand that HHAs may desire to destroy paper copies of signature documents in order to reduce physical paper storage space, we believe that maintaining the original, signed paper documents is essential for purposes of authentication of the documents. Furthermore, while we agree that electronic audit trails may be a useful tool for some HHAs, we do not believe that they should be incorporated into the regulations as a minimum requirement for all HHAs because there is more than one way for an HHA to achieve the goals accomplished by electronic audit trails. Furthermore, electronic audit trails would not apply to those HHAs that choose to use paper records. HHAs bear ultimate responsibility for continuous compliance with the requirements of these regulations, and are expected to manage all contracts, including those with software vendors, to assure such compliance. We urge HHAs to engage in due diligence to ensure that their vendors are providing them with EHR technology solutions that support patient health.

Comment: CMS received a few comments on record retention. One commenter recommended that retention of records mirror the timeframes in other federal law or regulation. For example, 5 years does not correlate with requirements for HIPAA or the look back periods for recovery audit contractors or zone program integrity contractors. While another commenter supported the 5 year time frame; stating it simplifies the timeframe during which the patient's records are kept (5 years from discharge as opposed to from filing of cost report) and for some states record retention regulations are stricter, requiring records be held form 6 years. Therefore this standard would not impose burdens on agencies in the state.

Response: We believe that retaining records for a period of 5 years is sufficient for health and safety purposes. We acknowledge that other rules may exist that contain different record retention or compliance documentation timeframes. HHAs need to develop their own agency-specific policies and procedures to assure that records are retained in accordance with the law, regulation, or policy that requires the longest retention period, which may exceed the 5 year period established here.

Comment: We received a few comments on the availability of clinical records. One commenter supports the standard, stating it facilitates access to records by patients, authorized individuals and entities to ensure transparency and continuity of care. Another commenter requested clarification on the timeframe for making records available, stating that, in cases where individuals are onsite awaiting information, HHAs should be allowed sufficient time to assemble records. In many HHAs, not all materials are electronic, including signed verbal orders, files from hospitals, and other content. HHAs may need several hours to compile the most up-to-date records. For other purposes, the commenter recommended that HHAs be allowed a minimum of 4 business days to make records available. Another commenter stated that this proposed condition will encourage more requests for copies of medical records which will increase costs. The commenters internal analysis indicates that as much as $230,000 annually may be incurred on HHAs should there be a large increase in medical record requests and urges CMS to acknowledge the increase in costs of this requirement.

Response: We believe that all patients should have the right to receive information contained in the clinical record, including the plan of care, free of charge. We agree with the commenter that suggested HHAs be allowed a maximum of 4 business days to make records available. Additionally we understand that the HHA may have another scheduled visit with the patient before the 4-day mark and that it would be advantageous for the HHA to deliver the record at that next scheduled visit. Likewise, if a patient requests to have the plan of care emailed, the HHA would have a maximum of 4 business days to comply. Therefore, we are finalizing this requirement to state that ''[a] patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).'' HHAs may also be governed by state laws and regulations that pertain to this issue, and are expected to comply with such laws and regulations to the extent that they provide greater rights of patient access than HIPAA. We also understand and agree that it may take several hours to assemble a complete clinical record to be reviewed onsite, such as for state surveyor review. We do not think that this regulation is going to dramatically increase record requests. For additional information and guidance on the HIPAA requirements for patient access with which HHA's must also comply, please see guidance issued earlier this year from the OCR available at *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html*.

Comment: We received several comments related to electronic health records (EHRs). A few commenters stated that incentives should be given to offset the costs and detailed training guidelines should be offered to HHAs who make the switch. One commenter offered support for EHRs, stating that they encourage the exchange of health information across all providers to improve the quality of care and care transitions. According to commenters, EHRs have been proven to reduce medical error rates and help improve the coordination of patient care. Therefore, according to commenters, assisting HHAs in making the leap to EHRs would be beneficial to improving the quality of patient care.

Response: We appreciate the commenter feedback related to EHRs. The Department of Health and Human Services is committed to accelerating health information exchange through the use of EHRs and other types of health information technology (health IT) across the broader care continuum through a number of initiatives including: (1) Alignment of incentives and payment adjustments to encourage provider adoption and optimization of health IT and health information exchange services through Medicare and Medicaid payment policies; (2) adoption of common standards and certification requirements for interoperable health IT; (3) support for privacy and security of patient information across all health information exchange-focused initiatives; and (4) governance of health information networks. These initiatives are designed to improve care delivery and coordination across the entire care continuum and encourage the electronic exchange of health information among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for such programs. However, providing additional incentives to any provider, including HHAs, is beyond the scope of this rule and subject to the limitations of statutory authority.

Comment: One commenter believes that HIE, in theory, is an outstanding idea. The efforts nationwide, however, are scattered and of varying success. In

the absence of ACA funding, some are failing. The commenter stated that he does not believe that use of an HIE should be addressed in the CoPs. With regard to interoperability, the commenter recommended consideration of the most recent ONC statement on interoperability, and stated that at this time full interoperability is too far in the future to make HIE an element of CoPs. Another commenter stated that a certification program, required or voluntary, cannot be successful without industry and provider commitment to the necessity of such a program and without participation requirements applicable to the provider community. The commenter also expressed concern that voluntary or required certification without the implementation of Meaningful Use Stage 3 will neither substantially improve the alignment of existing federal and state programs nor appropriately balance the required costs and benefits due to the current low adoption rates of Meaningful Use Stage 2 requirements by hospitals and other eligible providers.

Response: We agree that this is not the appropriate time to require, in the CoPs, the use of HIEs or compliance with any stage of the Meaningful Use criteria. We will continue to monitor the voluntary use of certified record systems and HIEs, and would use the notice and comment rulemaking process to promulgate any future HHA regulations related to these issues.

Comment: One commenter stated that it was important to point out that as a result of the growing discussion related to the use of massive collections of data, an integrated information database that is aimed at improving quality standards in HHAs and aimed at a more comprehensive approach towards current and long term health care specifically designed for each individual patient could be a wonderful tool if used correctly. The commenter cautioned, however, that the amassing of data and the technology that is used to analyze it may be vulnerable to exploitation.

Response: We agree that it is incumbent upon HHAs to appropriately secure data, and the systems used to collect and analyze it, against inappropriate access and use. Section 484.110(d), Protection of records, requires that HHAs must be in compliance with the HIPAA Privacy and Security rules regarding protected health information set out at 45 CFR parts 160 and 164. We believe that this requirement establishes an appropriate expectation of security in the maintenance of patient data, and the systems used to collect and analyze it. In addition to the steps taken by HHAs to assure the confidentiality of data that they collect, CMS takes all appropriate steps to assure the security of all data that is submitted to CMS by HHAs.

Personnel Qualifications

Comment: We received many supportive comments regarding personnel requirements. One commenter supported the retention of the requirement that ''social work assistants'' be supervised by a qualified social worker. One organization strongly supports the proposal to retain personnel qualification requirements, including those for occupational therapy. This commenter stated that keeping the qualification requirements intact protects the public health, safety, and welfare of the patients served by occupational therapy practitioners and ensures that services are performed by trained and qualified providers.

Response: We appreciate the support of the commenters, and agree that establishing minimum personnel qualifications is an essential part of assuring the safety and quality of HHA care.

Comment: We received many comments on the personnel qualification of the administrator. A few commenters requested that CMS grandfather in the current administrators, with one commenter stating that there should be an exception policy in place that acknowledges years of experience in the Medicare certified home health field as an appropriate qualification for a home health administrator. One commenter stated that they applaud expanding the standard for eligibility for the administrator. The commenter added that they supported the role of administrator being provided by persons with skill sets that do not require medical or nursing degrees. A few commenters requested that CMS not require a degree and experience, stating that experience all on its own is good enough and requiring both is too burdensome. One commenter stated that an undergraduate degree and 1 year of experience does not seem adequate to fulfill the role of administrator, which requires knowledge in many areas. The commenter suggested that a graduate degree or specialized clinical certification and additional years of experience in management would be appropriate. Another commenter advised that CMS not have any qualification requirements.

Response: It was not our intent to disqualify any currently employed administrator from continuing to perform his or her job duties with his or her current employer. Therefore, we agree that administrators who do not meet these qualifications should be allowed to continue employment in their current position, and we have revised the regulation at § 484.115(a) to reflect this policy. In light of the various suggestions from the public regarding the appropriate qualifications for those administrators that begin working for an HHA after the effective date of this final rule (July 13, 2017), we have chosen to finalize the originally proposed requirement. An administrator who begins working for an HHA after the effective date of this final rule, even if he or she was previously employed as an administrator for a different HHA, is required to be a licensed physician, a registered nurse, or hold an undergraduate degree. A registered nurse would include a Nurse Practitioner or other advance practice nurse. Additionally, an administrator who begins working for an HHA after the effective date of this final rule is required to have experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program. We believe that this combination of education and experience requirements strikes an appropriate balance between those commenters who sought to require that an administrator must possess a graduate degree and those who sought to remove all personnel requirements for an administrator. Furthermore, we believe that adding these personnel requirements for all future administrators will serve as a disincentive to the creation of HHAs that are operated with fraudulent intent, as many of these entities are opened by individuals who would not meet these minimum qualifications. Such HHAs pose a significant threat to the health and safety of Medicare beneficiaries in need of HHA services. The personnel requirements set forth in this rule are the minimum requirements. HHA governing bodies may establish more stringent requirements that meet the needs of their organizations.

Comment: We received one comment on the personnel requirements for occupational therapists and one comment on occupational therapy assistants. The commenter stated that the qualifications for occupational therapists are almost identical to current regulation. However, the current regulations allow therapists educated abroad to meet part of the necessary criteria by successfully completing a program that is substantially equivalent to occupational therapist entry-level

education in the U.S. offered by one of four categories of organizations. In the proposed rule, the therapist must have successfully completed a program that is substantially equivalent to occupational therapist assistant entry-level education in the U.S. by one of the four categories of organizations. The commenter questioned why the word ''assistant'' appears here, since there is a separate set of qualifications for occupational therapy assistants. The commenter who asked about occupational therapy assistants is requesting clarification stating that the qualifications outlined in the proposed rule for an occupational therapy assistant are almost exactly the same as those in current regulation. However, the proposed rule states that an occupational therapy assistant is a person who ''[a]fter January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.'' There is no paragraph (b)(6)(i) in the proposed rule text.

Response: Our intent was to maintain all of the current qualification options for occupational therapists and occupational therapy assistants, without change. We have revised the regulatory requirements to correct these technical errors.

Comment: We received a few comments on the personnel qualifications for physical therapists and physical therapy assistants. For physical therapists, one commenter requests clarification, stating that in the proposed rule, physical therapists must be licensed (if applicable) and must meet one of several additional categories of qualifications. In current regulations, the first category requires physical therapists to have successfully completed a physical therapist education program and passed an examination for physical therapists approved by the state. In the proposed rule, the word ''and'' is dropped, and the text is renumbered in a way that could imply that either education or passage of an exam is acceptable. An additional commenter requests clarification as to whether CMS intended to propose this change, stating that under current standards, the fifth category requires a physical therapist to have been admitted to membership by the American Physical Therapy Association (APTA); or admitted to registration by the American Registry of Physical Therapists; or have graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education. In the proposed rule, the fifth option includes the above mentioned membership, registration and graduation from a physical therapy curriculum. We received one comment on physical therapy assistants requesting that CMS consider clarifying and revising the qualifications for physical therapy assistants. This commenter stated that under the proposed rule, a physical therapy assistant is a person licensed, registered or certified as a physical therapy assistant, if applicable, by the state in which the assistant is practicing, unless licensure does not apply. In addition, the assistant must meet one of two other categories of criteria. In the first category, the assistant must meet the same specified education as listed in current regulations. In the second category, the assistant must have passed a national exam for physical therapist assistants before 2010, and he or she must meet one of the following criteria:

- Is licensed, or otherwise regulated in the state in which practicing; or
- In states where licensure or other regulations do not apply, graduated before 2010 from a 2-year college-level program approved by APTA and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

The commenter stated that it was unclear what was meant by the reference to (b)(8) of this section, as there was no (b)(8) in the proposed regulations text.

Response: We did not intend to alter the content of the requirements for physical therapists and physical therapy assistants in any way. Any appearance of alteration is due to changes in numbering and/or the unintentional switching of the terms ''and'' and ''or'', which we have revised accordingly in this final rule. We have also made other technical corrections, as described in this preamble.

Comment: We received several comments that noted the definition of Physician at 42 CFR 410.20(b) is not consistent with the specialties of physicians who may certify and establish the plan of care for home health services in the regulation at 42 CFR 424.22(a)(1)(iii). The commenter recommended the requirements for a physician should refer to 42 CFR 424.22(a)(1)(iii).

Response: The personnel requirements for a physician refer only to those physicians who are employed by, or are under arrangement with, an HHA. These requirements would not apply to hospital and community-based physicians who are responsible for issuing orders that establish the home health plan of care, as they would function outside of the purview of the HHA. The requirements set forth at § 424.22(a)(1)(iii) are specific Medicare payment requirements for physicians who certify the eligibility of patients for the Medicare home health benefit. We do not believe that it would be necessary or appropriate to narrow down the group of physicians who are eligible for HHA employment to just those physician types set forth in the payment regulations because HHA physicians may perform many roles that do not relate to certification of HHA patients.

Comment: We received a few comments on the personnel qualifications for social workers. One commenter supported the addition of doctoral degree as a qualification option. Another commenter stated that baccalaureate (BSW), master's (MSW), or doctoral degree in social work is the only sufficient preparation for social work.

Response: We agree that a master's or doctoral degree is an appropriate qualification, and are finalizing this proposal without change. HHAs may choose to further restrict those individuals who are employed as social workers in order to meet their specific needs; however we do not agree that it is appropriate for these regulations to impose such a restriction, as it would disqualify many long time social workers who happen to have degrees in other related fields. Therefore we are maintaining the current requirement that a degree in a related field would be considered an appropriate qualification for a social worker.

Comment: We received one comment on the personnel qualifications for speech language pathologists. Specifically, this commenter states that CMS is correct in the assumption that all states now have licensing requirements for speech-language pathologists (SLPs). However, the commenter asserted that ASHA certification and completion of a degree from a Council on Academic Accreditation in Audiology and Speech-Language Pathology (CAA) approved program remains the standard and ensures that speech-language pathologists are participating in a minimum number of continuing education hours. Additionally, not all U.S. Territories have licensure; therefore, continued use of ASHA certification is warranted. The commenter recommends that CMS continue to reference ASHA certification for minimum qualifications and requests that the revision maintain the ASHA certification.

Response: Section 1861(ll)(4)(A) of the Act, on which the regulation is based, does not limit SLPs to only those individuals who meet the ASHA certification standards. Since this

limitation does not exist in the Act, we do not believe it should exist in the regulations. Therefore, in order to align the regulatory requirements with those requirements set forth in the Act, we are not making the suggested change. States are free to require ASHA certification as part of their SLP licensure standards.

Comment: We received one comment on the personnel requirements for the clinical manager. The commenter states that while they support the creation of the clinical manager position, they advise that CMS consider the inclusion of specific qualification requirements for the clinical manager, since there are frequent deficient practices related to reassessments, referrals, coordination of care and updating plans of care.

Response: We agree that it is appropriate to establish minimum personnel requirements for clinical managers. In the October 2014 proposed rule we proposed that a clinical manager be either a licensed physician or RN (79 FR 61164, 61183). As stated previously, commenters also suggested a therapist or social worker could fill this role. We agree that those professionals may also be qualified to fulfill the duties of the clinical manager. Thus, we are finalizing a requirement at § 484.115(c), Clinical manager, requiring that a clinical manager be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse. A registered nurse would include a Nurse Practitioner or other advance practice nurse.

Comment: We received a few comments related to criminal background checks. Specially, one commenter stated that background checks should be done for all staff members, especially those who plan to go to a patient's home to deliver health care. A few additional commenters advised that CMS should require reasonable and appropriate standards for criminal background screenings and that criminal background checks should be required for all owners, operators, or employees that have direct patient contact or access to patient records in order to validate competency according to minimum standards established by the Secretary.

Response: The National Background Check Program (NBCP), as established by the Affordable Care Act, aims to create a nationwide system for conducting comprehensive background checks on applicants for employment by the LTC facilities and providers. The term ''long-term care facility or provider'' means the following facilities or providers: Skilled nursing facility, nursing facility, home health agency, provider of hospice care, a long-term care hospital, a provider of personal care services, a provider of adult day care, a residential care provider that arranges for, or directly provides, long-term care services, including an assisted living facility, an intermediate care facility for the intellectually disabled, and any other facility or provider of long-term care services as the participating state determines appropriate. Prior to passage of this law and creation of the NBCP, many states already required background checks for LTC workers, but state requirements and programs varied. The intent of the NBCP is to set-up a standard, effective, and economical program to conduct background checks that also includes fingerprint-based criminal history checks. The U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) administers the NBCP. Since the start of the program in 2010, CMS has awarded nearly $57 million in grant funds to a total of 25 states and U.S. Territories to design, implement, and operate background check programs that meet CMS criteria. We believe that this comprehensive program that fosters consistency in implementation is a preferable way to improve the volume and scope of background checks that are conducted for HHA employees and contractors.

Summary of Care

Comment: We received many comments on the removal of the 60-day summary of care requirement (79 FR 61166). A few commenters supported the elimination of the summary of care notification every 60 days. One commenter stated that their physicians did not see true value in having another document to review, but instead valued the verbal communication with them at pertinent times related to the care and treatment of their patient(s). Other commenters requested clarification as to whether it would be expected that the information typically contained in the summary of care notice would be provided to the physician by some other means or format. However, other commenters did not support the removal of the summary of care every 60 days. These commenters stated that, although immediate communication of timely events is undeniably important, it was not equivalent to summarizing the patient's status to the physician at the time of recertifying the plan of care because physicians do not always remember the relevant recent issues concerning a particular patient when asked to review and recertify a plan of care. Another commenter stated that CMS did not offer any other support or justification for this change. A commenter also stated that the Impact Analysis was unclear, specifically, the calculation that this requirement ''imposes a burden of 3 minutes per patient'' (it was unclear if CMS meant 3 minutes every 60 days or cumulatively for a year), and that removing the provision would amount to a savings of nearly $17 million annually.

Response: Section 484.60(c)(1) requires that the HHA must promptly alert the physician(s) issuing orders for the HHA plan of care to any changes in the patient's condition or needs that suggest that outcomes were not being achieved and/or that the plan of care should be altered; the requirements at § 484.60(c)(3) requires that revisions to the plan of care due to a change in health status or a change in discharge plans be communicated to the physician issuing orders for the condition(s) that led to the initiation of home health care who was responsible for the HHA plan of care; and § 484.75(b)(7) requires that every skilled professional be responsible for communicating with the physician(s) issuing orders for the HHA plan of care. All three of these requirements in this final rule clearly establish the expectation that HHAs would apprise physicians of the information necessary to make appropriate decisions regarding the content of the plan of care at all times. We do not believe that a 60-day summary of care is a necessary regulatory requirement on top of the requirements referenced above. The burden imposed by the summary of care was originally estimated in the currently-approved PRA package (OMB control number 0938–0365), originally published in the **Federal Register** on July 12, 2013 (78 FR 41931).[1] The burden estimate assumed a burden of 3 minutes per patient to develop the summary of care, and assumed that each patient would only be in HHA care long enough for a single 60-day summary of care to be prepared. We did not receive any public comments on this estimate at that time, and believe that they continue to be appropriate to use in this rule for purposes of estimating potential savings to HHAs. Savings to individual HHAs may be greater or lesser, depending on the HHA's average length of stay and technical capabilities to automate the production and distribution of the summary of care.

[1] This collection will be discontinued when a new collection is approved which will better align the PRA package with new regulations.

Miscellaneous

Comment: We received a few comments related to home health agency surveys. One commenter stated that home health agencies should go through a health accreditation every year based on how their patients receive care. Other commenters strongly urge CMS to ensure that the interpretive guidelines provided to surveyors are developed in collaboration with stakeholders across the industry, either through direct participation in their development or by providing an opportunity for stakeholders to comment on such guidelines before they are used for enforcement purposes. Other commenters encouraged CMS to share all such interpretive guidelines and surveyor training materials with HHAs prior to the start of enforcement.

Response: We appreciate the comments on this subject. However, the survey schedule, survey guidelines, and surveyor training materials are not within the scope of this rule.

Comment: One commenter asked if patients can receive care at their home if they are unable to go to a hospital. In addition, the commenter requested clarification on the kind of benefits patients can receive.

Response: The services covered under the Medicare home health benefit are set forth in section 1861(m) of the Act, as implemented in regulation at 42 CFR 409 subpart E. Medicaid and private insurers establish their own requirements for services, and we encourage the public to contact the relevant programs for any information that may be needed. HHA services are not meant to be a substitute for acute care providers, such as hospitals, in urgent and emergent situations. Rather, HHAs are expected to deliver part-time or intermittent skilled care to homebound patients who would otherwise receive care in an outpatient setting such as a physician office or physical therapy office, but who are confined to the home.

Comment: A few commenters suggested ways CMS could improve patient engagement. One commenter suggested that providing Medicare beneficiaries with materials similar to the annual update to *Medicare & You* that offer more details on the home health benefit and its requirements would be a place to begin. The commenter also suggested that a YouTube segment explaining the benefit would help beneficiaries, their families, and other caregivers. A few commenters stated that it would also help to hear from home health agency patients and their families to gather information about the quality of service they were observing, the necessity of certain procedures, and how they thought the quality of care was meeting the standards set out in the proposed rule.

Response: We appreciate these suggestions for additional Medicare outreach options. However, Medicare outreach to beneficiaries is beyond the scope of this rule. We will retain these suggestions for future consideration. We agree that a patient care survey is a valuable tool for quality of care purposes, and implemented the Home Health Consumer Assessment of Healthcare Providers and Systems survey in October 2009 (*https://homehealthcahps.org/*).

Comment: We received many comments on referrals. One commenter suggested that CMS should educate other providers about the value of home health care. One commenter urged CMS to clarify, in regulation, that care referrals to HHAs by emergency departments and other care settings are appropriate. The commenters also suggested that we publish guidance on appropriate care coordination pathways that would encourage referrals to HHAs, making them more likely and possible. Another commenter encouraged CMS to help HHAs educate emergency departments and other providers to make more frequent and appropriate use of home health care for a growing volume of beneficiaries with complex health conditions. Lastly, one commenter recommended that CMS consider updating the number of paid medical consultants, medical directors, and physicians who are permitted to refer patients to home health services.

Response: We appreciate these suggestions for referral source outreach. However, this topic is beyond the scope of this rule. We will retain these suggestions for future consideration.

Comment: We received multiple comments related to HHA payment policy issues. Some commenters stated the CMS should increase Medicare/Medicaid rates for home health services. Another commenter suggested that CMS should grant greater flexibility in the coverage and reimbursement of home monitoring for oral anticoagulation therapy, including CMS coverage for home visits by nurses to patients who find it difficult to do their own home monitoring or travel to get tested. One commenter requested that CMS provide funding to HHAs so that they can develop the computer and related systems needed to share data with physicians, hospitals and other providers.

Response: We appreciate these suggestions related to Medicare home health coverage policy and Medicare payment rates. Medicare home health coverage policy and payment rates are addressed in separate annual rulemaking, and comments related to this topic can be submitted during that process. This topic is beyond the scope of this rule therefore, we are not addressing these suggestions at this time.

Comment: Numerous commenters made suggestions for ways to revise Medicare home health coverage policy. One commenter requested that CMS consider permitting non-physician practitioners to perform face-to-face encounters and to sign a patient's plan of care, to the extent permitted by the licensing authority in the state in which the practitioner is licensed. Another organization urged CMS to re-examine the Medicare homebound requirement for Medicare home health services eligibility. One commenter shared that the home health industry advocates have long argued that case or care management is a natural activity for home health agencies, particularly for elderly individuals with multiple co-morbidities. However, in order for agencies to be successful care managers, the focus of the Medicare home health benefit must shift from exclusively short-term, skilled, post-acute intervention for the homebound patient to include a chronic care management and oversight function for patients who may not need skilled care or be homebound at any given point in time. Additionally, one commenter stated the inclusion of maintenance therapy guidelines is greatly needed, and that they agree with the new Medicare Benefit Policy Manual update that the maintenance of the patient's current condition and prevention or slowing of further deterioration of the patient's condition may both warrant the use of skilled care provided under the Medicare home health benefit. Another commenter suggested that the social determinants of health should be considered as relevant variables in the prospective payment system.

Response: We appreciate these suggestions related to Medicare home health coverage policy. Medicare home health coverage policy is addressed in separate annual rulemaking, and comments related to this topic can be submitted during that process. As this topic is beyond the scope of this rule, we are not addressing these suggestions at this time.

Comment: We received a few comments related to OASIS. Commenters urged CMS to update the OASIS instrument to:

• Allow HHAs to indicate when referrals come from EDs and other health care providers and settings; and

• Reflect the social determinants of health.

Response: We appreciate these suggestions related to the content of the OASIS; however, this topic is beyond the scope of this rule, therefore we are not addressing these suggestions at this time. We will retain these suggestions for future consideration.

Comment: A commenter stated that under the Patient Protection and Affordable Care Act, CMS was required specifically to assess and document the needs of vulnerable individuals accessing home health services, and that this should be implemented in the CoPs.

Response: Section 3131(d) of the Affordable Care Act directed the Secretary to conduct a study on HHA costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with high levels of severity of illness. A Report to Congress on this home health study was released at the end of 2014, and is available to view at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.* We awarded a follow-on contract to Abt Associates to further explore possible payment methodology changes as a result of the home health study. The work is ongoing at this time.

Comment: A commenter expressed confusion with the ''reimbursement rates'' described in the Collection of Information and Regulatory Impact Analysis sections. The commenter stated that ''there seems to be a discrepancy with how services will be reimbursed. According to the 2014–2015 outlook, the hourly rate for physicians, nurses, clinical managers and administrators is $180, $63, $85, and $98; respectively. There are asterisks near job titles and hourly rates performed by nurses. For example, the clinical manager and administrator roles have asterisks. Clarification is needed regarding the reimbursement rate for other health care providers, including physicians, performing these administrative roles.''

Response: The impact analysis does not set forth reimbursement rates for any HHA services. Rather, as stated in the title of Table 1, ''Assumptions and estimates used throughout the information collection and impact analysis section'', the impact analysis presents a set of assumptions regarding how much a typical HHA pays in terms of the salary, benefits, and overhead associated with a single hour of employment for a given employee class. What an HHA chooses to pay an individual fulfilling an administrative role is entirely up to the discretion of the HHA. For purposes of our analysis, we assumed that a typical HHA would pay a typical administrator $98 per hour (including salary, benefits, and overhead). A given HHA may pay more or less than this amount.

Comment: We received a few comments related to CMS data collection and one comment related to emergency preparedness. Specifically, one commenter encouraged CMS to consider collecting data on the quality of the HHA's respective training/education programs. The commenter stated that data should measure the impact of the training/education program from the patient's, family caregiver's, and, as appropriate, from the direct care staff's perspectives. CMS should consider whether a quality measure in this area is appropriate and feasible. Another commenter wrote that CMS's proposed rule, ''Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (78 FR 79082, 79111, December 27, 2013) would require the home health agency to develop an emergency preparedness plan and conduct training and a mock drill or table top exercise annually, and that these requirements should be included as a standard under the organization and administration CoP.

Response: We appreciate suggestions related to the development of additional CMS data collection items and quality measures. Furthermore, we appreciate the suggestion related to the placement of future emergency preparedness requirements. However, these topics are not within the scope of this rule and are addressed in separate rule (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, 81 FR 63859).

Comment: One commenter expressed concern on the economic impact to rural communities will lead to barriers to access in some areas due to a combination of negative margins, new standards, and limited referral sources.

Response: As its measure of significant economic impact, HHS uses a change in revenue of more than 3 to 5 percent. We estimate that the cost of this rule on a per-HHA basis is minimal (approximately a $30,000 net increase in burden per non-accredited HHA in the 1st year, and a $15,000 savings increase for accredited HHAs in the 1st year). Furthermore, many of the burdens occur on a one-time basis as HHAs update their forms, and policies and procedures to conform to the updated requirements. We believe that this rule offers sufficient implementation flexibility to be adapted to the operations of a wide variety of HHAs, including those in rural areas.

Comment: One commenter encourages CMS to think creatively about how to leverage HHAs and home health services to improve health outcomes and quality of care, and avoid unnecessary hospitalizations and other institutional admissions. For example, the commenter suggested that if HHA personnel were providing services to an individual, and while, in the course of working with the family caregiver, saw that the family caregiver had health needs, the HHA staff could offer advice, make referrals, or provide a simple service to the caregiver that could improve their health (indirectly assisting the home health patient), especially if the caregiver is receiving Medicare or Medicaid services. Another commenter suggested that CMS ensure the operational capability of providers by requiring those agencies with new provider numbers to demonstrate proof of sufficient capital to operate for 1 year, and by requiring that existing agencies provide a $100,000 surety bond. Additionally, one commenter suggested that CMS establish a 2-year moratorium on the entry of new home health agencies into counties with demonstrable over-penetration (subject to certain exceptions). Another commenter suggested CMS identify and withhold payment for aberrant episodes and LUPA claims. Another commenter suggested that CMS consult with the Inspector General of the Department of Health and Human Services to establish a claims validation process by screening each claim (or a sample of claims) so that, before payment is made, the Secretary would validate claims on the basis of an HHA's submission of OASIS assessments (or some other data set approved for home health agencies).

Response: We appreciate the commenters' suggestions. However, we believe these comments are outside the scope of this rule.

V. Provisions of the Final Regulations

We are adopting as final the provisions set forth in the proposed rule published in the **Federal Register** on October 9, 2014 (79 FR 61164), with the following changes:

• Revised the definition of ''representative'' at § 484.2 for additional clarity.

• Revised 484.45(c)(2) to align the regulatory text with the current CMS guidelines for data transmission by replacing the requirement that test data

be transmitted to the ''state agency'' with a requirement that test data be transmitted to the ''QIES ASAP system.'' We proposed to require that an HHA must, ''Successfully transmit test data to the state agency or CMS OASIS contractor.'' On January 1, 2015, CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the QIES ASAP System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.

- Revised § 484.50(a)(1) to clarify that it is the patient's legal representative that must be informed of the patient rights information prior to the start of care.
- Revised § 484.50(a)(1)(i) to require that an HHA must provide each patient with written notice regarding the HHA's transfer and discharge policies. This requirement was originally proposed at 484.50(d).
- Redesignated proposed § 484.50(a)(1)(ii) as § 484.50(a)(3).
- Redesignated proposed § 484.50(a)(2) as § 484.50(a)(1)(ii) and removed the requirement that HHA administrators are expected to receive patient questions.
- Redesignated proposed § 484.50(a)(3) as § 484.50(a)(1)(iii).
- Redesignated proposed § 484.50(a)(4) as § 484.50(a)(2), and clarified that a signature confirming receipt of the notice of patient rights is only required from a patient or a patient's legal representative.
- Revised § 484.50(a)(3), requiring that the HHA must provide verbal notice of the patient's rights no later than the completion of the second visit from a skilled professional.
- Added new § 484.50(a)(4), requiring that the HHA provide written notice of the patient's rights and the HHA's discharge and transfer policies to a patient-selected representative within 4 business days after the initial evaluation visit.
- Revised 484.50(b) to replace the term ''incompetence'' wherever it appears with the more precise term ''lack legal capacity to make health care decisions.''
- Revised § 484.50(c)(4)(i) to clarify that patients have the right to participate in and be informed about all assessments, rather than just the comprehensive assessment.
- Removed the requirement at § 484.50(c)(4)(iii) regarding providing a copy of the plan of care to each patient.
- Revised § 484.50(c)(10) to require HHAs to provide contact information for a defined group of federally-funded and state-funded entities.
- Revised § 484.50(d) to remove the requirement for HHAs to provide patients with information regarding HHA admission policies and clarified that the ''transfer and discharge policies'' are those set forth in paragraphs (1) through (7) of this standard.
- Revised § 484.50(d)(1) to clarify that HHAs are responsible for making arrangements for a safe and appropriate transfer.
- Revised § 484.50(d)(3) to clarify that discharge is appropriate when the physician and the HHA both agree that the patient has achieved the measurable outcomes and goals established in the individualized plan of care.
- Revised § 484.50(e)(1)(i) to clarify that the subject matter about which patients may make complaints is not limited to those subjects specified in the regulation. HHAs must investigate all such complaints.
- Revised § 484.50(e)(1)(iii) to specify that HHAs must take action to prevent retaliation while a patient complaint is being investigated.
- Revised § 484.50(e)(2) to specify that circumstances of mistreatment, neglect, abuse, or misappropriation of patient property must be reported in accordance with the requirements of state law.
- Added a requirement at § 484.55(c)(6)(i) and (ii) that the comprehensive assessment must include information about caregiver willingness and ability to provide care, and availability and schedules.
- Added a requirement at § 484.60 that patient and caregiver receive education and training including written instructions outlining medication schedule/instructions, visit schedule and any other pertinent instruction related to the patients care and treatments that the HHA will provide, specific to the patient's care needs.
- Moved proposed § 484.60(a)(3) to § 484.60(a)(2)(xii), making it applicable to all patients, and removed the terms ''low,'' ''medium,'' and ''high.''
- Revised § 484.60(b)(1) to permit drugs, services and treatment to be ordered by any physician, not just the one responsible for the patient's plan of care.
- Revised § 484.60(b)(4) to permit any nurse acting in accordance with state licensure requirements to receive verbal orders from a physician.
- Added requirements at § 484.60(d)(1) and (2) that HHAs must assure communication with all physicians involved in the plan of care, and integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.
- Redesignated proposed § 484.60(d)(1) through (3) as § 484.60(d)(3) through (5).
- Added a requirement at § 484.60(e), Written information to the patient.
- Revised § 484.65 to require that QAPI program indicators include the use of emergent care services.
- Revised § 484.75(b)(7) to require skilled professionals to communicate with all physicians involved in the plan of care.
- Revised § 484.80(b)(3)(xiii) by withdrawing part of the provision under home health aide training requirements for aides to recognize and report changes in pressure ulcers. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.
- Revised § 484.80(g)(1) by removing the requirement that the skilled professional who is responsible for the supervision of a home health aide must be the individual who prepares written patient care instructions for the home health aide.
- Revised § 484.80(h)(1)(i) by adding a requirement that the registered nurse or other appropriate skilled professional who conducts supervision of a home health aide must be familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g).
- Revised § 484.80(h)(1)(ii) by removing the word ''potential deficiency'' and replacing it with ''area of concern.''
- Redesignated § 484.22—Emergency Preparedness under subpart B as § 484.102 under subpart C to align with CoP's related to ''Organizational Environment.'' Section 484.22 was implemented as part of the Emergency Preparedness final rule published on September 16, 2016 (81 FR 63859).
- Revised the requirement at § 484.105 to clarify that an HHA must

organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs.

- Added a requirement at § 484.105(b)(1)(i) that the administrator must report to the governing body.
- Revised § 484.105(b)(1)(iii) to require that the administrator assures that a clinical manager is available during all operating hours.
- Added a requirement at § 484.105(b)(1)(iv) that the administrator must ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.
- Revised § 484.105(b)(2) to clarify that an individual that is pre-designated to fill the administrator role in the absence of the administrator (including the clinical manager) must be qualified to do so.
- Revised § 484.105(c) to specify that one or more qualified individuals must provide oversight of all patient care services and personnel.
- Revised § 484.105(c) Clinical manager by retaining a description of the clinical manager's duties while relocating the personnel specifications for this role to new § 484.115(c), which sets for the specific personnel requirements for the clinical manager.
- Removed § 484.105(c)(6).
- Added a requirement at § 484.110(a)(4) that the clinical record must include contact information for the patient's primary caregiver(s).
- Revised § 484.110(a)(6)(i) by changing the discharge summary deadline for completion from 7 calendar days to 5 business days.
- Revised § 484.110(a)(6)(ii) by changing the transfer summary deadline for completion from 2 calendar days to 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility.
- Added § 484.110(a)(6)(iii), requiring that a completed transfer summary must be sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.
- Revised § 484.110(e), requiring that a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).
- Revised the personnel qualification requirements for HHA administrators at § 484.115(a) to grandfather in currently employed HHA administrators.
- Added § 484.115(c) to specify personnel qualifications for clinical managers.
- Redesignated paragraphs § 484.115 (c) through (m) as (d) through (n).
- Revised the proposal at § 484.115(e) licensed practical nurse to utilize existing regulatory language regarding vocational nurses, and align the requirement with state practice acts. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. This procedure can be waived, however, if an agency finds good cause to do so. In section VI of this preamble, we have provided our rationale for finalizing these provisions without prior notice and comment.
- Made technical changes to the requirements at § 484.115(f) through (i) to align with current personnel qualification requirements for occupational therapists, occupational therapy assistants, physical therapists, and physical therapy assistants.

VI. Good Cause To Waive Notice and Comment Rulemaking

As discussed in section IV of this preamble, at § 484.45 we proposed to require that an HHA must, ''Successfully transmit test data to the state agency or CMS OASIS contractor.'' However, on January 1, 2015, CMS changed the OASIS transmission guidelines to require that an HHA must successfully transmit test data to the QIES ASAP System or CMS OASIS contractor. We have revised the final rule at § 484.45 to reflect this change and maintain consistency between the transmission guidelines and the regulatory requirements.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance 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. We believe that finalizing the previously proposed language is contrary to the public interest because it conforms our rules to transmission guidelines that have changed since this rule has been proposed. We wish to waive notice and comment for rulemaking because waiting until a future rulemaking to resolve this inconsistency would create unnecessary confusion within the HHA community. Such confusion would likely lead to inconsistent compliance with either the regulations or the transmission guidelines, potentially leading to information gaps in CMS databases that could negatively impact HHA payments and the accuracy of quality measure information that is reported to the public. Because this change is operational, non-controversial, and has already been implemented at the sub-regulatory level, we find good cause to waive the notice of proposed rulemaking related to this change, and to issue this provision of the final rule.

In section IV of this preamble, at § 484.80 ''Condition of participation: Home Health Aide Services,'' we proposed to add a requirement under home health aide training at § 484.80(b)(3)(xiii) to require home health aides to be trained on ''Recognizing and reporting changes in skin condition, including pressure ulcers.'' We believe that it is important for home health aides to be taught to recognize and report changes in skin condition; however, during the process of developing this final rule, CMS stakeholders identified concerns that this requirment is beyond the aide's scope of practice and possibly the aide's ability to report changes in pressure ulcers. Out of an abundance of caution, we are withdrawing the proposal for the aide to be taught to recognize and report changes in pressure ulcers. The revision will require only recognizing and reporting changes in skin condition.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance 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. We believe that finalizing the previously proposed language is contrary to the public interest because requiring home health aides to perform skills that are inconsistent with their state scope of practice requirements would create a direct conflict between state and federal requirements. This direct conflict would

impede the ability of home health aides to do their jobs efficiently and effectively, and would negatively impact patient care and outcomes. Therefore, we find good cause to waive the notice of proposed rulemaking related to this change, and to withdraw this provision from the final rule.

In section IV of this preamble, at § 484.115 ''Condition of participation: Personnel qualifications,'' we proposed to remove the word ''vocational'' from the current CFR at § 484.4, ''Personnel qualifications.'' During a meeting of state leaders that occurred outside of the public comment process we were notified that two states currently use the term ''licensed vocation nurse.'' We believe that there are no significant substantive differences that exist between LPNs and LVNs other than the geographical locations and local variants in nomenclature; there are no major differences in educational preparation, licensure, roles, or skill sets. Therefore, after discussions with the states and an internal review we have amended § 484.115(e). We have withdrawn our proposal to delete the word ''vocational'' from the position title, and have amended the proposed definition to utilize existing regulatory language inclusive of both LVNs and LPNs. The final provision states: *Licensed Practical (vocational) Nurse.* A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposal. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance 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. We believe that finalizing the previously proposed language is contrary to the public interest because the only significant difference between LPNs and LVNs is the geographical locations in which these terms are used. The terms are used interchangeably, and continuing the use of both terms, as has been required in the HHA CoPs for more than a decade, will have no impact on patient care or HHA operations. Therefore, we find good cause to waive the notice of proposed rulemaking related to this change, and to withdraw this provision from the final rule.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs) during the proposed rulemaking.

Assumptions and Estimates

We have made several assumptions and estimates in order to assess both the time that it would take for an HHA to comply with the new provisions as well as the costs associated with that compliance. We have detailed these assumptions and estimates in Table 1, and have used these assumptions as the basis for both the Collection of Information and the Regulatory Impact Analysis sections of this rule.

TABLE 1—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE INFORMATION COLLECTION AND IMPACT ANALYSIS SECTIONS

Number of Medicare participating HHAs nationwide in 2015	12,602
Number of Medicare participating HHAs that are accredited in 2015	4,972
Number of HHA patients in Medicare participating HHAs nationwide in 2014	17,751,840
Number of HHA patients in Medicare participating in 2015, accredited HHAs	7,005,548
Number of Medicare beneficiaries in HHAs in 2015	3,475,730
Average number of new HHAs per year (based on growth in the number of HHAs from 2010–2015)	455
Average number of new, non-accredited HHAs per year (based on growth in the number of HHAs from 2010–2015)	14
Average number of patients per HHA per year	1,409
Hourly rate of registered nurse *	$63
Hourly rate of HHA office employee *	$26
Hourly rate of administrator *	$98
Hourly rate of home health aide *	$20
Hourly rate of clinical manager *	$85
Hourly rate of QAPI coordinator **	$63
Hourly rate of physician *	$180
Hourly rate of therapist (average of PT, OT, SLP) *	$72
Hourly rate of clinician (average of Nurse, Aide, Therapist) *	$60

* Estimate from the Bureau of Labor Statistics Occupational Outlook Handbook, 2014–2015 edition; includes 100 percent benefit and overhead package.

** Based on a registered nurse fulfilling this role.

Collection of Information Requirements—Discussion and Summary

A. ICRs Regarding Condition of Participation: Reporting OASIS Information (§ 484.45)

Section 484.45 states that HHAs must electronically report all OASIS data in accordance with § 484.55. Specifically, an HHA would have to encode and electronically transmit each completed OASIS assessment to the state agency or the CMS OASIS contractor within 30 days of completing an assessment of a beneficiary. The burden associated with this requirement is the time and effort necessary to conduct the OASIS assessment on a beneficiary and encode and transmit the information to the state agency or the CMS OASIS contractor. We did not make any changes to the OASIS data set, so the time to conduct the OASIS assessment on a beneficiary has stayed the same. We did change the destination of transmitted data; however, this does not change the time necessary to encode and transmit the data. While this requirement is subject to the PRA, the burden is currently approved under OMB control number 0938–1279.

B. ICRs Regarding Condition of Participation: Patient Rights (§ 484.50)

Section 484.50 implements the patient rights provisions of section 1891(a)(1) of the Act, which are currently specified in § 484.10. The purpose is to recognize certain rights that home health patients are entitled to, and protect their rights. HHAs are required to inform each patient of their rights. In § 484.50, we require HHAs to inform patients about the expected outcomes of treatment and the factors that could affect treatment. The HHAs are asked to devote efforts to improve patient's health literacy which lead to an increased comprehension of diagnosis and treatment for both patients and family. Increased comprehension allows patients to remain active and make the best possible decisions for their medical care. The requirements currently specified in § 484.10, that are retained in the final rule include:

- An HHA must provide the patient and representative (legal or patient-selected) with an oral and a written notice of the patient's rights in a manner that the individual can understand. The HHA must also document that it has complied with the requirements of this section.
- An HHA must document the existence and resolution of complaints about the care furnished by the HHA that were made by the patient, representative, and family.
- An HHA must advise the patient in advance of the disciplines that will furnish care, the plan of care, expected outcomes, factors that could affect treatment, and any changes in the care to be furnished.
- An HHA must advise the patient of the HHA's policies and procedures regarding the disclosure of patient records.
- An HHA must advise the patient of his or her liability for payment.
- An HHA must advise the patient of the number, purpose, and hours of operation of the state home health hotline.

In addition to the retained requirements, we require that HHAs must also advise the patient of the following:

- The names, addresses, and telephone numbers of specified State-funded and federally-funded entities.
- The right to access auxiliary aids and language services, and how to access these services.

We foresee that HHAs will develop a standard notice of rights to fulfill the requirements contained in § 484.50(a) of this section. A copy of the signed notice would serve as documentation of compliance. We estimate that a home health agency will utilize an administrator to develop the patient rights form. All newly established HHAs would need to develop a notice of patient rights document. In order to speed up the process of becoming Medicare-approved, the majority of new HHAs are choosing to become accredited by a national accrediting organization for Medicare deeming purposes. The patient rights standards and patient notification requirements of the national accrediting organizations would meet or exceed those included in this rule; therefore this rule does not impose a burden upon those new HHAs that choose to obtain accreditation status for Medicare deeming purposes. We estimate that it would take 8 hours for each new non-accredited home health agency to develop the form. The total annual burden for new HHAs is 112 hours (8 hours per HHA × 14 HHAs). The estimated cost associated with this requirement is $784 per HHA and $10,976 for all new non-accredited HHAs, annually. In addition, we estimate that it would take each existing HHA 1 hour to update its existing patient rights form, for a one-time total of 12,602 hours and a cost of $1,234,996.

The burden associated with § 484.50(e), which requires an HHA to document both the existence of a patient complaint regarding care provided (or not provided) or inappropriate treatment by HHA staff and those working on behalf of the HHA, and the resolution of the complaint, would be the time and effort necessary to document a patient complaint and its resolution. We estimate that, in a 1 year period, an HHA would need to document complaints involving about 5 percent (70) of its patients. We estimate that the documentation would require 5 minutes per investigation. HHAs accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care are already required by their accrediting bodies to adhere to stringent patient rights violation investigation and record-keeping standards; therefore accredited HHAs are not be burdened by this new standard. The total annual burden per non-accredited HHA (7,630) would be 6 hours (70 investigations × 5 minutes per investigation/60).

We believe that the requirements of standard (f), ''Accessibility,'' related to providing information to patients in a manner that can be understood would not impose a burden because all HHAs have already attested to CMS that they are in compliance with the requirements of Title VI of the Civil Rights Act of 1964, the Americans With Disabilities Act, and section 504 of the Rehabilitation Act (see 42 CFR 489.10, as implemented by form HHS–690, currently approved under OMB control number 0938–1279, current expiration August 31, 2017). Since HHAs have already attested that they are in compliance with these longstanding requirements, and since the requirements of this rule are not intended to go beyond these statutes, no new burden would be imposed.

C. ICRs Regarding Condition of Participation: Comprehensive Assessment of Patients (§ 484.55)

Section 484.55 requires the HHA to conduct, document and update, within a defined timeframe, a patient-specific comprehensive assessment that identifies the patient's need for HHA care and services, and the patient's need for physical, psychosocial, emotional and spiritual care. Although we have included additional areas of focus within the patient assessment requirements, these areas are already addressed in the OASIS data set that HHAs have been required to collect since 1999. Therefore, no new burden has been added with these changes. The information collection burden associated with the OASIS data set is currently approved under OMB control

number 0938–1279. The current expiration date is December 31, 2019.

D. ICRs Regarding Condition of Participation: Care Planning, Coordination of Services, and Quality of Care (§ 484.60)

The requirements in this section reflect an interdisciplinary, coordinated approach to home health care delivery. Section 484.60 requires that each patient's written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Additionally, the written plan of care will be required to contain the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This section incorporates several of the requirements under former § 484.18. Section 484.18 consists of longstanding requirements that implement statutory provisions found in sections 1835, 1814, and 1891(a) of the Act. While these requirements are subject to the PRA, the associated collection is currently approved under OMB control number 0938–0365.[2] Additionally the plan of care must also specify the patient and caregiver education and training specific to the patient's care needs. A typical HHA patient will have one original plan of care, and we believe compliance with the new plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 10 minutes per patient, per plan of care. We believe that most HHAs are already addressing these areas during the care planning process, so for purposes of this analysis only, we assume that 90 percent of HHAs are already compying with these requirements and that 10 percent will need to comply. We estimate that the 1,260 HHAs that are not already addressing these new factors in their care planning process will use 296,482 hours (1,409 patients per HHA × 0.167 hours per patient × 1,260 HHAs) at a cost of $18,678,366 for a nurse to document the new required information in the plan of care.

Section 484.60(a) requires that each patient's written plan of care be established and periodically reviewed by a doctor of medicine, osteopathy, or podiatry. While HHAs average 1,409 home health patient admissions per year, on average 276 of those are Medicare patients. Having a doctor of medicine, osteopathy, or podiatry establish and periodically review the HHA plan of care is also a requirement for Medicare payment; therefore HHAs do this in the absence of this requirement. Thus this requirement will not impose a burden with respect to those 276 Medicare patients. The anticipated burden associated with this requirement involves a member of the office support staff who would facilitate interaction with the physician with regard to non-Medicare patients. We estimate that this would take 5 minutes per admission for a total estimated burden of 94 hours per HHA ([1,133 non-Medicare admits per year × 5 minutes]/60 minutes per hour).

Section 484.60(a)(4) and (b)(1) requires HHAs to conform and fulfill all medical orders issued in writing or telephone (and later authenticated) by a patient's physician or qualified medical professional. We believe compliance with this requirement will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3 (b)(2). Issuing orders for patient care is one of the most fundamental tasks performed by physicians. Likewise, documenting and adhering to physician orders is one of the most fundamental tasks performed by the physician and all other clinicians within a patient's health care team, including the nurses, therapists, and social workers that are involved in home health care.

Section 484.60(c) requires an HHA to review, revise and document the plan on a timely basis. The burden associated with these requirements is the time and effort associated with reviewing, revising, and maintaining the plan of care. We believe compliance with the new plan of care requirements, such as addressing each patient's psychosocial status and interventions to address readmission risk factors, will impose a new burden of 5 minutes per patient, per updated plan of care. Assuming that a typical HHA patient will have one update to the plan of care, we estimate that all HHAs will use 147,353 hours (1,409 patients per HHA × 0.083 hours per patient × 1260 HHAs) at a cost of $9,283,329 for a nurse to document the new required information in the plan of care.

Section 484.60(e) is a new provision that was added based on comments and which partially replaces other requirements previously placed elsewhere. This provision requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care, and the name and contact information of the HHA clinical manager. Giving written instruction to the patient and care giver outlining the medication schedule/instructions, visit schedule, pertinent instruction related to the patient's care and treatments and contact information of the HHA has been a long standing practice in the home health industry and is one of the most fundamental elements in patient education. For purposes of this analysis only, we assume that 90 percent of HHAs are already providing this information and 10 percent are not. We estimate that it would take 20 minutes to provide a patient with this written information and that each patient will receive written information twice while under the HHA's care. Based on these assumptions, we estimate that this provision will impose 1,182,376 hours of burden at a cost of $74,489,688 for a nurse to provide the written information.

E. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (§ 484.65)

Section 484.65 requires HHAs to develop, implement, maintain and evaluate an effective, data driven quality assessment and performance improvement program. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services. This new provision replaces the former conditions at § 484.16, ''Group of professional personnel,'' and § 484.52, ''Evaluation of an agency's program.''

The first standard under § 484.65 requires that an HHA's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance. The second standard requires the HHA to track its performance to assure that improvements are sustained over time. The third standard requires that the HHA must set priorities for performance improvement, consider prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes. Lastly, the fourth standard requires the HHA to conduct performance improvement

[2] This collection will be discontinued when a new collection is approved which will better align the PRA package with new regulations.

projects that reflect the scope, complexity, and past performance of the HHA's services and operations, and document these projects.

We believe the writing of internal policies governing the HHA's approach to the development, implementation, maintenance, and evaluation of the quality assessment and performance improvement program, as described in § 484.65, will impose a new burden. We want HHAs to utilize maximum flexibility in their approach to quality assessment and performance improvement programs. Flexibility is provided to HHAs to ensure that each program reflects the scope of its services. We believe that this requirement provides a performance expectation that HHAs will set their own QAPI plan and goals and use the information to continuously strive to improve their performance over time. Given the variability across HHAs and the flexibility provided, we believe that the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the quality assessment and performance improvement program will reflect that diversity. We estimate that the burden associated with writing the internal policies would be an average of 4 hours annually per HHA, for an industry-wide total of 30,520 hours. (4 hours per HHA × 7,630 non-accredited HHAs), and an industry-wide cost of $1,922,760 (30,520 hours × $63/hour).

HHAs accredited by the Joint Commission, the Community Health Accreditation Partner, and the Accreditation Commission for Health Care are already required by their accrediting bodies to undertake and document performance improvement projects. In the absence of accreditation requirements, we believe that most HHAs already document the quality projects that they have undertaken as part of standard business practice. For purposes of this analysis only, we assume that 10 percent of non-accredited HHAs would use additional resources to document their quality projects. We we estimate that the affected HHAs would use 1 hour per quarter to document performance improvement project activities and that the QAPI coordinator would perform this function, for a total of 3,052 hours (0.1 × 7,630 non-accredited HHAs × 1 hour per quarter × 4 quarters per year) at a cost of $192,276.

F. ICRs Regarding Condition of Participation: Infection Prevention and Control (§ 484.70)

Section 484.70 requires an HHA to maintain and document an infection control program with the goal of preventing and controlling infections and communicable diseases. Specifically, § 484.70(b) states that the HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's QAPI program. Section 484.70(c) requires that each HHA provide infection control education to staff, patients, and caregivers. All aspects of the infection prevention and control CoP, from teaching patients and caregivers about proper prevention practices to monitoring infectious disease occurrences within an HHA's population to cooperating with outside bodies during disease outbreaks, are current standards of practice. Since health care-acquired infections have been a source of significant research, education, and training efforts by both the public and private health care sectors for more than a decade, we believe that all HHAs already have infection prevention and control programs. The burden associated with the infection prevention and control program would be the time necessary to document the program. We estimate that each HHA will spend 1 hour per quarter documenting its infection prevention and control program, for a total of 50,408 hours at a cost of $3,175,704 for a nurse to complete the documentation.

G. ICRs Regarding Condition of Participation: Skilled Professional Services (§ 484.75)

We consolidated former provisions governing skilled nursing services at § 484.30, therapy services at § 484.32, and medical social services at § 484.34, under one new condition, § 484.75. Section 484.75 requires skilled professionals who provide services to HHA patients as employees or under arrangement to participate in all aspects of care. This includes, but is not limited to, participation in the on-going patient assessment process; development and maintenance of the interdisciplinary plan of care; patient, caregiver, and family counseling; patient and caregiver education; and communication with other health care providers. Section 484.75 also requires skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings. Furthermore, § 484.75 requires skilled professional services to be supervised. In the proposed rule that published on October 9, 2014 (79 FR 61114), we incorrectly stated that these requirements would be exempt under the implementing regulations of the PRA at 5 CFR 1320.3(b)(3). We still maintain that the burden associated with these requirements would be exempt; however, the correct exemption is located at 5 CFR 1320.3(b)(2). These are usual and customary business practices. Clinician involvement in patient care, quality improvement efforts, and continuing education are all commonly accepted as good medical practice and are typically part of state licensure requirements. The supervision of clinician services is also standard medical practice to ensure that patient care is delivered in a safe and effective manner.

H. ICRs Regarding Condition of Participation: Home Health Aide Services (§ 484.80)

This section governs the requirements for home health aide services. Many requirements in this section directly mirror the statutory requirements of sections 1891 and 1861 of the Act and include the following requirements: (1) The HHA must maintain sufficient documentation to demonstrate that training requirements are met; (2) The HHA's competency evaluation must address all required subjects; (3) The HHA must maintain documentation that demonstrates that requirements of competency evaluation are met; and (4) a registered nurse or appropriate skilled professional prepares written instructions for care to be provided by the home health aide.

We retained, for the most part, the requirements at previous § 484.36, but place them in a new condition of participation at § 484.80. We also added the provisions from previous § 484.4 concerning the qualifications for home health aides. All home health aide services must be provided by individuals who meet the personnel requirements and training criteria as specified. An HHA is required to maintain documentation that each home health aide meets these qualifications as specified in § 484.80(a). The burden associated with these standards is the time required to document that each new aide meets the qualification requirements. We estimate that it will take 5 minutes per newly hired home health aide per year to document the information. We assume that the average home health agency would replace 30 percent of its home health aides in a given year, or roughly two home health

aides a year based an average of six home health aide FTEs (Basic Statistics About Home Care Updated 2010, National Association for Home Care, *http://www.nahc.org/facts/10HC_Stats.pdf*). Based on an estimate of 5 minutes per newly hired aide and two newly hired aides per agency, per year, we estimate that there will be 2,100 annual burden hours ([5 minutes per aide × 2 aides per HHA]/60 minutes per hour × 12,602 HHAs) for the home health industry. We assume, based on our experience with a similar requirement in the hospice environment, that an office employee ($26/hour) would perform this function at a cost of $4 per HHA per year. The total cost for all HHAs is $54,600 (2,100 hours × $26/hour).

Section 484.80(b)(1) through (3) sets forth the content and duration of the home health aide classroom and supervised practical training. With respect to the recordkeeping requirements, § 484.80(b)(4) states that an HHA is required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,603 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ([5 minutes per aide × 2 aides per HHA]/60 minutes per hour × 12,602 HHAs). The cost burden associated with this requirement is $54,600, based on an office employee completing the documentation ($26/hour × 2,100 hours).

Section 484.80(c) contains the standard for competency evaluation. An individual could furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. With respect to the recordkeeping requirements, § 484.80(c)(5) states that an HHA is required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 12,602 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 2,100 hours ([5 minutes per aide × 2 aides per HHA]/60 minutes per hour × 12,602 HHAs). The cost burden associated with this requirement is $54,600, based on an office worker completing the documentation ($26/hour × 2,100 hours).

Section 484.80(d) states that a home health agency is required to maintain documentation that all home health aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement would be the time and effort necessary to document and maintain records of the required in-service training. We assume that it would require 5 minutes per aide to document the in-service training, and that these trainings would be conducted on a quarterly basis, for a total of approximately 2 hours per HHA, annually, to meet this requirement ([0.083 hours (aka 5 minutes) per aide per training × 4 trainings per year × 6 aides]/60 minutes per hour). The estimated total annual burden for this requirement is 25,103 hours (0.083 hours (aka 5 minutes) per aide per training × 4 trainings per year × 6 aides per HHA × 12,602 HHAs).

Section 484.80(g) states that written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional who is responsible for the supervision of a home health aide. The burden associated with this requirement would be the time and effort necessary for a registered nurse or other skilled professional to draft written patient care instructions for a home health aide. Providing written patient care instructions is a usual and customary business practice in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Home health aide licensure standards require aides to practice under the direction of a nurse or other qualified medical professional. Likewise, the scope of practice for nurses and other qualified medical professionals includes the preparation of patient care instructions.

This rule at § 484.80(h) also requires HHAs to document the supervision of home health aides in accordance with specified timeframes. Supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and state and federal compliance purposes constitutes a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2).

I. ICRs Regarding Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients (§ 484.100)

We are retaining most of the provisions of former § 484.12, ''Compliance with Federal, State and local laws, disclosure of ownership information and accepted professional standards and principles'' with minor changes, now set forth at § 484.100. As stated in § 484.100(a), the HHA is required to disclose to the state survey agency at the time of the HHA's initial request for certification the name and address of all persons with an ownership or control interest in the HHA, the name and address of all officers, directors, agents, and managers of the HHA, as well as the name and address of the corporation or association responsible for the management of the HHA and the chief executive and chairman of that corporation or association. This requirement directly implements section 1891 of the Act. This provision expands upon a similar requirement currently contained in § 405.1221(b). It would impose a minimal burden of adding the necessary additional information to the current disclosure used by HHAs as required by former § 484.12(b), which further reference the requirements of 42 CFR part 420, subpart C related to Medicare Program Integrity requirements. We estimate that modifying the current disclosure would require 5 minutes (0.083 hours) per HHA, for a total of 1,046 hours for the HHA industry as a whole on a one-time basis (0.083 hours per modification × 12,602 existing agencies). Additionally, we estimate that it would require new HHAs 1 hour to develop a disclosure statement, for a total of 455 annual hours industry wide each year (1 hour per new HHA × 455 new HHAs).

J. ICRs Regarding Condition of Participation: Organization and Administration of Services (§ 484.105)

This section sets forth the organization and administration of services provided by an HHA. It states that the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity for each patient regarding medical, nursing, and rehabilitative needs as indicated by the plan of care. Although there are reporting and documentation requirements associated with the requirements, these activities are

standard business practice and would not impose a burden on HHAs. For example, § 484.105(d)(1) states that the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. Similarly, § 484.105(e)(2) states that an HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. We believe the burden associated with the aforementioned will constitute a usual and customary business practice and will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Paragraph (h) of this section, ''Institutional planning,'' imposes a minimal burden of the time required by new HHAs to develop the initial plan and by existing HHAs to review and revise the existing plan. We estimate the burden for developing a new plan at 1½ hours (90 minutes) and the burden for reviewing and revising an existing plan at 30 minutes. Accredited HHAs are required by their accrediting bodies to engage in institutional planning efforts that exceed these minimum federal requirements; therefore this requirement would not impose a burden upon accredited agencies. In addition, the vast majority of new HHAs are entering the Medicare program via accreditation from a national accrediting body; therefore this provision would not be imposing a burden upon new agencies as well. The estimated annual burden for existing HHAs is 3,815 hours ([7,630 existing non-accredited HHAs × 30 minutes]/60 minutes per hour). The estimated annual burden for anticipated new HHAs is 21 hours (1.5 hours per HHA × 14 new HHAs).

K. ICRs Regarding Condition of Participation: Clinical Records (§ 484.110)

This section sets forth the requirements that clinical records contain pertinent past and current findings, and are maintained for every patient who is accepted by the HHA for home health services. A clinical record containing pertinent past and current findings would be maintained for every patient receiving home health services. All entries in the clinical record must be authenticated, dated and timed, which is usual and customary clinical practice and does not impose a burden. Clinical records must be retained for 5 years after the month the cost report for the records is filed with the intermediary. HHAs are required to have written procedures that govern the use and removal of records, and the conditions for release of information. This section contains longstanding provisions that are specifically required in section 1861(o) of the Act, and are necessary to preserve the patient's privacy and the quality of care. The aforementioned documentation and record retention requirements are considered usual and customary business practices; therefore the burden associated with those requirements will not be subject to the PRA in accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2). At § 484.110(a)(5) HHAs are required to send a copy of a patient's discharge or transfer summary to the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA, or the facility, if the patient leaves HHA care to enter a facility for further treatment. We estimate that an HHA would spend 5 minutes per patient sending the discharge or transfer summary to the patient's next source of health care services, for a total of 117 hours per average HHA annually ([5 minutes per patient × 1,409 patients]/60 minutes per hour) at a cost of $3,042 for an office employee to send the required documentation ($26 per hour × 117 hours).

Furthermore, a patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first). The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. Making clinical records available to the appropriate authority is part of the survey and certification process, and we believe compliance with this requirement will constitute a usual and customary business practice. Therefore, the burden associated with this requirement will not be subject to the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2). Furthermore, we do not believe that this requirement would alter the frequency or scope of requests stemming from other appropriate authorities such as law enforcement.

L. ICRs Regarding Personnel Qualifications (§ 484.115)

In § 484.115, we defer to state certification or state licensure requirements in cases where personnel requirements are not statutory or do not relate to a specific payment provision. As defined in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), these requirements are usual and customary business practices. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), we believe this state requirement would exist even in the absence of the federal requirement; therefore, the associated burden is not subject to the PRA.

TABLE 2—BURDEN AND COST ESTIMATES ASSOCIATED WITH INFORMATION COLLECTION REQUIREMENTS

Regulation section	OMB control No.	Respondents	Responses	Burden per response (in hours)	Total annual burden (in hours)	Hourly labor cost of reporting ($)	Total cost of reporting ($)	Total costs ($)
§ 484.50(a)*	0938–New	14	14	8	*112	98	10,976	10,976
§ 484.50(a)*	0938–New	12,602	12,602	1	*12,602	98	1,234,996	1,234,996
§ 484.50(e)	0938–New	7,630	534,100	0.083	44,330	63	2,792,790	2,792,790
§ 484.60(a)	0938–New	12,602	14,276,110	0.083	1,184,917	26	30,809,662	30,809,662
§ 484.60(a)	0938–New	1260	1,775,340	0.167	296,482	63	18,678,366	18,678,366
§ 484.60(c)	0938–New	1260	1,775,340	0.083	147,353	63	9,283,239	9,283,239
§ 484.60(e)	0938–New	1260	3,550,680	0.333	1,182,376	63	74,489,688	74,489,688
§ 484.65(e)*	0938–New	7,630	7,630	4	*30,520	63	1,922,760	1,922,760
§ 484.65(d)	0938–New	763	3,052	1	3,052	63	192,276	192,276
§ 484.70	0938–New	12,602	50,408	1	50,408	63	3,175,704	3,175,704
§ 484.80(a)	0938–New	12,602	25,204	0.083	2,100	26	54,600	54,600

TABLE 2—BURDEN AND COST ESTIMATES ASSOCIATED WITH INFORMATION COLLECTION REQUIREMENTS—Continued

Regulation section	OMB control No.	Respondents	Responses	Burden per response (in hours)	Total annual burden (in hours)	Hourly labor cost of reporting ($)	Total cost of reporting ($)	Total costs ($)
§ 484.80(b)	0938–New	12,602	25,204	0.083	2,100	26	54,600	54,600
§ 484.80(c)	0938–New	12,602	25,204	0.083	2,100	26	54,600	54,600
§ 484.80(d)	0938–New	12,602	302,448	0.083	25,103	26	652,678	652,678
§ 484.100(a)	0938–New	12,602	12,602	0.083	1,046	98	102,508	102,508
§ 484.100(a)*	0938–New	455	455	1	*455	98	44,590	44,590
§ 484.105(h)		7,630	7,630	0.5	3,815	98	373,870	373,870
§ 484.105(h)	0938–New	14	14	1.5	21	98	2,058	2,058
§ 484.110(a)	0938–New	12,602	17,751,840	0.083	1,473,403	26	38,308,478	38,308,478
Total		140,189	40,135,877	19	4,462,805	1,185	182,350,264	182,350,264

* Denotes a one-time information collection requirement.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 2. In addition, the column for the total costs is also represents the total cost of reporting; therefore, we have removed the total cost of reporting column from Table 2 as well.

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

This final rule is a revision of the Medicare and Medicaid CoPs for HHAs. The CoPs are the basic health and safety requirements that an HHA must meet in order to receive payment from the Medicare and Medicaid programs. This final rule incorporates advances and current medical practices in caring for home health patients while removing unnecessary process and procedure requirements contained in the current CoPs. This is a major rule because the overall economic impact for all of the new CoPs is estimated to be $293.3 million in year 1 and $290.1 million in year 2 and thereafter.

B. Statement of Need

As the single largest payer for health care services in the United States, the federal government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum federal standards, but this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

This final rule adopts a new approach that focuses on the care delivered to patients by home health agencies while allowing HHAs greater flexibility and eliminating unnecessary procedural requirements. As a result, we are revising the HHA requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. We have developed a set of fundamental requirements for HHA services that encompasses patient rights, comprehensive patient assessment, and patient care planning and coordination by an interdisciplinary team. Overarching these requirements is a QAPI program that builds on the philosophy that a provider's own quality management system is key to improved patient care performance.

These regulations contain two critical improvements that support and extend our focus on patient-centered, outcome-oriented surveys. First, the regulations are designed to enable surveyors to look at outcomes of care, because the regulations specify that each individual receives the care which his or her assessed needs demonstrate is necessary, rather than focusing simply on the services and processes that must be in place. Second, the addition of a strong QAPI requirement not only stimulates the HHA to continuously monitor its performance and find opportunities for improvement, it also affords the surveyor the ability to assess how effectively the provider was pursuing a continuous quality improvement agenda. All of the changes are be directed toward improving patient-centered outcomes of care. We believe that the overall approach of the final CoPs will increase performance expectations for HHAs, in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided.

C. Public Comments

As discussed in section III, ''Analysis of and Responses to Public Comments,'' of this rule, we received several public comments related to the estimates presented in the RIA section of the proposed rule. As a general summation, commenters stated that the estimates did not fully account for the burdens that HHAs will encounter in implementing this rule. However, by and large, commenters did not provide suggestions for estimates that should be used or evidence to guide the development of new estimates. Responses to particular comments are included under the relevant subject

matter headings. That is to say, comments regarding the RIA estimates related to patient rights, for example, are located in the discussion of all other patient rights comments. Those who submitted comments on particular burden estimates made general, vague statements that the estimates for the time and cost associated with compliance were understated. With one exception, commenters did not provide suggestions of more appropriate estimates. We received one specific comment, which asserted that requiring HHAs to notify patients of their right to access their own medical records would cost the HHA and additional $230k, annually, because many more patients would be accessing their records. However, notifying each patient of his right to receive a copy of information contained in his medical record is already included in the standard HIPAA notice that HHAs are required to provide (see 45 CFR 164.520, as accounted for by OMB Control Number 0945–0003). Therefore, we are not creating a new right, nor are we creating a new notice of this right. Thus, we do not believe that this requirement will create the exponential increase in record requests that the commenter claims.

D. Summary of Impacts

Section VII of this rule, Collection of Information Requirements, provides a detailed analysis of the burden hours and associated costs for all burdens related to the collection of information by HHAs that is required by this rule. That section, in tandem with this regulatory impact analysis section, present a full account of the burdens that will be imposed by this rule. Because the burdens have already been assessed in the Collection of Information Requirements section, we will not recount them in this RIA section. All estimates presented in this RIA section are based on the assumptions presented in Table 1, located at the beginning of the Section VII of this rule, Collection of Information Requirements.

Although we endeavor to provide the most accurate account of the burdens that will be imposed by this rule that is possible, we acknowledge that such analysis is inevitably imprecise. We believe that many of the tasks set forth in this final rule are already being done by the majority of HHAs as part of good business and health care practice. We have identified several activities, such as developing and updating a written plan of care for each patient, as usual and customary practices that would occur in the absence of regulation. While we believe that these identifications are an accurate reflection of current HHA practices as a whole, uncertainty remains regarding whether such usual and customary practices occur in all HHAs in all appropriate circumstances. Additionally, there are some estimates for which we lack information regarding implementation in the HHA environment because we have not previously regulated those activities. Following implementation of this final rule, we will monitor HHA practices to assess the impact of these new regulations.

Where appropriate, we have differentiated between the burdens that this rule would impose on accredited versus non-accredited HHAs in recognition of the fact that current accreditation standards established by the three main HHA accreditation entities will meet or exceed the minimum standards that are established in this rule. Accredited HHAs will experience less burden when implementing new the patient rights, QAPI, infection prevention and control, and organization and administration of services requirements.

In addition to analyzing the burden hours and associated costs for all burdens related to these requirements, we have also assessed the potential savings associated with our removal of certain outdated, burdensome requirements that exist in the current HHA CoPs.

TABLE 3—SUMMARY OF ESTIMATED BURDEN FOR ALL COPS

CoP	Total time (hours)	Total cost in year 1	Annual cost in year 2 and thereafter
Burden and Cost Estimates Associated with Information Collection Requirements	4,462,805	$182,350,264	$179,136,942
Patient rights	2,398,446	147,326,970	147,326,970
QAPI	618,030	29,070,300	25,316,340
Infection prevention and control	595,140	37,493,820	37,493,820
Removal of 60 day summary requirement	887,592	−16,864,248	−16,864,248
Removal of Group of professional personnel requirement	203,620	−16,924,452	−16,924,452
Removal of Evaluation of the agency's program	1,335,073	−69,111,119	−69,111,119
Total	5,648,136	293,341,535	290,128,213

1. Burden Assessment

Reporting OASIS Information (§ 484.45)

We are making one change to replace the requirement that an HHA has a ''direct telephone connection'' to transmit the OASIS data with a requirement that an HHA must transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140–2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site. The FIPS 140–2 applies to all federal agencies that use cryptographic-based security systems to protect sensitive information in computer and telecommunication systems (including voice systems) as defined in section 5131 of the Information Technology Management Reform Act of 1996, Public Law 104–106, including CMS. Therefore, this requirement does not impose a new burden upon HHAs.

Patient Rights (§ 484.50)

The final rule requires that an HHA must provide a patient with a written notice of rights. The final rule requires that an HHA must provide a patient's representative (legal) with a written notice of rights, and must provide a patient's representative (patient-selected) with a written notice of rights in accordance with patient preferences. Communicating with patients and representatives, including the provision of a written notice of rights, is a standard practice in the health care industry and would impose no additional costs. Similar requirements already exist for many other health care provider types, including hospice providers, long term care facilities, ambulatory surgery centers, and end-stage renal disease facilities.

Verbal notification of rights in a language and manner that the individual understands, however, may create a new burden for some HHAs. The national accrediting organizations already require their accredited HHAs to orally apprise their patients of their rights in situations where patients cannot read or understand the written notice. We assume, for purposes of this analysis only, that accredited HHAs are providing oral notification to the 25 percent of their patients that cannot read or understand the written notice. Based on this assumption, 1,751,387 patients are already orally notified of their rights each year; therefore, we are excluding these patients from this analysis. For the remaining 75 percent of patients receiving care from an accredited HHA, we estimate that it would take approximately 5 minutes per patient to describe the content of the notice of rights and obtain the patient's signature confirming that he or she has received a copy of the notice. We assume that patients would be informed of their rights by a registered nurse at a cost of $5 per patient (5 minutes × $63/hour). The total number of hours per accredited HHA would be 88 hours (1,057 patients × 5 minutes per patient/60 minutes), at a cost of $5,285 (1,057 patients × $5 per patient).

For non-accredited HHAs, the requirement to provide this verbal notice is a new requirement for all 1,409 patients served in an average HHA each year. The total cost of this provision per non-accredited HHA would be $7,045 (1,409 patients × $5 per patient). The total number of hours per non-accredited HHA would be 117 hours (1,409 patients × 5 minutes per patient/60 minutes). The total cost for all HHAs would be $80,030,370 ([$7,045 per non-accredited × 7,630 HHAs] + [$5,285 per accredited HHA × 4,972 HHAs]). The total number of hours for all HHAs would be 1,330,246 hours ([117 hours per non-accredited HHA × 7,630 HHAs] + [88 hours per non-accredited HHA × 4,972 HHAs]).

We note that the requirement to communicate with patients in a language and manner that the patient understands is not a new expectation for Medicare-approved HHAs, as they are already required to be in compliance with the current civil rights requirements and guidance (see 42 CFR 489.10(b)). Specifically, HHAs are already required to comply with the requirements of Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, section 1557 of the Affordable Care Act and ''other pertinent requirements of the Office for Civil Rights of HHS.'' HHS guidance, issued in 2003, further explains the expected role of interpreters in communications with patients (''Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' August 8, 2003, 68 FR 47311). As such, the requirement to communicate with patients in a language and manner that the patient understands would not impose a new burden on HHAs.

Standard 484.50(e) requires that all patient/family complaints be investigated. We estimate that, in a 1 year period, an HHA would need to investigate complaints involving about 5 percent (70) of its patients, and that each investigation would take 2 hours to complete. The total annual burden per HHA would be 140 hours (70 investigations × 2 hour per investigation). All national accrediting organizations already require their accredited HHAs to document, investigate, and resolve patient complaints; therefore all 4,972 accredited HHAs would not be burdened by this requirement. The total annual burden hours for the industry would be 1,068,200 (140 hours per HHA × 7,630 non-accredited HHAs). The total annual cost for the QAPI coordinator to complete all investigations would be $8,820 per HHA ($63/hour × 140 hours), and $67,296,600 for all non-accredited HHAs ($63/hour × 1,068,200 hours).

TABLE 4—PATIENT RIGHTS

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Providing notice of rights (annual, non-accredited/accredited HHAs)	117/88	1,330,246	$7,045/5,285	$80,030,370
Investigations (annual, non-accredited HHAs)	140	1,068,200	$8,820	$67,296,600
Total (annual, non-accredited/accredited)	257 or 88	2,398,446	$15,865 or $5,285	$147,326,970

Comprehensive Assessment of Patients (§ 484.55)

We are retaining the requirements of current § 484.55, with a reorganization of several sections related to the content of the comprehensive assessment and the addition of several broad focus areas. We believe that the new focus areas (for example, cognitive status and patient goals) are standard practice and would not impose an additional burden. In addition, we are making a minor change to allow for the completion of an OASIS update upon the physician-ordered resumption of care date. Allowing for a physician to order the resumption of care date increases HHA flexibility; therefore there is no new burden associated with this retention.

Care Planning, Coordination of Services, and Quality of Care (§ 484.60)

The current regulations at § 484.12(c), ''Compliance with accepted professional standards and principles''; § 484.14(g), ''Coordination of patient services''; and § 484.18 ''Acceptance of patients, plan of care, and medical supervision,'' are reorganized and revised at § 484.60.

The change in § 484.18, ''Acceptance of patients, plan of care, and medical supervision,'' requires each patient to receive an individualized written plan of care, including any additions or revisions. The plan of care includes all orders, specifies the care and services necessary to meet the patient-specific needs and the measurable outcomes that the HHA anticipates would occur as a result of implementing and coordinating the plan of care with the patient and physician, and includes all patient and caregiver education and training. The intent of the current standard at § 484.12(c) is retained under this CoP with the requirement that services be furnished in accordance with accepted standards of practice. No burden is associated with this part of the CoPs, as these requirements constitute current industry practices regarding plans of care.

Standard 484.60(a), ''Plan of care,'' codifies current industry standards of practice through the revision of current § 484.18(a), ''Plan of care,'' including references to the identification of patient-specific needs and measurable outcomes that are already currently required under current § 484.55,

''Comprehensive assessment of patients.'' Therefore, this requirement does not present a new burden.

Proposed § 484.60(b), ''Conformance with physician orders,'' retains the provision of the current regulation at 42 CFR 484.18(c) that allows HHAs to administer influenza and pneumococcal vaccinations without specific physician orders, provided that certain requirements are adhered to. As an allowance of flexibility, rather than an imposition of a specific requirement, we believe that this provision does not impose a burden upon HHAs.

This standard also retains many of the current requirements regarding verbal orders with the exception of the requirement at § 484.60(b)(5), ''Conformance with physician orders,'' which requires the physician to countersign and date all verbal orders. Although this requirement is not in the current regulations, this and similar physician order practices are consistent with current standards of practice and with many state laws. Therefore, we expect no new burden with this provision.

Standard 484.60(c), ''Review and revision of the plan of care,'' incorporates some current requirements. Although there has been some revision to current § 484.18(b), ''Periodic review of plan of care,'' to include mention of measurable outcomes for patients, the intent of this requirement already exists at § 484.55, ''Comprehensive assessment of patients.'' Section 484.55 requires an HHA to demonstrate patient progress toward the achievement of desired outcomes. Therefore, the current standard remains essentially intact in this final rule and the new standard does not constitute any new burden.

Standard 484.60(d), ''Coordination of care,'' revises current § 484.14(g), ''Coordination of patient services,'' and some elements of current § 484.18(a), ''Plan of care.'' The intent of the current standards remains intact, and these revisions do not generate new burden.

Standard 484.60(e), ''Written information to the patient,'' requires the HHA to provide written instructions to the patient and care giver outlining visit schedule including frequency of visits, medication schedule/instructions, treatments administered by HHA personnel and personnel acting on the behalf of the HHA, pertinent instructions related to patient care and the name and contact information of the HHA clinical manager. Giving written instruction to the patient and care giver has been a longstanding practice in the home health industry and is one of the most fundamental elements in patient education. Patient education practices are fundamental to patient care and are consistent with current standards of practice. Therefore, we expect no new burden with this provision.

Quality Assessment and Performance Improvement (QAPI) (§ 484.65)

The quality assessment and performance improvement (QAPI) requirement replaces the current quality-related requirements of § 484.16, ''Group of professional personnel,'' and § 484.52, ''Evaluation of the agency's program.'' Quality assessment is already part of standard HHA practice through annual evaluations of an agency's total program using both administrative reviews and a quarterly review of a sample of clinical records. Furthermore, HHAs are already familiar with the basic concept of measuring quality on both a patient and aggregate level. This rule further refines current HHA quality efforts and brings HHA quality programs in line with their counterparts in a variety of other settings, such as hospitals and hospices. Likewise, this rule brings non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more enhancing, expanding, and refining their quality-related standards, and those standards far exceed the current Medicare regulations. Indeed, many of the current quality-related standards established by the accrediting organizations, we believe, exceed those that we require in this rule. Since accredited HHAs already have QAPI programs that should meet the requirements of this rule by virtue of meeting the already existing accreditation standards, we are not including accredited HHAs in our analysis of the impact of this requirement. This rule provides a basic outline of what QAPI is and how we expect it to function in the HHA environment. Each HHA is free to decide how to implement the QAPI requirement in a manner that reflects its own unique needs and goals.

For purposes of this impact analysis we have described the impact in three general phases that we believe an average HHA will go through. These phases are based on our experience in implementing the QAPI requirements in hospices, another home-based provider type with a similar operating structure and patient population. While we have outlined these phases below, we stress that an HHA is not be required to approach QAPI in this manner. The QAPI requirement does not stipulate that an HHA must collect data for a specific domain; use specific quality measures, policies and procedures, or forms; submit QAPI data to an outside body; or conduct a specified number of performance improvement projects. An HHA may choose to implement a data-driven, comprehensive QAPI program that meets the requirements of this rule in any way that meets its individual needs. These phases described below simply provide a framework for assessing the potential impact of the QAPI requirement upon an average non-accredited HHA. In phase one, we believe that an HHA will—

- Identify quality domains and measurements that reflect its organizational complexity; involve all HHA services; affect patient outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas; and track adverse patient events;
- Develop and revise policies and procedures to ensure that data is consistently collected, documented, retrieved, and analyzed in an accurate manner; and
- Educate HHA employees and contractors about the QAPI requirement, philosophy, policies, and procedures. In phase two, we believe that an HHA will—
- Enter data into patient clinical records during patient assessments;
- Aggregate data by collecting the same pieces of data from patient clinical records and other sources (for example, human resource records);
- Analyze the data that is aggregated through charts, graphs, and various other methods to identify patterns, anomalies, areas of concern, etc. that may be useful in targeting areas for improvement; and
- Develop, implement, and evaluate major and minor performance improvement projects based on a thorough analysis of the data collected. In phase three, we believe that an HHA will—
- Identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the HHA;
- Develop and/or revise policies and procedures to accommodate the new domains and measures; and
- Educate HHA employees and contractors on the new domains and measures, as well as the policies and procedures for them.

In addition to these three phases, an HHA will likely allocate resources to an individual responsible for the general overall coordination of its QAPI program. For simplicity, we refer to this individual as the QAPI coordinator; however, an HHA is not required to use this title. For purposes of this analysis only, we assume that an HHA would

choose a QAPI coordinator who has a clinical background, such as a nurse.

Based on these three phases, we have anticipated the impact of the QAPI requirement on an HHA's resources. In phase one, we anticipate that an HHA will use 9 hours to identify quality domains and measures. HHA quality domains and measures are readily available. Indeed, HHAs already collect data for a wide variety of domains and measures each year as part of the OASIS patient assessment data collection tool, and this data is already used to calculate quality measures as presented in OBQI, OBQM, and PBQI reports and the home health compare Web site. These sources provide a robust starting point for HHAs in the quality measurement efforts. We expect that these hours will be distributed among the three members of the HHA's QAPI committee. While we do not require an HHA to have a QAPI committee, we believe that most HHAs would choose to do so to ensure a variety of perspectives are represented in the QAPI decision-making process. We believe that the QAPI committee will include the QAPI coordinator, the HHA administrator, and a clinical manager. We estimate that the QAPI committee will meet three times per year for 1 hour each meeting to identify appropriate quality domains and measures. We estimate that, in total, the QAPI committee will need 9 hours annually to identify appropriate quality domains and measures (3 staff hours per meeting × 3 meetings per year). The total annual cost for an average HHA to identify the domains and measures is $738 ($189 per QAPI coordinator + $294 per administrator + $255 per clinical manager). The total cost for all HHAs is $5,630,940 ($738 per HHA × 7,630 non-accredited HHAs).

In addition to selecting measures and developing policies and procedures for QAPI activities, we anticipate that HHAs will train appropriate staff in data collection for any new data elements necessary to calculate quality measures, as well as the overall QAPI philosophy and efforts within the agency. For purposes of this analysis, we assume HHAs will train all clinical staff in the basic concept of QAPI, the agency's implementation of this requirement, and any agency-specific policies and procedures. We estimate that an HHA will spend 1 hour per staff member to provide this training, as many staff are already familiar with data collection and its role in quality measurement and improvement through the OASIS, OBQI, and PBQI instruments. For purposes of our analysis we are including patient care clinicians because they are the staff members that are most likely to be performing data collection. In 2009, Medicare-certified HHAs had 242,020 clinician FTEs, for an average of 24 clinical FTEs per HHA. The cost per HHA is $1,824. (1 hour per clinical staff member × 24 clinical staff members × $76 per hour per clinical staff member) The total hour for non-accredited HHAs is 183,120 (24 hours per average HHA × 7,630 non-accredited HHAs) and the total cost is $13,917,120 (183,120 hours × $76/hour).

Phase two is related to gathering, entering, and analyzing data for quality assessment and performance improvement purposes. Thoroughly assessing a patient and collecting patient data in a standardized manner is already standard practice due to the OASIS regulations. The presence of the OASIS data set and quality reporting measures has been in place for several years and the concepts of each are fully integrated into standard HHA practices. Therefore, we do not believe that it would be a burden for HHAs to incorporate new data gathered for dual patient care planning and QAPI purposes into their current systems and processes.

We believe that any additional burden will arise from the act of entering, aggregating, and analyzing other types of available data that HHAs already collect for other purposes (for example, staffing productivity, staff vacancy rates, timeliness of delivery of services). We estimate that, in order to ensure that the volume of gathered data is manageable, an HHA will gather its data once a month. An HHA may choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some HHAs may choose to gather all patient-level data, but we believe that most HHAs will choose to gather data from a sample of clinical records. Likewise, some HHAs may choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources. There are many combinations that an HHA may choose to use when it comes to gathering data, and no single approach is considered preferable to another. Given this variability, it is difficult to estimate how long an average HHA may spend gathering and organizing data. For purposes of this analysis only, we assume that an average HHA will use 4 hours per month to gather data, for a total of 48 hours a year. We believe that an office employee would perform the data aggregation and organization at a cost of $1,248 (4 hours × 12 months × $26/hour) per HHA. The total cost is $9,522,240 ($1,248 per HHA × 7,630 HHAs). Following data gathering and organization, an HHA will analyze the data to identify trends, patterns, anomalies, areas of strength and concern. We believe that this data analysis will be done by the QAPI committee described previously. In order to identify trends and patterns, the committee will need to examine several months of data at the same time. Therefore, we assume that the committee will meet once every quarter to examine the data and make decisions based on the analysis. Meeting to discuss quality measure data is standard practice in the HHA industry. HHAs are well versed in quality measure reports due to the OBQI and PBQI reports produced by CMS, and the quality measure reports available to the public on the Home Health Compare Web site. Since HHAs already meet to discuss and analyze quality measure results, we do not believe that this requirement will impose a new burden.

Performance improvement projects follow all of the data entry, gathering, organization, and analysis. An HHA must conduct projects to improve its performance in areas where a weakness was identified. Performance improvement projects must reflect the HHA's scope, complexity, and past performance. They must also be data-driven, and affect patient outcomes, patient safety, and quality of care. Although this rule more clearly describes a performance improvement project, its basis, and its purpose, it is based on the same concept as the current requirement at § 484.52, ''Evaluation of the agency's program,'' which requires that ''Results of the evaluation are reported and acted upon by those responsible for the operation of the agency. . . .'' Since an HHA already takes action to ensure that its program is appropriate, adequate, effective, and efficient, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, we believe that conducting both major and minor performance improvement projects is already a standard of practice within the HHA industry. Therefore, there will be no additional burden associated with this provision. Although we do not believe that the requirement to conduct performance improvement projects will require additional time and resources, we do believe that the required focus of such projects, and their data-driven nature, will help HHAs improve the efficiency and effectiveness that they achieve in these projects. We believe that the improved project efficiency and effectiveness may result in improved patient outcomes,

avoidance of future adverse events, more appropriate resource allocation, and a wide variety of other beneficial outcomes, based on the projects selected by each HHA.

Phase three of the QAPI process builds upon the QAPI program that an HHA already has in place. We estimate that an HHA will use 3 hours a year to identify new domains and quality measures, and we believe that the QAPI committee will perform this task, at a total cost of $246 (1 hour × $63/hour for QAPI coordinator + 1 hour × $98/hour for administrator + 1 hour × $85/hour rate for clinical manager). The total annual cost for non-accredited HHAs in updating domain and measures is $1,876,980 ($246 per HHA × 7,630 HHAs) in year 2 and thereafter.

TABLE 5—QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Identify domains and measures (1st year)	9	68,670	$738	$5,630,940
Train staff (1st year and on-going)	24	183,120	1,824	13,917,120
Aggregate data (1st year and on-going)	48	366,240	1,248	9,522,240
Update domains and measures (on-going)	3	22,890	246	1,876,980
Total 1st year	81	618,030	3,810	29,070,300
Total yearly on-going	75	572,250	3,318	25,316,340

Infection Prevention and Control (§ 484.70)

There is no specific current requirement addressing infection control in the current HHA CoPs. However, current § 484.12(c), ''Compliance with accepted professional standards and principles,'' requires an HHA and its staff to comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Given this broad requirement, we believe that HHA personnel are already using well-documented infection control practices and well-accepted professional standards and principles in their patient care practices. This regulation reinforces positive infection control practices and addresses the serious nature, as well as the potential hazards, of infectious and communicable diseases in the home health environment. This rule also brings non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more developing and refining their infection prevention and control standards in the absence of specific Medicare regulations. Indeed, the current infection prevention and control standards established by the accrediting organizations would, we believe, even exceed those that we require in this rule.

Specifically, the regulation requires HHAs to have an organized, agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The agency's program is required to include the following:

- The use of accepted standards of practice, including standard precautions, to prevent the transmission of infections and communicable diseases;
- A method for identifying infectious and communicable disease problems;
- A plan for the appropriate actions that are expected to result in improvement and disease prevention; and
- Education to staff, patients, and caregivers about infection prevention and control issued and practices.

We believe that developing this organized program will require HHA resources, and estimate that an HHA will use 1.5 hours of staff time each week, or 78 hours per year (1.5 hours × 52 weeks), to develop and maintain the infection prevention and control program. At a cost of $63 per hour for a nurse to provide program leadership, the cost will be $4,914 per HHA (78 hours × $63/hour)

While we cannot quantify the benefits of having an organized program for the prevention and control of infections or the costs of replacing current infection control practices with practices conducted under an organized program, we believe a program should produce benefits for HHAs and their patients. For example, a program may improve the manner in which HHAs identify to HHA staff those patients who are infected or colonized with antibiotic resistant bacteria so that staff may take additional precautions in order to protect themselves during interactions with patients, thereby reducing the amount of sick leave used by HHA staff. We do not have adequate data from which to create accurate estimates of the potential benefits or ongoing costs of this requirement, but we believe that they are substantial.

TABLE 6—INFECTION PREVENTION AND CONTROL

Standard	Time per HHA (hours)	Total time (hours)	Cost per HHA	Total cost
Develop and maintain program	78	595,140	$4,914	$37,493,820
Total	78	595,140	4,914	37,493,820

Skilled Professional Services (§ 484.75)

We consolidated provisions previously located at § 484.30, ''Skilled nursing services''; § 484.32, ''Therapy services''; and § 484.34, ''Medical social services,'' into this new requirement. We added a requirement that skilled professionals participate in the QAPI program. Involvement in patient care and patient care-related activities is a professional responsibility, and therefore we believe involvement in the

agency's QAPI program imposes little or no additional burden. We also added a requirement, somewhat similar to the requirement at § 484.14(d), regarding the supervision of nursing assistants, therapy assistants, and medical social service assistants. We require that all nursing services be provided under the supervision of a registered nurse; all rehabilitative therapy assistant services be provided under the supervision of a physical therapist or occupational therapist; and all medical social services be provided under the supervision of a social worker. These supervision requirements codify current HHA supervision practices, and therefore do not impose a new burden upon HHAs.

Home Health Aide Services (§ 484.80)

Home health aide services are an integral part of home health care, and the CoP retains many of the current longstanding requirements. However, in an effort to make the current requirements for home health aides more consistent throughout, improve overall clarity, and reflect current standards of practice more accurately, we have reorganized and revised the requirements in this CoP. The burdens associated with this section are described in the Collection of Information section of this rule. Therefore, we are not repeating those burdens in this section. Other changes, such as requiring HHAs to supervise aides when performing skills for which the aides have not passed a competency evaluation or requiring aides to report changes in a patient's condition to a registered nurse or other appropriate skilled professional, constitute standard practice within the HHA industry. Therefore, no new burdens are imposed by these changes.

Compliance With Federal, State, and Local Laws and Regulations Related to Health and Safety of Patients (§ 484.100)

The current regulations at § 484.12(a), ''Compliance with Federal, State, and local laws and regulations''; § 484.12(b), ''Disclosure of ownership and management information''; and § 484.14(j), ''Laboratory services,'' have been reorganized with only minor clarifying revisions to the language of each standard. The current condition statement is modified slightly for clarification purposes. However, the current regulation regarding compliance with all applicable laws and regulations related to patient health and safety, state licensing of HHAs, and laboratory services, essentially remains intact under this rule. The burden associated with this provision is the disclosure of certain information, which was discussed in the Collection of Information section of this rule, and there are no other burdens associated with this provision.

Organization and Administration of Services (§ 484.105)

Several of the requirements currently found at § 484.14, ''Organization, services, and administration,'' have been reorganized and revised under this condition.

In order to facilitate compliance with § 484.60(d) and to ensure that each patient's care is coordinated, we have combined, revised, and elaborated on former § 484.14(d) and (e) at § 484.105(c), ''Clinical manager.'' This standard requires one or more qualified individuals to provide oversight of all patient care services and HHA personnel. Oversight includes making patient and personnel assignments; coordinating patient care; coordinating referrals; and assuring the development, implementation, and updates of the individualized plan of care. The clinical manager role in the regulations is a further refinement of the former ''Supervising physician or registered nurse'' role found in regulation at § 418.14(d); therefore the general duties described above are already required of home health agencies. The complex, multi-disciplinary nature of home health care necessitates both personnel supervision and patient care coordination to ensure the effective delivery of patient care and positive patient outcomes. The clinical manager position does not constitute any new functions within an HHA; rather, it provides a more structured approach for patient care coordination and personnel supervision tasks. Since the various patient care coordination functions already in existence are consolidated under the clinical manager position and are thus be a realignment of current resource allocations, we do not believe that this requirement poses a new burden.

Clinical Records (§ 484.110)

The former regulation at § 484.48, ''Clinical records,'' is revised, and reorganized under this CoP. We believe that the majority of the revisions to the former clinical record requirement reflect contemporary professional standards already in place in the home health industry. Therefore, no additional burden is imposed. In addition, the requirements allow HHAs to maintain and send a patient's clinical record in electronic form. This flexibility may result in a reduction in burden for many HHAs with systems of electronic record keeping already in place.

Personnel Qualifications (§ 484.115)

We reorganized the personnel qualification requirements formerly found at § 484.4, ''Personnel qualifications,'' in a new CoP dedicated to personnel qualification standards. Within this new condition we use the term ''licensed practical (vocational) nurse'' instead of the current term of ''practical (vocational) nurse'' since state practice acts vary and both of these terms are accepted and typically used interchangeably We also require that the possession of any undergraduate degree would be sufficient for a newly-hired administrator. In addition, we are expanding the qualifications for social workers to include those individuals who possess either a master's (M.S.W) or a doctor's degree (D.S.W.) in social work. Furthermore, we are deferring to state licensure requirements as the basis for determining the qualifications of SLPs. This expansion of the qualifications for administrators, social workers, and SLPs could provide an agency more flexibility in hiring these professions if it chose, and could provide a potential reduction in burden, though we are not able to quantify what this reduction might be at this time. These changes create no new burden for HHAs.

2. Deleted Requirements

We deleted three requirements of the former HHA regulations in their entirety. First, we deleted § 484.14(g), removing the requirement that an HHA must send a written summary report for each patient to the attending physician every 60 days. This requirement imposes a burden of 3 minutes per patient, and 887,592 hours, annually, for all HHAs at a cost of $16,864,248, as indicated by the currently-approved PRA package (OMB control number 0938–0365). Therefore, removing this requirement saves HHAs $16,864,248 each year.

Second, we deleted § 484.16, ''Group of professional personnel,'' because the QAPI requirements address the same goals as are currently required of the group of professional personnel. This requirement imposes a documentation burden of 10 minutes per HHA, and 1,988 hours, annually, for all HHAs at a cost of $37,772, as indicated by the currently-approved PRA package (OMB control number 0938–0365).

In addition to the burden related to documentation, we believe that eliminating this requirement also alleviates the burden of holding meetings with the group of professional

personnel for the sole purpose of complying with this regulatory requirement. The regulation requires that the group must consist of at least one physician, one registered nurse, and representation from other professional disciplines, with at least one member who is not employed by or an owner of the HHA. Since the regulations at § 484.14(a) require HHAs to provide skilled nursing services as well as the services of at least one other discipline, not including physician services, we know that the group of professional personnel is required to have at least three members. For purposes of this analysis, we assume that the group of professional personnel would include a physician ($180), a registered nurse ($63), a therapist ($72), and a home health aide ($20). The regulation also requires that the group of professional personnel must meet ''frequently.'' For purposes of this analysis, we assume that the frequency requirement would be met by holding quarterly meetings of the group. Furthermore, we assume that most quarterly meetings would require 1 hour of each member's time, for a total of 4 labor hours per meeting, or 16 labor hours per year per HHA. We estimate the cost associated with this requirement to be $335 per meeting, or $1,340 per HHA per year ($335 per meeting × 4 meetings per year), for a total of 201,632 hours (16 hours per HHA × 12,602 HHAs) at cost of $16,886,680 ($1,340 per HHA × 12,602 HHAs) per year. Therefore, we estimate that the total reduction of burden is 203,620 hours (201,632 hours + 1,988 hours) and $16,924,452 ($16,886,680 + $37,772).

Third, we deleted § 484.52, ''Evaluation of the agency's program,'' because the prescriptive quarterly review of clinical records is outdated and unnecessary. This requirement currently imposes a documentation burden of 11,863 hours, annually, for all HHAs at a cost of $304,199, as indicated by the currently-approved PRA package (OMB control number 0938–0365).

In addition to the documentation burden imposed by this requirement, we believe that there is a burden associated with the time necessary to complete the quarterly clinical record reviews. The regulation requires that appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care. Each professional may review the records separately, at different times. For purposes of this analysis, we assume that an HHA would review a 5 percent sample of its clinical records, or an average of 70 clinical records per year per facility. Furthermore, for purposes of this analysis, we assume that a registered nurse ($63/hour), a therapist ($72/hour), and a home health aide ($20/hour) reviews each clinical record, and that each review would require 30 minutes per discipline, for a total of 90 minutes per record review. We estimate that each HHA uses 105 hours per year to meet this requirement, for a total of 1,323,210 hours for all HHAs. The total cost per record review is $78, or $5,460 per HHA per year, for a total of $68,806,920 for all HHAs. Therefore, we believe that removing this requirement alleviates a total burden of 1,335,073 hours and $69,111,119.

3. Impact on Patient Care

Although the positive effects of these changes cannot be quantified, we note that the changes are focused on improving the delivery of care to each and every patient. For example, the QAPI standard encourages HHAs to use their own internally-generated data to proactively identify patient care inefficiencies, contradictions, lapses, and other issues in the care delivery system so that HHAs can rapidly implement performance improvement projects designed to remedy the issue(s) at hand. Proactively identifying care issues and implementing projects to correct those issues will ultimately lead to more effective and efficient patient care and improved patient outcomes. However, as previously indicated, we cannot quantify the impact on patients.

E. Alternatives Considered

We considered finalizing the proposed requirement that HHAs must proactively provide each patient with a copy of his or her plan of care. We considered multiple options for implementing the originally proposed requirement.

Option 1—Require HHAs to provide each patient with a copy of only the initial plan of care. No written updates would be required in this option. We estimate that this requirement would create approximately 600,000 annual burden hours, at a cost of $15.6 million, annually.

Option 2—Require HHAs to provide each patient with a copy of only the initial plan of care, and require HHAs to translate key elements of the plan of care into layman's terms. No written updates would be required. We estimate that this requirement would create approximately 3 million annual burden hours at a cost of $189 million annually (based on the assumption of a nurse using 10 minutes to translate the clinical plan of care into layman's terms).

Option 3—Require HHAs to provide each patient with a copy of plan of care for each 60-day episode of care. We estimate that this requirement would create approximately 11 million annual burden hours at a cost of $285 million, annually.

Option 4—Require HHAs to provide each patient with a copy of plan of care and translate key elements of the plan of care into layman's terms for each 60-day episode of care. We estimate that this requirement would create approximately 55 million annual burden hours at a cost of $3.5 billion, annually.

Option 5—Require HHAs to provide each patient with a copy of plan of care and require it to be updated for significant changes. Assuming 4 plans of care per 60 day episode for complex patients and 1 plan of care per 60 day episode for non-complex patients, we estimate that this requirement would create approximately 31 million annual burden hours at a cost of $799 million, annually.

Option 6—Require HHAs to provide each patient with a copy of plan of care and translate key elements into layman's terms. Also require the plan of care to be updated for significant changes. Assuming 4 plans of care per 60 day episode for complex patients and 1 plan of care per 60 day episode for non-complex patients, we estimate that this requirement would create approximately 153.6 million annual burden hours at a cost of $9.7 billion, annually.

Option 7—Do not require HHAs to provide patients with written information regarding the plan of care under any circumstances. Removing this concept from the regulations entirely would be consistent with current requirements, and would signal to HHAs, states, and accreditation organizations that such written communication is unnecessary. We believe that most HHAs are already providing certain written information to patients. Removing this concept from the rules entirely may encourage those entities to stop providing such written information, thus reducing their self-imposed burden.

We also considered retaining the broad requirement from the proposed rule that HHAs provide patients with the names, addresses, and telephone

numbers of pertinent, Federally-funded and State-funded, State and local consumer information, consumer protection, and advocacy agencies. Commenters stated that such a broad requirement would impose a significant burden due to the volume of entities to be identified and the need to assure updated contact information for such entities at all times. Although commenters did not provide an estimate of the burden, we believe that HHAs may have expended one hour per quarter, or approximately 50,000 hours annually at a cost of $1.3 million, annually.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), we have prepared an accounting statement in Table 7 showing the classification of the transfers and costs associated with the provisions of this rule for Calendar Year (CY) 2017 to 2021.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED NET COSTS FROM CY 2017 TO CY 2021

[In millions]

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs:				
Annualized Monetized ($million/year)	291	2015	7	2017–2021
	291	2015	3	2017–2021

Although the benefits and some of the costs of these changes cannot be quantified, we note that the changes are focused on improving the delivery of care to each and every patient. An increased focus on identifying and proactively addressing risk factors for emergency department visits and hospital re-admissions has the potential to reduce both, leading to improved patient health and decreased payer expenditures. Likewise, requiring HHAs to educate and teach patients the necessary self-care skills to facilitate a timely discharge may lead to more and better patient engagement in managing chronic health conditions such as diabetes, ultimately leading to improved patient health and reduced payer expenditures. However, as previously indicated, we cannot quantify the impact on patients.

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and states are not included in the definition of a small entity. For the purposes of the RFA, most HHAs are considered to be small entities, either by virtue of their nonprofit status or government status, or by having revenues less than $15 million in any 1 year (for details, see the Small Business Administration's (SBA) Web site at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf* (refer to the 620000 series). There are 12,602 Medicare-certified HHAs with average annual patient census of 1,409 patients per HHA. An average Medicare-participating HHA in 2010 had annual revenues (all payment sources) of $6.55 million. Therefore, the vast majority of these Medicare-certified HHAs would be considered small entities under the SBA's NAICS.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because the cost of this rule on a per-HHA basis is minimal (approximately a $15,100 net increase in burden per typical non-accredited HHA in the 1st year, and a small net savings of approximately $700 for accredited HHAs in the 1st year). There are a small number of HHAs that will experience a larger increase in burden than a typical HHA, ranging anywhere from an additional $500 to $59,000 per year, depending on which aspects of the rule constitute a significant departure from their current practices. We believe that these HHAs account for up to 10 percent of the entire HHA population. An HHA tht would need to come into compliance with the most costly provision (providing specified written information to patients per the requirements of 484.60(e), approximately $59,000 per affected HHA) would still only experience a change in revenue equal to 1.13 percent ($15,100+ $59,000). Therefore, we certify that this rule would 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 and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals because there are few HHAs in those facilities. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. It includes no mandates on state, local, or tribal governments. The estimates presented in this section of the final rule exceed this threshold and, as a result, we have provided a detailed assessment of the anticipated costs and benefits in RIA section as well as other parts of the preamble.

I. 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 rule has no Federalism implications.

J. Congressional Review Act

This regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 409.43	(a)	§ 484.18(a)	§ 484.60(a)
§ 409.43	(c)(1)(i)(C)	42 CFR 484.4	42 CFR 484.115
§ 409.43	(d)	§ 484.4	§ 484.115
§ 409.44	(b)(1) introductory text and (c)(2)(ii)	§ 484.4	§ 484.115
§ 409.45	(c)(4)	§ 484.4	§ 484.115
§ 409.46	(b)	§ 484.36(d)	§ 484.80(h)
§ 409.47	(b) introductory text	§ 484.14(h)	§ 484.105(e)

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

§ 410.62 [Amended]

■ 4. In § 410.62(a) introductory text, remove ''§ 484.4'' and add in its place ''§ 484.115''.

PART 418—HOSPICE CARE

■ 5. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 6. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 418.76	(f)(1)	§ 484.36(a) and § 484.36(b)	§ 484.80
§ 418.76	(f)(2)	§ 484.36(a)	§ 484.80(a)

PART 440—SERVICES: GENERAL PROVISIONS

■ 7. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

§ 440.110 [Amended]

■ 8. In § 440.110(a)(2) and (b)(2), remove ''§ 484.4'' and add in its place ''§ 484.115''.

PART 484—HOME HEALTH SERVICES

■ 9. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 10. Part 484 is amended by revising subparts A through C to read as follows:

Subpart A—General Provisions

Sec.
484.1 Basis and scope.
484.2 Definitions.

Subpart B—Patient Care

484.40 Condition of participation: Release of patient identifiable OASIS information.
484.45 Condition of participation: Reporting OASIS information.
484.50 Condition of participation: Patient rights.
484.55 Condition of participation: Comprehensive assessment of patients.
484.60 Condition of participation: Care planning, coordination of services, and quality of care.
484.65 Condition of participation: Quality assessment and performance improvement (QAPI).
484.70 Condition of participation: Infection prevention and control.
484.75 Condition of participation: Skilled professional services.
484.80 Condition of participation: Home health aide services.

Subpart C—Organizational Environment

484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.
484.102 Condition of participation: Emergency preparedness.
484.105 Condition of participation: Organization and administration of services.
484.110 Condition of participation: Clinical records.
484.115 Condition of participation: Personnel qualifications.

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) *Basis.* This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet.

(b) *Scope.* The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.

§ 484.2 Definitions.

As used in subparts A, B, and C, of this part—

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Parent home health agency means the agency that provides direct support and administrative control of a branch.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

Subpart B—Patient Care

§ 484.40 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

§ 484.45 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding and transmitting OASIS data.* An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* An HHA must—

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the QIES ASAP System or CMS OASIS contractor.

(3) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140–2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

§ 484.50 Condition of participation: Patient rights.

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights.* The HHA must—

(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:

(i) Written notice of the patient's rights and responsibilities under this rule, and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities;

(ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.

(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.

(2) Obtain the patient's or legal representative's signature confirming

that he or she has received a copy of the notice of rights and responsibilities.

(3) Provide verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the second visit from a skilled professional as described in § 484.75.

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.

(b) *Standard: Exercise of rights.* (1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights.

(3) If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

(c) *Standard: Rights of the patient.* The patient has the right to—

(1) Have his or her property and person treated with respect;

(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

(3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;

(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to—

(i) Completion of all assessments;

(ii) The care to be furnished, based on the comprehensive assessment;

(iii) Establishing and revising the plan of care;

(iv) The disciplines that will furnish the care;

(v) The frequency of visits;

(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;

(vii) Any factors that could impact treatment effectiveness; and

(viii) Any changes in the care to be furnished.

(5) Receive all services outlined in the plan of care.

(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(7) Be advised of—

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,

(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,

(iii) The charges the individual may have to pay before care is initiated; and

(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

(9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.

(10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides:

(i) Agency on Aging,

(ii) Center for Independent Living,

(iii) Protection and Advocacy Agency,

(iv) Aging and Disability Resource Center; and

(v) Quality Improvement Organization.

(11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

(12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.

(d) *Standard: Transfer and discharge.* The patient and representative (if any), have a right to be informed of the HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

(2) The patient or payer will no longer pay for the services provided by the HHA;

(3) The transfer or discharge is appropriate because the physician who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with § 484.60(a)(2)(xiv) have been achieved, and the HHA and the physician who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

(4) The patient refuses services, or elects to be transferred or discharged;

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

(i) Advise the patient, representative (if any), the physician(s) issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

(ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;

(iii) Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and

(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;

(6) The patient dies; or

(7) The HHA ceases to operate.

(e) *Standard: Investigation of complaints.* (1) The HHA must—

(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:

(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and

(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.

(ii) Document both the existence of the complaint and the resolution of the complaint; and

(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.

(f) Standard: Accessibility. Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible Web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Content of the comprehensive assessment.* The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

(1) The patient's current health, psychosocial, functional, and cognitive status;

(2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;

(3) The patient's continuing need for home care;

(4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs;

(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(6) The patient's primary caregiver(s), if any, and other available supports, including their:

(i) Willingness and ability to provide care, and

(ii) Availability and schedules;

(7) The patient's representative (if any);

(8) Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician-ordered resumption date;

(3) At discharge.

§ 484.60 Condition of participation: Care planning, coordination of services, and quality of care.

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible

discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

(a) *Standard: Plan of care.* (1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.

(2) The individualized plan of care must include the following:

(i) All pertinent diagnoses;

(ii) The patient's mental, psychosocial, and cognitive status;

(iii) The types of services, supplies, and equipment required;

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(vii) Functional limitations;

(viii) Activities permitted;

(ix) Nutritional requirements;

(x) All medications and treatments;

(xi) Safety measures to protect against injury;

(xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.

(xiii) Patient and caregiver education and training to facilitate timely discharge;

(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;

(xv) Information related to any advanced directives; and

(xvi) Any additional items the HHA or physician may choose to include.

(3) All patient care orders, including verbal orders, must be recorded in the plan of care.

(b) *Standard: Conformance with physician orders.* (1) Drugs, services, and treatments are administered only as ordered by a physician.

(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient to determine for contraindications.

(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

(4) When services are provided on the basis of a physician's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

(c) *Standard: Review and revision of the plan of care.* (1) The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

(3) Revisions to the plan of care must be communicated as follows:

(i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians issuing orders for the HHA plan of care.

(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

(d) *Standard: Coordination of care.* The HHA must:

(1) Assure communication with all physicians involved in the plan of care.

(2) Integrate orders from all physicians involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

(3) Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.

(4) Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

(5) Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.

(e) *Standard: Written information to the patient.* The HHA must provide the patient and caregiver with a copy of written instructions outlining:

(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.

(2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.

(3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.

(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.

(5) Name and contact information of the HHA clinical manager.

§ 484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI

program and be able to demonstrate its operation to CMS.

(a) *Standard: Program scope.* (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

(2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

(b) *Standard: Program data.* (1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

(2) The HHA must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be approved by the HHA's governing body.

(c) *Standard: Program activities.* (1) The HHA's performance improvement activities must—

(i) Focus on high risk, high volume, or problem-prone areas;

(ii) Consider incidence, prevalence, and severity of problems in those areas; and

(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

(3) The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* Beginning January 13, 2018 HHAs must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.

(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) *Standard: Executive responsibilities.* The HHA's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;

(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;

(3) That clear expectations for patient safety are established, implemented, and maintained; and

(4) That any findings of fraud or waste are appropriately addressed.

§ 484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

(a) *Standard: Prevention.* The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

(b) *Standard: Control.* The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

(1) A method for identifying infectious and communicable disease problems; and

(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

(c) *Standard: Education.* The HHA must provide infection control education to staff, patients, and caregiver(s).

§ 484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in § 409.44 of this chapter, and physician and medical social work services as specified in § 409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

(a) *Standard: Provision of services by skilled professionals.* Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under § 484.115 and who practice according to the HHA's policies and procedures.

(b) *Standard: Responsibilities of skilled professionals.* Skilled professionals must assume responsibility for, but not be restricted to, the following:

(1) Ongoing interdisciplinary assessment of the patient;

(2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);

(3) Providing services that are ordered by the physician as indicated in the plan of care;

(4) Patient, caregiver, and family counseling;

(5) Patient and caregiver education;

(6) Preparing clinical notes;

(7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;

(8) Participation in the HHA's QAPI program; and

(9) Participation in HHA-sponsored in-service training.

(c) *Supervision of skilled professional assistants.* (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of § 484.115(k).

(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of § 484.115(f) or (h), respectively.

(3) Medical social services are provided under the supervision of a social worker that meets the requirements of § 484.115(m).

§ 484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) *Standard: Home health aide qualifications.* (1) A qualified home health aide is a person who has successfully completed:

(i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or

(iii) A nurse aide training and competency evaluation program approved by the state as meeting the requirements of § 483.151 through § 483.154 of this chapter, and is

currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in § 409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) *Standard: Content and duration of home health aide classroom and supervised practical training.* (1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of 16 hours of supervised practical training as part of the 75 hours.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

(A) Bed bath;

(B) Sponge, tub, and shower bath;

(C) Hair shampooing in sink, tub, and bed;

(D) Nail and skin care;

(E) Oral hygiene;

(F) Toileting and elimination;

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

(xiii) Recognizing and reporting changes in skin condition; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

(c) *Standard: Competency evaluation.* An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as ''unsatisfactory,'' and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

(d) *Standard: In-service training.* A home health aide must receive at least 12 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

(e) *Standard: Qualifications for instructors conducting classroom and supervised practical training.* Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

(f) Standard: Eligible training and competency evaluation organizations. A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

(2) Permitted an individual who does not meet the definition of a ''qualified home health aide'' as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or

(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

(g) *Standard: Home health aide assignments and duties.* (1) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).

(2) A home health aide provides services that are:

(i) Ordered by the physician;

(ii) Included in the plan of care;

(iii) Permitted to be performed under state law; and

(iv) Consistent with the home health aide training.

(3) The duties of a home health aide include:

(i) The provision of hands-on personal care;

(ii) The performance of simple procedures as an extension of therapy or nursing services;

(iii) Assistance in ambulation or exercises; and

(iv) Assistance in administering medications ordinarily self-administered.

(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

(h) *Standard: Supervision of home health aides.* (1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in § 484.80(g), must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

(ii) If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete a competency evaluation in accordance with paragraph (c) of this section.

(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient's condition; and

(vi) Honoring patient rights.

(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;

(ii) Supervising aide services as described in paragraphs (h)(1) and (2) of this section; and

(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

(i) *Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.* An individual may furnish personal care services, as defined in § 440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C—Organizational Environment

§ 484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

(a) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in § 420.201, § 420.202, and § 420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(b) *Standard: Licensing.* The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

(c) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

(2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§ 484.102 Condition of participation: Emergency preparedness.

The Home Health Agency (HHA) must comply with all applicable Federal, State, and local emergency preparedness requirements. The HHA must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The HHA must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the HHA has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the HHA's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at § 484.55.

(2) The procedures to inform State and local emergency preparedness officials about HHA patients in need of evacuation from their residences at any time due to an emergency situation based on the patient's medical and psychiatric condition and home environment.

(3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.

(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(c) *Communication plan.* The HHA must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, or local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the HHA's staff, Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the HHA's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(6) A means of providing information about the HHA's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The HHA must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The HHA must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(ii) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The HHA must conduct exercises to test the emergency plan at least annually. The HHA must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the HHA experiences an actual natural or man-made emergency that requires activation of the emergency plan, the HHA is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the HHA's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the HHA's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a HHA is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the HHA may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

§ 484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

(a) *Standard: Governing body.* A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.

(b) *Standard: Administrator.* (1) The administrator must:

(i) Be appointed by and report to the governing body;

(ii) Be responsible for all day-to-day operations of the HHA;

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.

(3) The administrator or a pre-designated person is available during all operating hours.

(c) *Clinical manager.* One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following—

(1) Making patient and personnel assignments,

(2) Coordinating patient care,

(3) Coordinating referrals,

(4) Assuring that patient needs are continually assessed, and

(5) Assuring the development, implementation, and updates of the individualized plan of care.

(d) *Standard: Parent-branch relationship.* (1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

(2) The parent HHA provides direct support and administrative control of its branches.

(e) *Standard: Services under arrangement.* (1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x (w)).

(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

(i) Denied Medicare or Medicaid enrollment;

(ii) Been excluded or terminated from any federal health care program or Medicaid;

(iii) Had its Medicare or Medicaid billing privileges revoked; or

(iv) Been debarred from participating in any government program.

(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

(f) *Standard: Services furnished.* (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

(g) *Standard: Outpatient physical therapy or speech-language pathology services.* An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in § 485.711, § 485.713, § 485.715, § 485.719, § 485.723, and § 485.727 of this chapter to implement section 1861(p) of the Act.

(h) *Standard: Institutional planning.* The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would,

under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health Services Block Grant) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a–1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

§ 484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

(a) *Standard: Contents of clinical record.* The record must include:

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders;

(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

(4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);

(5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and

(6)(i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or

(ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or

(iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

(b) *Standard: Authentication.* All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

(c) *Standard: Retention of records.* (1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

(d) *Standard: Protection of records.* The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding protected health information set out at 45 CFR parts 160 and 164.

(e) *Standard: Retrieval of clinical records.* A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

§ 484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

(a) *Standard: Administrator, home health agency.* (1) For individuals that began employment with the HHA prior to July 13, 2017, a person who:

(i) Is a licensed physician;

(ii) Is a registered nurse; or

(iii) Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program.

(2) For individuals that begin employment with an HHA on or after July 13, 2017, a person who:

(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and

(ii) Has experience in health service administration, with at least 1 year of supervisory or administrative

experience in home health care or a related health care program.

(b) *Standard: Audiologist.* A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(c) Standard: Clinical manager. A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

(d) *Standard: Home health aide.* A person who meets the qualifications for home health aides specified in section 1891(a)(3) of the Act and implemented at § 484.80.

(e) *Standard: Licensed practical (vocational) nurse.* A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

(f) *Standard: Occupational therapist.* A person who—

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;

(ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or

(ii) When licensure or other regulation does not apply—

(A) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(3) On or before January 1, 2008—

(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapist; and

(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:

(i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Successor organizations of ACOTE.

(C) The World Federation of Occupational Therapists.

(D) A credentialing body approved by the American Occupational Therapy Association.

(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

(g) *Standard: Occupational therapy assistant.* A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the state in which practicing, unless licensure does apply.

(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or

(ii) Must meet both of the following:

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(B) After January 1, 2010, meets the requirements in paragraph (f)(1) of this section.

(3) After December 31, 1977 and on or before December 31, 2007—

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapy assistant; and

(ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, on or after January 1, 2008—

(i) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Its successor organizations.

(C) The World Federation of Occupational Therapists.

(D) By a credentialing body approved by the American Occupational Therapy Association; and

(E) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the

National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) [Reserved]

(h) *Standard: Physical therapist.* A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(2) On or before December 31, 2009—

(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(ii) Meets both of the following:

(A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) Before January 1, 1966—

(i) Was admitted to membership by the American Physical Therapy Association;

(ii) Was admitted to registration by the American Registry of Physical Therapists; or

(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(7) If trained outside the United States before January 1, 2008, meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(i) *Standard: Physical therapist assistant.* A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(2) On or before December 31, 2009, meets one of the following:

(i) Is licensed, or otherwise regulated in the state in which practicing.

(ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (h)(1) of this section.

(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(j) *Standard: Physician.* A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at § 410.20(b) of this chapter.

(k) *Standard: Registered nurse.* A graduate of an approved school of professional nursing who is licensed in the state where practicing.

(l) *Standard: Social Work Assistant.* A person who provides services under the supervision of a qualified social worker and:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.

(m) *Standard: Social worker.* A person who has a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(n) *Standard: Speech-language pathologist.* A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 11. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

■ 12. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 485.58	Introductory text	and 484.4	and 484.115.
§ 485.70	(c) and (e)	§ 484.4	§ 484.115.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 13. The authority citation for part 488 continues 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.

§ 488.805 [Amended]

■ 14. In § 488.805, in the definition of ''temporary management'', remove ''§§ 484.4 and 484.14(c)'' and add in its place ''§§ 484.105(b) and 484.115''.

Dated: December 8, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: December 9, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–00283 Filed 1–9–17; 4:15 pm]

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Part IV

Environmental Protection Agency

40 CFR Part 68

Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 68

[EPA–HQ–OEM–2015–0725; FRL–9954–46–OLEM]

RIN 2050–AG82

Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA), in response to Executive Order 13650, is amending its Risk Management Program regulations. The revisions contain several changes to the accident prevention program requirements including an additional analysis of safer technology and alternatives as part of the process hazard analysis for some Program 3 processes, third-party audits and incident investigation root cause analysis for Program 2 and Program 3 processes; enhancements to the emergency preparedness requirements; increased public availability of chemical hazard information; and several other changes to certain regulatory definitions and data elements submitted in risk management plans. These amendments seek to improve chemical process safety, assist local emergency authorities in planning for and responding to accidents, and improve public awareness of chemical hazards at regulated sources.

DATES: This final rule is effective on March 14, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OEM–2015–0725. 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.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov*.

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Electronic copies of this document and related news releases are available on EPA's Web site at *http://www.epa.gov/rmp*. Copies of this final rule are also available at *http://www.regulations.gov.*

SUPPLEMENTARY INFORMATION: The contents of this preamble are:

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I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The purpose of this action is to improve safety at facilities that use and distribute hazardous chemicals. In response to catastrophic chemical facility incidents in the United States, including the explosion that occurred at the West Fertilizer facility in West, Texas, on April 17, 2013 that killed 15 people (on May 11, 2016, ATF ruled that the fire was intentionally set.) [1] President Obama issued Executive Order 13650, ''Improving Chemical Facility Safety and Security,'' on August 1, 2013.[2]

Section 6(a)(i) of Executive Order 13650 requires that various Federal agencies develop options for improved chemical facility safety and security that identify ''improvements to existing risk management practices through agency programs, private sector initiatives, Government guidance, outreach, standards, and regulations.'' One existing agency program is the Risk Management Program implemented by EPA under section 112(r) of the Clean Air Act (CAA) (42 U.S.C. 7412(r)). Section 6(c) of Executive Order 13650 requires the Administrator of EPA to review the chemical hazards covered by the Risk Management Program and expand, implement and enforce the Risk Management Program to address any additional hazards.

EPA proposed changes to its Risk Management Program regulations (40 CFR part 68) on March 14, 2016 (81 FR 13637) after publishing a ''Request for Information'' notice or ''RFI'' that solicited comments and information from the public regarding potential changes to the Risk Management

[1] See ATF Announces $50,000 Reward in West, Texas Fatality Fire, *https://www.atf.gov/news/pr/atf-announces-50000-reward-west-texas-fatality-fire*.

[2] For more information on the Executive Order see *https://www.whitehouse.gov/the-press-office/2013/08/01/executive-order-improving-chemical-facility-safety-and-security*.

Program regulations (July 31, 2014, 79 FR 44604). While developing the proposed rulemaking, EPA convened a Small Business Advocacy Review (SBAR) panel to receive input from Small Entity Representatives (SERs). EPA also hosted a public hearing on March 29, 2016 to provide interested parties the opportunity to present data, views or arguments concerning the proposed action.

The Risk Management Program regulations have been effective in preventing and mitigating chemical accidents in the United States. However, EPA believes that revisions could further protect human health and the environment from chemical hazards through advancement of process safety management based on lessons learned.

2. Summary of the Major Provisions of the Regulatory Action

This action amends EPA's Risk Management Program regulations at 40 CFR part 68. These regulations apply to stationary sources (also referred to as ''facilities'') that hold specific ''regulated substances'' in excess of threshold quantities. These facilities are required to assess their potential release impacts, undertake steps to prevent releases, plan for emergency response to releases, and summarize this information in a risk management plan (RMP) submitted to EPA. The release prevention steps vary depending on the type of process, but progressively gain granularity and rigor over three program levels (*i.e.,* Program 1, Program 2, and Program 3).

The major provisions of this rule include several changes to the accident prevention program requirements, as well as enhancements to the emergency response requirements, and improvements to the public availability of chemical hazard information. Each of these revisions is introduced in the following paragraphs of this section and described in greater detail in sections IV through VI, later in this preamble.

Certain revised provisions would apply to a subset of the processes based on program levels described in 40 CFR part 68 (or in one case, to a subset of processes within a program level). A full description of these program levels is provided in section II of this preamble.

a. Accident Prevention Program Revisions

This action includes three changes to the accident prevention program requirements. First, the rule requires all facilities with Program 2 or 3 processes to conduct a root cause analysis as part of an incident investigation of a catastrophic release or an incident that could have reasonably resulted in a catastrophic release (*i.e.,* a near-miss). This provision is intended to reduce the number of chemical accidents by requiring facilities to identify the underlying causes of an incident so that they may be addressed. Identifying the root causes, rather than isolating and correcting solely the immediate cause of the incident, will help prevent similar incidents at other locations, and will yield the maximum benefit or lessons learned from the incident investigation.

Second, the rule requires regulated facilities with Program 2 or 3 processes to contract with an independent third-party, or assemble an audit team led by an independent third-party, to perform a compliance audit after the facility has an RMP reportable accident. Compliance audits are required under the existing rule, but are allowed to be self-audits (*i.e.,* performed by the owner or operator of the regulated facility). This provision is intended to reduce the risk of future accidents by requiring an objective auditing process to determine whether the owner or operator of the facility is effectively complying with the accident prevention procedures and practices required under 40 CFR part 68.

The third revision to the prevention program adds an element to the process hazard analysis (PHA), which is updated every five years. Specifically, owners or operators of facilities with Program 3 regulated processes in North American Industrial Classification System (NAICS) codes 322 (paper manufacturing), 324 (petroleum and coal products manufacturing), and 325 (chemical manufacturing) are required to conduct a safer technology and alternatives analysis (STAA) as part of their PHA, and to evaluate the practicability of any inherently safer technology (IST) identified. The current PHA requirements include consideration of active, passive, and procedural measures to control hazards. These revisions support the analysis of those measures and adds consideration of IST alternatives. The provision is intended to reduce the risk of serious accidental releases by requiring facilities in these sectors to conduct a careful examination of potentially safer technology and designs that they could implement in lieu of, or in addition to, their current technologies.

b. Emergency Response Enhancements

This action also enhances the rule's emergency response requirements. Owners or operators of all facilities with Program 2 or 3 processes are required to coordinate with the local emergency response agencies at least once a year to determine how the source is addressed in the community emergency response plan and to ensure that local response organizations are aware of the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility to respond to an accidental release of a regulated substance.

Additionally, all facilities with Program 2 or 3 processes are required to conduct notification exercises annually to ensure that their emergency contact information is accurate and complete. This provision is intended to reduce the impact of accidents by ensuring that appropriate mechanisms and processes are in place to notify local responders when an accident occurs. One of the factors that can contribute to the severity of chemical accidents is a lack of effective coordination between a facility and local emergency responders. Increasing such coordination and establishing appropriate emergency response procedures can help reduce the effects of accidents.

This action also requires that all facilities subject to the emergency response program requirements of subpart E of the rule (or ''responding facilities'') conduct field exercises and tabletop exercises. The frequency of these exercises shall be established in consultation with local emergency response officials, but at a minimum, full field exercises will be conducted at least once every ten years and tabletop exercises conducted at least once every three years. Responding facilities that have an RMP reportable accident, and document the response activities in an after-action report comparable to the exercise evaluation reports may use that response to satisfy the field exercise requirements. Furthermore, owner and operators of responding facilities that conduct exercises to meet other Federal, state or local exercise requirements may satisfy the RMP exercise requirements provided that the scope of the exercise includes the objectives of an RMP exercise. The purpose of this provision is to reduce the impact of accidents by ensuring that emergency response personnel understand their roles in the event of an incident, that local responders are familiar with the hazards at a facility, and that the emergency response plan is up-to-date. Improved coordination with emergency response personnel will better prepare responders to respond effectively to an incident and take steps to notify the community of appropriate actions, such as shelter-in-place or evacuation.

c. Enhanced Availability of Information

This action includes various enhancements to the public availability of chemical hazard information. The rule requires all facilities to provide certain basic information to the public, upon request. The owner or operator of the facility shall provide ongoing notification of availability of information elements on a company Web site, social media platforms, or through some other publicly accessible means. The rule also requires all facilities to hold a public meeting for the local community within 90 days of an RMP reportable accident. This provision will ensure that first responders and members of the community have easier access to appropriate facility chemical hazard information, which can significantly improve emergency preparedness and their understanding of how the facility is addressing potential risks.

EPA proposed requirements for facilities to provide certain information to the Local Emergency Planning Committee (LEPC), Tribal Emergency Planning Committee (TEPC)[3] or other local emergency response agencies. However, rather than prescribe information elements that must be provided upon request, EPA is requiring the owner or operator of a stationary source to share information that is relevant to emergency response planning as part of the coordination activities that occur annually between facility representatives and local emergency response agencies.

In addition to the major provisions described previously in this section, this action discusses comments received on other aspects of the proposed action including revisions to the list of regulated substances, location of stationary sources (related to their proximity to public receptors), requirements for emergency shutdown systems, compliance dates, technical corrections and revisions to the RMP requirements.

3. Costs and Benefits

a. Summary of Potential Costs

Approximately 12,500 facilities have filed current RMPs with EPA and are potentially affected by the revised rule. These facilities range from petroleum refineries and large chemical manufacturers to water and wastewater treatment systems; chemical and petroleum wholesalers and terminals; food manufacturers, packing plants, and other cold storage facilities with ammonia refrigeration systems; agricultural chemical distributors; midstream gas plants; and a limited number of other sources, including Federal installations that use RMP-regulated substances.

Table 1 presents the number of facilities according to the latest RMP reporting as of February 2015 by industrial sector and chemical use.

TABLE 1—NUMBER OF AFFECTED FACILITIES BY SECTOR

Sector	NAICS codes	Total facilities	Chemical uses
Administration of environmental quality programs (*i.e.,* governments).	924	1,923	Use chlorine and other chemicals for treatment.
Agricultural chemical distributors/wholesalers.	111, 112, 115, 42491	3,667	Store ammonia for sale; some in NAICS 111 and 115 use ammonia as a refrigerant.
Chemical manufacturing	325	1,466	Manufacture, process, store.
Chemical wholesalers	4246	333	Store for sale.
Food and beverage manufacturing	311, 312	1,476	Use—mostly ammonia as a refrigerant.
Oil and gas extraction	211	741	Intermediate processing (mostly regulated flammable substances and flammable mixtures).
Other	44, 45, 48, 54, 56, 61, 72	247	Use chemicals for wastewater treatment, refrigeration, store chemicals for sale.
Other manufacturing	313, 326, 327, 33	384	Use various chemicals in manufacturing process, waste treatment.
Other wholesale	423, 424	302	Use (mostly ammonia as a refrigerant).
Paper manufacturing	322	70	Use various chemicals in pulp and paper manufacturing.
Petroleum and coal products manufacturing.	324	156	Manufacture, process, store (mostly regulated flammable substances and flammable mixtures).
Petroleum wholesalers	4247	276	Store for sale (mostly regulated flammable substances and flammable mixtures).
Utilities	221	445	Use chlorine (mostly for water treatment) and other chemicals.
Warehousing and storage	493	1,056	Use mostly ammonia as a refrigerant.
Total		12,542	

Table 2 presents a summary of the annualized costs estimated in the regulatory impact analysis.[4] In total, EPA estimates annualized costs of $131.2 million at a 3% discount rate and $131.8 million at a 7% discount rate.

[3] Note for the purposes of this document the term TEPC can be substituted for LEPC, as appropriate.

[4] A full description of costs and benefits for this final rule can be found in the *Regulatory Impact Analysis—Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7).* This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

TABLE 2—SUMMARY OF ANNUALIZED COSTS

[Millions, 2015 dollars]

Provision	3 (percent)	7 (percent)
Third-party Audits	$9.8	$9.8
Incident Investigation/Root Cause	1.8	1.8
STAA	70.0	70.0
Coordination	16.0	16.0
Notification Exercises	1.4	1.4
Facility Exercises	24.7	24.7
Information Sharing with the Public	3.1	3.1
Public Meeting	0.4	0.4
Rule Familiarization	3.9	4.6
Total Cost*	131.2	131.8

*Totals may not sum due to rounding.

The largest average annual cost of the final rule is the STAA costs ($70.0 million), followed by the exercise costs ($24.7 million), coordination ($16 million), and third-party audits ($9.8 million). The remaining provisions impose average annual costs under $5 million each, including rule familiarization ($3.9–4.6 million), information sharing with the public ($3.1 million), incident investigation/root cause analysis ($1.8 million), notification exercises ($1.4 million), and public meetings ($0.4 million).

b. Summary of Potential Benefits

EPA anticipates that promulgation and implementation of this rule would result in a reduction of the frequency and magnitude of damages from releases. Accidents and releases from RMP facilities occur every year, causing fires and explosions; damage to property; acute and chronic exposures of workers and nearby residents to hazardous materials; and resulting in serious injuries and death. Although we are unable to quantify what specific reductions may occur as a result of these revisions, we are able to present data on the total damages that currently occur at RMP facilities each year. The data presented is based on a 10-year baseline period, summarizing RMP accident impacts and, when possible, monetizing them. EPA expects that some portion of future damages would be prevented through implementation of this final rule. Table 3 presents a summary of the quantified damages identified in the analysis.

TABLE 3—SUMMARY OF QUANTIFIED DAMAGES

[Millions, 2015 dollars]

	Unit value	10-year total	Average/year	Average/accident
On-site				
Fatalities	$8.6	$497.8	$49.8	$0.33
Injuries	0.05	105.2	10.5	0.69
Property Damage	.....	2,054.9	205.5	1.4
On-site Total	.....	2,657.9	265.8	1.8
Offsite				
Fatalities	8.6	8.6	0.86	0.01
Hospitalizations	0.4	6.8	0.68	0.004
Medical Treatment	0.001	14.8	1.5	0.01
Evacuations*	0.0	7.0	0.70	0.004
Sheltering in Place*	0.0	40.9	4.1	0.03
Property Damage	.....	11.4	1.1	0.007
Offsite Total	.....	89.5	8.9	0.06
Total	.....	2,747.3	274.7	1.8

*The unit value for evacuations is less than two hundred dollars and for sheltering in place is less than one hundred dollars so when expressed in rounded millions the value represented in the table is zero.

EPA monetized both on-site and offsite damages. EPA estimated total average annual on-site damages of $265.8 million. The largest monetized average annual on-site damage was on-site property damage, which resulted in average annual damage of approximately $205.5 million. The next largest impact was on-site fatalities ($49.8 million) and injuries ($10.5 million).

EPA estimated total average annual offsite damages of $8.9 million. The largest monetized average annual offsite damage was from sheltering in place ($4.1 million), followed by medical treatment ($1.5 million), property damage ($1.1 million), fatalities ($0.86 million), evacuations ($0.7 million), and hospitalizations ($0.68 million).

In total, EPA estimated monetized damages from RMP facility accidents of $274.7 million per year. The 10-year RMP baseline suggests that considering

only the monetized impacts of RMP accidents would mean that the rule's costs may outweigh the portion of avoided impacts from improved prevention and mitigation that were monetized. The annualized cost of the final rule (approximately $142 million annually) is approximately 52% of the average annual monetized costs in the 10-year baseline. However, the monetized impacts omit many important categories of accident impacts including lost productivity, the costs of emergency response, transaction costs, property value impacts in the surrounding community (that overlap with other benefit categories), and environmental impacts. Also not reflected in the 10-year baseline costs are the impacts of non-RMP accidents at RMP facilities and any potential impacts of rare high consequence catastrophes. A final omission is related to the information provision. Reducing the probability of chemical accidents and the severity of their impacts, and improving information disclosure by chemical facilities, as the provisions intend, would provide benefits to potentially affected members of society.

Table 4 summarizes four broad social benefit categories related to accident prevention and mitigation including prevention of RMP accidents, mitigation of RMP accidents, prevention and mitigation of non-RMP accidents at RMP facilities, and prevention of major catastrophes. The table explains each and identifies ten associated specific benefit categories, ranging from avoided fatalities to avoided emergency response costs. Table 4 also highlights and explains the information disclosure benefit category and identifies two specific benefits associated with it: Improved efficiency of property markets and allocation of emergency resources.

When considering the rule's likely benefits that are due to avoiding some portion of the monetized accident impacts, as well as the additional non-monetized benefits described previously, EPA believes the costs of the rule are reasonable in comparison to its benefits.

TABLE 4—SUMMARY OF SOCIAL BENEFITS OF FINAL RULE PROVISIONS

Broad benefit category	Explanation	Specific benefit categories
Accident Prevention	Prevention of future RMP facility accidents	• Reduced Fatalities.
Accident Mitigation	Mitigation of future RMP facility accidents	• Reduced Injuries.
Non-RMP accident prevention and mitigation	Prevention and mitigation of future non-RMP accidents at RMP facilities.	• Reduced Property Damage.
Avoided Catastrophes	Prevention of rare but extremely high consequence events.	• Fewer People Sheltered in Place. • Fewer Evacuations. • Avoided Lost Productivity. • Avoided Emergency Response Costs. • Avoided Transaction Costs. • Avoided Property Value Impacts.* • Avoided Environmental Impacts.
Information Disclosure	Provision of information to the public	• Improved efficiency of property markets. • Improved emergency response resource allocation.

* These impacts partially overlap with several other categories such as reduced health and environmental impacts.

B. Does this action apply to me?

This rule applies to those facilities (referred to as ''stationary sources'' under the CAA) that are subject to the chemical accident prevention requirements at 40 CFR part 68. This includes stationary sources holding more than a threshold quantity (TQ) of a regulated substance in a process. Table 5 provides industrial sectors and the associated NAICS codes for entities potentially affected by this action. The Agency's goal is to provide a guide for readers to consider regarding entities that potentially could be affected by this action. However, this action may affect other entities not listed in this table. If you have questions regarding the applicability of this action to a particular entity, consult the person(s) listed in the introductory section of this action under the heading entitled **FOR FURTHER INFORMATION CONTACT**.

TABLE 5—INDUSTRIAL SECTORS AND ASSOCIATED NAICS CODES FOR ENTITIES POTENTIALLY AFFECTED BY THIS ACTION

Sector	NAICS code
Administration of Environmental Quality Programs	924.
Agricultural Chemical Distributors:	
Crop Production	111.
Animal Production and Aquaculture	112.
Support Activities for Agriculture and Forestry Farm	115.
Supplies Merchant Wholesalers	42491.
Chemical Manufacturing	325.
Chemical and Allied Products Merchant Wholesalers	4246.
Food Manufacturing	311.
Beverage Manufacturing	3121.
Oil and Gas Extraction	211.
Other[5]	44, 45, 48, 54, 56, 61, 72.
Other manufacturing	313, 326, 327, 33.
Other Wholesale:	
Merchant Wholesalers, Durable Goods	423.
Merchant Wholesalers, Nondurable Goods	424.

[5] For descriptions of NAICS codes, see *http://www.census.gov/cgi-bin/sssd/naics/naicsrch.*

TABLE 5—INDUSTRIAL SECTORS AND ASSOCIATED NAICS CODES FOR ENTITIES POTENTIALLY AFFECTED BY THIS ACTION—Continued

Sector	NAICS code
Paper Manufacturing	322.
Petroleum and Coal Products Manufacturing	324.
Petroleum and Petroleum Products Merchant Wholesalers	4247.
Utilities	221.
Warehousing and Storage	493.

II. Background

A. Events Leading to This Action

Recent catastrophic chemical facility incidents in the United States prompted President Obama to issue Executive Order 13650, ''Improving Chemical Facility Safety and Security,'' on August 1, 2013.[6] The purpose of the Executive Order is to enhance the safety and security of chemical facilities and reduce risks associated with hazardous chemicals to owners and operators, workers, and communities. The Executive Order establishes the Chemical Facility Safety and Security Working Group (''Working Group''), co-chaired by the Secretary of Homeland Security, the Administrator of EPA, and the Secretary of Labor or their designated representatives at the Assistant Secretary level or higher, and composed of senior representatives of other Federal departments, agencies, and offices. The Executive Order requires the Working Group to carry out a number of tasks whose overall aim is to prevent chemical accidents. In addition to the tragedy at the West Fertilizer facility in West, Texas, on April 17, 2013,[7] a number of other incidents have demonstrated a significant risk to the safety of American workers and communities. On March 23, 2005, explosions at the BP Refinery in Texas City, Texas, killed 15 people and injured more than 170 people.[8] On April 2, 2010, an explosion and fire at the Tesoro Refinery in Anacortes, Washington, killed seven people.[9] On August 6, 2012, at the Chevron Refinery in Richmond, California, a fire involving flammable fluids endangered 19 Chevron employees and created a large plume of highly hazardous chemicals that traveled across the Richmond, California, area.[10] Nearly 15,000 residents sought medical treatment due to the release. On June 13, 2013, a fire and explosion at Williams Olefins in Geismar, Louisiana, killed two people and injured many more.[11]

Section 6 of the Executive Order is entitled ''Policy, Regulation, and Standards Modernization.'' This section, among other things, requires certain Federal agencies to consider possible changes to existing chemical safety and security regulations. To solicit comments and information from the public regarding potential changes to EPA's Risk Management Program regulations (40 CFR part 68), on July 31, 2014, EPA published an RFI (79 FR 44604). Information collected through the RFI informed the proposed rulemaking that was published on March 14, 2016 (81 FR 13637).

EPA received a total of 61,716 public comments on the proposed rulemaking. Several public comments were the result of various mass mail campaigns and contained numerous copies of letters or petition signatures. Approximately 61,467 letters and signatures were contained in these several comments. The remaining comments include 235 submissions with unique content, 10 duplicate submissions, and 4 non-germane submissions. In addition to these public submissions, EPA also received 8 written comments and had 22 members of the public provide verbal comments at a public hearing on March 29, 2016. Discussion of public comments can be found in topics included in this final rule and in the Response to Comments document,[12] available in the docket for this rulemaking.

B. Overview of EPA's Risk Management Program Regulations

Both EPA's 40 CFR part 68 RMP regulation [13] and Occupational Safety and Health Administration's (OSHA) 29 CFR 1910.119 Process Safety Management (PSM) standard were authorized in the CAA Amendments of 1990. This was in response to a number of catastrophic chemical accidents occurring worldwide that had resulted in public and worker fatalities and injuries, environmental damage, and other community impacts. OSHA published the PSM standard in 1992 (57 FR 6356, February 24, 1992), as required by section 304 of the 1990 CAAA, using its authority under 29 U.S.C. 653.

The 1990 CAA Amendments added accidental release provisions under section 112(r). The statute required EPA to develop a list of at least 100 regulated substances for accident prevention and related thresholds (CAA section 112(r)(3) through (5)), and authorized EPA to issue accident prevention regulations (CAA section 112(r)(7)(A)). The statute also required EPA to develop ''reasonable regulations'' requiring facilities with over a TQ of a regulated substance to undertake accident prevention steps and submit a ''risk management plan'' to various local, state, and Federal planning entities (CAA section 112(r)(7)(B)).

[6] For more information on the Executive Order see *https://www.whitehouse.gov/the-press-office/2013/08/01/executive-order-improving-chemical-facility-safety-and-security.*

[7] CSB. January 2016. Final Investigation Report, West Fertilizer Company Fire and Explosion, West, TX, April 17, 2013. REPORT 2013–02–I–TX. *http://www.csb.gov/west-fertilizer-explosion-and-fire-/.* On May 11, 2016, ATF ruled that the fire was intentionally set. See ATF Announces $50,000 Reward in West, Texas Fatality Fire, *https://www.atf.gov/news/pr/atf-announces-50000-reward-west-texas-fatality-fire.*

[8] U.S. Chemical Safety and Hazard Investigation Board (CSB). March 2007. Investigation Report: Refinery Explosion and Fire, BP, Texas City, Texas, March 23, 2005. Report No. 2005–04–I–TX. *http://www.csb.gov/assets/1/19/CSBFinalReportBP.pdf.*

[9] CSB. May 2014. Investigation Report: Catastrophic Rupture of Heat Exchanger, Tesoro Anacortes Refinery, Anacortes, Washington, April 2, 2010. Report No. 2010–08–I–WA. *http://www.csb.gov/assets/1/7/Tesoro_Anacortes_2014-May-01.pdf.*

[10] CSB. January 2014. Regulatory Report: Chevron Richmond Refinery Pipe Rupture and Fire, Chevron Richmond Refinery #4 Crude Unit, Richmond, California, August 6, 2012. Report No. 2012–03–I–CA. *http://www.csb.gov/assets/1/19/CSB_Chevron_Richmond_Refinery_Regulatory_Report.pdf.*

[11] CSB. October 2016. Case Study: Williams Geismar Olefins Plant Reboiler Rupture and Fire, Geismar, Louisiana. Incident Date: June 13, 2013, No. 2013–03–I–LA. US Chemical Safety and Hazard Investigation Board, Washington, DC *http://www.csb.gov/williams-olefins-plant-explosion-and-fire-/.*

[12] 2016. EPA Response to Comments on the 2016 Proposed Rulemaking Amending EPA's Risk Management Program Regulations. This document is available in the docket for this rulemaking.

[13] 40 CFR part 68 is titled, ''Chemical Accident Prevention Provisions,'' but is more commonly known as the ''RMP regulation,'' the ''RMP rule,'' or the ''Risk Management Program.'' This document uses all three terms to refer to 40 CFR part 68. The term ''RMP'' refers to the document required to be submitted under subpart F of 40 CFR part 68, the Risk Management Plan. See *https://www.epa.gov/rmp* for more information on the Risk Management Program.

EPA published the RMP regulation in two stages. The Agency published the list of regulated substances and TQs in 1994 (59 FR 4478, January 31, 1994) (the ''list rule'') [14] and published the RMP final regulation, containing risk management requirements for covered sources, in 1996 (61 FR 31668, June 20, 1996) (the ''RMP rule'').[15] [16] Both the OSHA PSM standard and the EPA RMP rule aim to prevent or minimize the consequences of accidental chemical releases through implementation of management program elements that integrate technologies, procedures, and management practices. In addition to requiring implementation of management program elements, the RMP rule requires covered sources to submit (to EPA) a document summarizing the source's risk management program—called a Risk Management Plan (or RMP). The RMP rule required covered sources to comply with its requirements and submit initial RMPs to EPA by June 21, 1999. Each RMP must be revised and updated at least once every five years from the date the plan was initially submitted.

EPA later revised the list rule and the RMP rule. EPA modified the regulated list of substances by exempting solutions with less than 37% concentrations of hydrochloric acid (62 FR 45130, August 25, 1997). EPA also deleted the category of Department of Transportation Division 1.1 explosives, and exempted flammable substances in gasoline used as fuel and in naturally occurring hydrocarbon mixtures prior to initial processing (63 FR 640, January 6, 1998).

EPA subsequently modified the RMP rule five times. First, in 1999, EPA revised the facility identification data and contact information reported in the RMP (64 FR 964, January 6, 1999). Next, EPA revised assumptions for the worst case scenario analysis for flammable substances and clarified what the Agency means by chemical storage not incidental to transportation (64 FR 28696, May 26, 1999). After the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (CSISSFRRA) was enacted on August 5, 1999, EPA excluded regulated flammable substances when used as a fuel or held for sale as a fuel at a retail facility (65 FR 13243, March 13, 2000). Later, EPA restricted access to offsite consequence analysis (OCA) data for the public and government officials to minimize the security risks associated with posting the information on the Internet (65 FR 48108, August 4, 2000). Finally, EPA revised the RMP executive summary to remove a requirement to describe the OCA; revised reporting deadlines for RMP reportable accidents and emergency contact changes; and made other minor revisions to RMP facility contact information (69 FR 18819, April 8, 2004).

The RMP rule establishes three ''program levels'' for regulated processes:

Program 1 applies to processes that would not affect the public in the case of a worst-case release and that have had no accidents with specific offsite consequences within the past five years. Program 1 imposes limited hazard assessment requirements, requires coordination with local response agencies, and requires submission of an RMP.

Program 2 applies to processes not eligible for Program 1 or subject to Program 3, and imposes streamlined prevention program requirements, including safety information, hazard review, operating procedures, training, maintenance, compliance audits, and incident investigation elements. Program 2 also imposes additional hazard assessment, management, and emergency response requirements.

Program 3 applies to processes not eligible for Program 1 and either subject to OSHA's PSM standard under Federal or state OSHA programs or classified in one of ten specified industry sectors identified by their 2002 NAICS codes listed at § 68.10(d)(1). These industries were selected because they had a higher frequency of the most serious accidents as compared to other industry sectors. The ten NAICS codes and the industries they represent are 32211 (pulp mills), 32411 (petroleum refineries), 32511 (petrochemical manufacturing), 325181 (alkalies and chlorine manufacturing), 325188 (all other basic inorganic chemical manufacturing), 325192 (cyclic crude and intermediate manufacturing), 325199 (all other basic chemical manufacturing), 325211 (plastics material and resin manufacturing), 325311 (nitrogenous fertilizer manufacturing), or 32532 (pesticide and other agricultural chemicals manufacturing).[17] Program 3 imposes elements nearly identical to those in OSHA's PSM standard as the accident prevention program. The Program 3 prevention program includes requirements relating to process safety information (PSI), PHA, operating procedures, training, mechanical integrity, management of change (MOC), pre-startup review, compliance audits, incident investigations, employee participation, hot work permits, and contractors. Program 3 also imposes the same hazard assessment, management, and emergency response requirements that are required for Program 2.

The RMP rule has been effective in preventing and mitigating chemical accidents in the United States and protecting human health and the environment from chemical hazards. However, major incidents, such as the West, Texas explosion,[18] highlight the importance of reviewing and evaluating current practices and regulatory requirements, and applying lessons learned from other incident investigations to advance process safety where needed.

III. Additional Information

A. Agency's Authority for Taking This Action

The statutory authority for this action is provided by section 112(r) of the CAA as amended (42 U.S.C. 7412(r)). Each of the portions of the Risk Management Program rule we are amending in this document are based on EPA's rulemaking authority under section 112(r)(7) of the CAA (42 U.S.C. 7412(r)(7)). A more detailed discussion of the underlying statutory authority for the current requirements of the Risk Management Program rule appears in the action that proposed the Risk Management Program (58 FR 54190, 54191–93, October 20, 1993). The prevention program provisions discussed in this preamble (auditing, incident investigation, and safer technologies alternatives analysis) address the ''prevention and detection of accidental releases.'' The emergency coordination and exercises provisions in this rule modify existing provisions that provide for ''response to such release by the owners or operators of the sources of such releases'' (CAA section 112(r)(7)(B)(i)). This paragraph in the

[14] Documents and information related to development of the list rule can be found in the EPA docket for the rulemaking, docket number A–91–74.

[15] Documents and information related to development of the RMP rule can be found in EPA docket number A–91–73.

[16] 40 CFR part 68 applies to owners and operators of stationary sources that have more than a TQ of a regulated substance within a process. The regulations do not apply to chemical hazards other than listed substances held above a TQ within a regulated process.

[17] NAICS codes 325181 and 325188 are now combined and represented as revised NAICS code 325180 in the 2012 and 2017 code versions (other basic inorganic chemical manufacturing). NAICS code 325192 is now revised NAICS code 325194 (cyclic crude, intermediate, and gum and wood chemical manufacturing) in the 2012 and 2017 code versions.

[18] CSB. January 2016. Final Investigation Report, West Fertilizer Company Fire and Explosion, West, TX, April 17, 2013. REPORT 2013–02–I–TX. *http://www.csb.gov/west-fertilizer-explosion-and-fire-/*.

statute calls for EPA's regulations to recognize differences in ''size, operations, processes, class and categories of sources.'' In this document, we maintain the distinctions in prevention program levels and in response actions authorized by this provision. The information disclosure provisions discussed in this document generally assist in the development of ''procedures and measures for emergency response after an accidental release of a regulated substance in order to protect human health and the environment.'' This information disclosure ensures the emergency plans for impacts on the community are based on more relevant and accurate information than would otherwise be available and ensures that the public can become an informed participant in such emergency planning.

Various commenters suggested that particular provisions of the proposed rulemaking were not consistent with CAA section 112(r) or other relevant statutes. We address these comments in each relevant section of the preamble and in the Response to Comments document,[19] available in the docket for this rulemaking. Some commenters also suggested that EPA has not complied with the requirements in CAA section 112(r)(7)(D) for the Administrator to ''consult with the Secretary of Labor and the Secretary of Transportation'' and ''coordinate any requirements under this paragraph with any requirements established for comparable purposes by the Occupational Safety and Health Administration or the Department of Transportation.''

EPA disagrees with these comments. Under section 6 of Executive Order 13650, ''Improving Chemical Facility Safety and Security,'' the Executive Order Working Group, chaired by EPA, OSHA, and Department of Homeland Security (DHS), was tasked with enhancing safety at chemical facilities by identifying key improvements to existing risk management practices through guidance, policies, procedures, outreach, and regulations. As part of this task, the Working Group conducted extensive interagency coordination, and solicited public comment on potential options for improving chemical facility safety. EPA's coordination efforts included discussions with numerous Federal agencies, including OSHA and the Department of Transportation (DOT), on potential changes to the Risk Management Program rule. As EPA explained in the preamble to the proposed rulemaking, the OSHA PSM standard and EPA RMP regulation are closely aligned in content, policy interpretations, Agency guidance, and enforcement. Since the inception of these regulations, EPA and OSHA have coordinated closely on their implementation in order to minimize regulatory burden and avoid conflicting requirements for regulated facilities. This coordination has continued throughout the development of this rule and on OSHA's initial steps toward proposing potential changes to the PSM standard. EPA's coordination with DOT was less extensive because nothing in this rule changes its basic applicability provisions, which apply the rule only to stationary sources, and exclude transportation. However, EPA continues to coordinate with DOT through ongoing Executive Order activities, which includes updates on RMP regulatory development, and this coordination is sufficient to meet EPA's obligations under CAA section 112(r)(7)(D). As with OSHA, EPA has a long history of close coordination with DOT on implementation of the RMP, particularly where potential transportation-related issues arise, and the Agency fully intends for such coordination to continue.

B. List of Regulated Substances

As part of its work under Executive Order 13650, the Working Group solicited public comment on potential changes to the list of regulated substances for the Risk Management Program, including what actions to take to address ammonium nitrate (AN). EPA did not propose revisions to the list of regulated substances. Instead, EPA explained the actions other agencies in the Executive Order Working Group are considering to address AN and indicated that EPA will coordinate any potential changes to the list of substances in 40 CFR part 68 with the actions of these other agencies. EPA received several comments related to revising the list of regulated substances and whether to expand the list to include AN.

1. Discussion of Comments on the List of Regulated Substances

A couple of commenters expressed support for expanding the scope of regulated substances under the RMP rule. One private citizen stated that EPA should broaden the range of chemicals covered under RMP and account for effects on vulnerable populations including children and the elderly. A professional organization asserted that EPA should update the list of regulated substances and require facilities to ''evaluate the risk of a reactive chemical accident and take appropriate measures, even if the chemicals in question are not on the list.''

However, multiple commenters supported EPA's decision not to revise the list of regulated substances in this action. These commenters opposed adding toxic or flammable substances to the list of regulated substances in a separate action. One industry commenter opposed the addition of combustible dust to the list, arguing that it is already regulated under OSHA and constitutes a low risk to the public.

EPA will consider these comments when determining whether to propose revisions to the list of substances.

2. Discussion of Comments on AN

Many commenters supported regulating AN in the RMP rule. Several commenters requested that EPA consider the danger to the public from AN, and other reactive chemicals, in its rulemaking. A state agency further asked EPA to ensure that calculations for the OCA consider the unique explosive characteristics of fertilizer grade ammonium nitrate (FGAN) and develop specific RMP guidance for regulated FGAN facilities. One commenter supported adding AN to the list of regulated substances but requested unique requirements for AN formulated as an explosive or blasting agent and FGAN. Another commenter claimed that EPA failed to address Executive Order 13650 by failing to address AN in the proposed rulemaking.

However, EPA also received comments opposed to adding AN to the list of regulated substances. One commenter stated that EPA didn't have authority to regulate FGAN under the CAA and urged the Agency against including FGAN under the RMP regulations. Another commenter supported EPA's decision not to change current threshold quantities and toxic endpoints.

An industry trade association requested EPA's support and recognition of its voluntary private sector comprehensive inspection and assessment organization and FGAN guidelines for fertilizer retail facilities.

EPA acknowledges that there is both support and opposition to regulating AN and will consider these comments when determining whether to take further action on this issue. In the interim, EPA encourages fertilizer retailers to review and use existing guidance. OSHA compiles several resources on their Fertilizer Industry Guidance on Storage and Use of Ammonium Nitrate Web

[19] 2016. EPA Response to Comments on the 2016 Proposed Rulemaking Amending EPA's Risk Management Program Regulations. This document is available in the docket for this rulemaking.

page at *https://www.osha.gov/dep/fertilizer_industry/*.

EPA disagrees with the commenter that indicated that EPA failed to address Executive Order 13650 when we chose not to propose to list AN in the list of regulated substances for the RMP regulations. In the proposed rulemaking, EPA explained that other agencies, including OSHA and DHS, are considering modifications to their regulations, and EPA will coordinate any potential changes to the list of substances in 40 CFR part 68 with the actions of these other agencies.

IV. Prevention Program Requirements

A. Incident Investigation and Accident History Requirements

1. Summary of Proposed Rulemaking

a. Definitions, § 68.3

EPA proposed to revise the definition of ''catastrophic release'' in § 68.3 to include impact categories identical to the description of accidental releases required to be reported under the accident history reporting requirements in § 68.42. The proposed definition, in § 68.3, would replace the phrase ''that presents imminent and substantial endangerment to public health and the environment'' with impacts categories including impacts that resulted in:

- On-site: Deaths, injuries, or significant property damage; or
- Offsite: Known deaths, injuries, evacuations, sheltering in place, property damage, or environmental damage.

EPA proposed to define ''root cause'' in § 68.3 to mean a fundamental, underlying, system-related reason why an incident occurred that identifies a correctable failure(s) in management systems.

b. Incident Investigation Sections, §§ 68.60 and 68.81

EPA proposed a number of revisions to the incident investigation provisions. EPA proposed to revise § 68.60, which is applicable to Program 2 processes, and § 68.81, which is applicable to Program 3 processes, by revising paragraph (a) to add subparagraphs (a)(1) and (a)(2) to better clarify the scope of incidents that must be investigated. Proposed subparagraph (a)(1) applied to an incident that resulted in a catastrophic release and clarifies that the owner or operator must investigate the incident even if the process involving the regulated substance is destroyed or decommissioned. Proposed subparagraph (a)(2) applied to a near-miss, which is an incident that could reasonably have resulted in a catastrophic release. EPA also proposed removing the phrase ''of a regulated substance'' from paragraph (a) because it is duplicative. The definition of ''catastrophic release'' refers to releases of regulated substances.

EPA also proposed to add a new paragraph (c) to § 68.60 requiring that an incident investigation team be established and consist of at least one person knowledgeable in the process involved and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident. This is similar to the existing requirement in § 68.81(c) for Program 3 processes. EPA proposed that current § 68.60(c) through (f) would become § 68.60(d) through (g).

EPA proposed to revise the redesignated paragraph (d) in § 68.60 and current paragraph (d) in § 68.81 to revise the incident investigation report requirements. EPA proposed to change the word ''summary'' to ''report'' and require facility owners or operators to complete incident investigation reports within 12 months unless the implementing agency approves, in writing, an extension of time.

In addition, EPA proposed to amend and add new subparagraphs in the redesignated paragraph (d) in § 68.60 and current paragraph (d) in § 68.81 requiring additional elements in an incident investigation report. Specifically, EPA proposed to:

- Revise paragraph (d)(1) to require the time and location of the incident in the investigation report;
- Revise paragraph (d)(3) to specify that the description of the incident be in chronological order and provide all relevant facts;
- Add paragraph (d)(4) to require that the investigation report include the name and amount of the regulated substance involved in the release or near miss and the duration of the event;
- Add paragraph (d)(5) to require a description of the consequences, if any, of the incident;
- Add paragraph (d)(6) to require a description of emergency response actions taken;
- Renumber current paragraph (d)(4) to (d)(7) and require additional criteria related to the factors contributing to the incident, including the initiating event, direct and indirect contributing factors, and root causes. EPA also proposed to add language to paragraph (d)(7) to require that root causes be determined through the use of a recognized method.
- Renumber the current paragraph (d)(5) to (d)(8) and add language to require a schedule for addressing recommendations resulting from the investigation to be included in the investigation report.

Finally, in the redesignated § 68.60(g), EPA proposed to add the word incident before investigation and change ''summaries'' to ''reports'' for consistency.

c. Accident History, § 68.42

EPA also proposed to amend the five-year accident history section to require reporting of categories of root causes identified in the root cause analysis proposed to be required in §§ 68.60(d)(7) and 68.81(d)(7).

d. Hazard Review, § 68.50

For the Hazard review section, EPA proposed to amend subparagraph (a)(2) by adding a phrase at the end to require the owner or operator to consider findings from incident investigations.

e. Process Hazard Analysis (PHA), § 68.67

In the PHA section, EPA proposed to add subparagraph (c)(2) to require the owner or operator to address findings from incident investigations, as well as any other potential failure scenarios (*e.g.,* incidents that occurred at other similar facilities and or processes, failure mechanisms discovered in literature or from other sources of information).

f. Updates, § 68.190

In the Updates section, EPA proposed to amend paragraph (c) to require the owner or operator to report any accidents covered by § 68.42 and conduct incident investigations required under § 68.60 and/or § 68.81 prior to de-registering a process or stationary source that is no longer subject to the RMP rule.

2. Summary of Final Rule

EPA is not finalizing the proposed definition for catastrophic release and is instead maintaining the existing definition. Additionally, EPA is finalizing a modified version of the proposed definition of the term ''root cause.'' In the final definition EPA deleted the phrase ''that identifies a correctable failure(s) in management systems.''

EPA is not finalizing the proposed revisions to the five-year accident history section in the final rule.

EPA is finalizing the following provisions as proposed:

- Hazard review section, § 68.50;
- Incident investigation section §§ 68.60 and 68.81;
- Process hazard analysis (PHA) section, § 68.67, to add subparagraph (c)(2).

- Updates section, § 68.190.

3. Discussion of Comments and Basis for Final Rule Provisions

EPA's rationale for modifying the accident investigation provisions to explicitly require root cause analysis for investigations of catastrophic releases and near miss events and to have the findings of these investigations integrated into the PHA remains generally the same as in the proposed rulemaking. In the discussion that follows and in the Response to Comment document, we explain the modifications to our approach and the basis for these modifications.[20] The most significant change in approach is to retain the catastrophic release definition. As became apparent in the comments, our view that having a common definition of reportable accidental release and catastrophic release would simplify and clarify compliance was outweighed by the potential burden of inadvertently expanding the number of investigated accidental releases. We continue to require investigations of near misses, but have provided additional guidance as to what we intend by the term. Other changes from the proposal are similarly intended to clarify terms used in the rule. Identification of root cause categories in accident history reporting has been eliminated because identifying root cause categories only provides limited information for understanding the root cause which is best attained by reviewing the complete incident investigation report. Implementing agencies and/or local emergency planners may still obtain the investigation report through direct contact with the facility. The changes we adopt in this final rule strike a balance between ensuring facilities and planners learn about the causes of catastrophic releases and near misses while also better targeting the reporting to minimize burden.

a. Definitions

Catastrophic release. Although EPA received some support for the proposed definition of ''catastrophic release,'' many commenters were opposed to the revision. Many commenters, including government agencies, industry trade associations, and facilities, argued that EPA's proposed definition of ''catastrophic release'' (1) expands its scope, rather than clarifying it, (2) is redundant of OSHA's authority to regulate workplace safety by including on-site damage or injuries, and (3) exceeds the CAA authority to regulate only ambient air beyond a facility's property.

EPA also received some comments identifying other concerns with the proposed change to the definition of ''catastrophic release.'' Some commenters, including a few facilities, said that the proposed definition is too vague, and some commenters noted that terms such as ''injuries,'' ''significant property damage,'' ''environmental damage,'' and ''major'' are not defined. A facility and a private citizen commented that the wording of the definition implies that a ''catastrophic release'' could include a fire, regardless of whether an actual release of regulated material occurs due to the fire, and also implies that releases involving on-site environmental damage would not be considered catastrophic.

Many commenters, including a state government agency, facilities, and industry trade associations, argued that EPA's proposed definition of ''catastrophic release'' would regulate workplace safety concerns that are outside EPA's authority to regulate under the CAA. Commenters asserted that EPA has authority to address through regulation and enforcement offsite impacts of facility releases, not on-site impacts. A facility asserted that the proposed definition inappropriately expands the scope of EPA's reach into workplace safety by requiring investigations of releases that would also include impacts to on-site workers or property. An industry trade association stated that the definition ignores Congress's express prohibition against EPA ''exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.'' This commenter further argued that on-site injuries should be excluded from the proposed definition because OSHA already has jurisdiction in this area and because these often do not pose any risk to public health or the environment.

A facility stated that the proposed revision directly contradicts EPA's long-held interpretation that the references in section 112(r)(2)(A) to ''ambient'' air limit the Agency's authority to activities with offsite consequences. The commenter asserted that in the proposed rulemaking the EPA does not acknowledge the contradiction from its previous position or explain what new statutory authority exists or why it now has the authority to regulate workplace incidents.

Due to the large number of comments opposing the proposed revision to the definition of ''catastrophic release,'' EPA has decided not to finalize the proposed language. EPA believed that providing a consistent trigger for accident investigations and reportable accidents under the accident history requirements of § 68.42 would simplify compliance for the regulated community. EPA acknowledges that the proposed revision may have inadvertently expanded the definition and therefore the type of accident that could trigger an investigation. Some reportable incidents under the accident history provision may not pose an imminent and substantial threat to public health and the environment (see 40 CFR 68.3 (*Catastrophic release*)). Due to EPA's decision to retain the existing ''catastrophic release'' definition and not go forward with the proposed revision, the authority issues raised in comments are moot. However, contrary to one commenter's claim, it has never been EPA's position that the references in section 112(r) to ''ambient'' air limit the Agency's authority to regulate only activities with offsite consequences. On the contrary, it has been the Agency's longstanding position that incidents that primarily or even exclusively impact on-site receptors are potentially relevant to protection of the public and the environment from the risks of an accidental release. As EPA explained in the Response to Comments document for the original RMP rule, certain on-site accident impacts are relevant because they ''may reflect safety practices at the source'' and because ''accidental releases from covered processes which resulted in deaths, injuries, or significant property damage on-site, involve failures of sufficient magnitude that they have the potential to affect offsite areas.''[21]

For similar reasons, requiring investigation of accidents with on-site impacts is not redundant to OSHA's authority when such accidents have the potential to affect offsite areas.

Root cause. Many commenters opposed the proposed definition of ''root cause.'' These commenters, which included industry trade associations, facilities, and a private citizen, said that EPA should revise the definition of ''root cause'' to remove ''system-related'' and ''management system,'' reasoning that not all incidents are due to system failures. One commenter also stated that the definition assumes that there is only

[20] 2016. EPA Response to Comments on the 2016 Proposed Rulemaking Amending EPA's Risk Management Program Regulations. This document is available in the docket for this rulemaking.

[21] EPA, Risk Management Plan Rule: Summary and Response to Comments, Excerpt from Volume 1: Table of Contents, Introduction, and Sections 3, 16 and 17. May 24, 1996, pp 3–11 and 17–4. Document No. EPA–HQ–OEM–2015–0725–0153, *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0153.*

one root cause and that the failure is correctable, when there can be many causes and the investigators may not be able to determine what is ''correctable.'' An association of government agencies agreed that the investigation should identify all root causes of failure, regardless of whether they are deemed correctable or related to the management system. An industry trade association stated that EPA should not define ''root cause'' and instead should defer to facilities to rely on standard definitions from independent safety organizations. Another industry trade association also argued that EPA does not need to define ''root cause'' because current incident investigator requirements, which call for the investigator to uncover ''the factors that contributed to the incident,'' are sufficient. Other industry trade associations commented that it is very misleading and may lead to incorrect enforcement proceedings to require a facility to identify a management system failure as a root cause of incidents whose true root cause is a design deficiency, equipment failure, or misuse of equipment.

EPA agrees with some of the comments, and is finalizing the proposed definition of ''root cause'' with modifications. EPA deleted the language regarding identifying correctable failure(s) in management systems. In response to the comment that the definition assumes that there is only one root cause, EPA agrees that there are often multiple root causes. The final rule defines ''root cause'' in the singular, but does not preclude the possibility of more than one root cause. EPA agrees with the comments that support investigations identifying all root causes, and the Agency notes that the root cause requirements in the final rule require the owner or operator to identify ''root causes.''

b. Accident History Reporting

Some government agencies, an industry trade association, and a professional association agreed that the RMP accident history should include the root causes of incidents. However, other commenters, including industry trade associations and a facility, stated that the existing reporting requirements in § 68.42 are sufficient, and that requiring root cause reporting in the five-year accident history is an additional burden that is not offset by improved performance.

Although EPA believes there could be some benefit to identifying root cause categories within a facility's accident history, in most cases, the Agency believes the incident investigation report must be reviewed in order to fully understand root causes attributed to that incident. Implementing agency officials can obtain investigation reports during inspections or by using the Agency's information gathering authorities when needed. Therefore, EPA did not finalize the proposed requirement.

c. Changes to Hazard Review (§ 68.50) and Process Hazard Analysis (PHA) (§ 68.67) Requirements

Hazard review and PHA. Some commenters, including several government agencies, a professional organization, and an industry trade association, supported the requirement to include incident investigation findings in the hazard review. Other commenters opposed the requirement. Some of these commenters stated that the OSHA PSM standard already requires PHAs to address previous incidents, and EPA's changes are therefore unnecessary. One industry trade association commented that, as written, the proposal would require facilities to include all findings from all investigations for the facility's entire history.

Another commenter argued that incident investigation findings should not be required for PHAs because PHA teams typically use established techniques and requiring the ''findings from incident investigations'' to be included would not be a good fit for these types of assessments.

EPA disagrees with commenters and is finalizing these requirements as proposed, so that findings from incident investigations are considered when hazard reviews are conducted. EPA notes that the basic purpose of a hazard review is to identify what process equipment malfunctions or human errors could potentially lead to accidental releases, and then to identify what safeguards are needed in order to prevent such malfunctions and errors from occurring. An obvious source of information about such malfunctions and errors is information gained from investigating incidents that have previously occurred within the covered process. For this reason, the Program 3 analog to the hazard review, the PHA, already requires the owner or operator to identify any previous incidents that had a likely potential for catastrophic consequences when conducting the PHA.

EPA therefore not only disagrees with the commenter who stated that including findings from incident investigations within the PHA ''would not be a good fit'' for the PHA (as the existing rule already contains this requirement), but also believes that this requirement should be incorporated into the hazard review. EPA also disagrees that widely-used PHA (or hazard review) techniques preclude consideration of prior incidents—all PHA and hazard review techniques that EPA is aware of are easily adapted to allow consideration of prior incident scenarios. The commenter provided the example of the Hazard and Operability Study (HAZOP) PHA technique as an example of a technique for PHAs that is widely accepted but does not consider prior incidents. EPA disagrees that the HAZOP may not be adapted to consider prior incident causes. In fact, this PHA technique, which EPA acknowledges is widely used, is specifically intended to identify process deviations that can lead to undesirable consequences, as well as the causes and consequences of such deviations, and safeguards necessary to protect against the deviation from occurring. Incident scenarios are a key source of knowledge for conducting this technique. According to the Center for Chemical Process Safety (CCPS) ''Guidelines for Hazard Evaluation Procedures—Second Edition with Worked Examples'' (AIChE/CCPS, 1992, pp 143) ''the knowledge-based HAZOP Analysis study can help ensure that the company's practices, and therefore its experience, have indeed been incorporated in the design.'' The CCPS Guidelines also provide a specific example of how incident information can be incorporated into the HAZOP:

> As a more specific example, consider the discharge from a centrifugal pump. The guide-word HAZOP approach would apply the guide word ''Reverse'' to identify the need for a check valve. The knowledge-based HAZOP approach might also identify the need for a check valve *because an actual problem was experienced with reverse flow* . . . [emphasis added].

In response to the comment regarding the requirements of OSHA PSM, EPA notes that this final rule requirement is applicable to Program 2 covered processes, which are not subject to the OSHA PSM standard.

Other potential failure scenarios. Some commenters opposed including ''other potential failure scenarios'' in the process hazards analysis (PHA). A state agency and an industry trade association stated that it is unclear what ''any other potential failure scenarios'' means. The state agency also said that facilities may not have access to or knowledge of issues at similar facilities. A facility said that EPA should provide a clearinghouse of ''potential failure scenarios'' so that facilities will have access to them. An industry trade association commented that a literature

review would not provide much information and would be costly to conduct.

In response, as stated in the preamble to the proposed rulemaking, other potential failure scenarios can include incidents that occurred at other similar facilities and or processes, failure mechanisms discovered in literature, or from other sources of information. EPA believes that it is appropriate to research information about other potential scenarios and consider these scenarios when conducting a (PHA). Regarding the comment to provide a clearinghouse of scenarios, given the variety of processes and stationary sources, and ongoing changes to technologies, it would be difficult to establish a one-stop resource that would identify all potential failure scenarios for all processes covered under the rule. However, EPA believes that owners and operators are in the best position to obtain incident information relevant to their own covered processes. In most cases, industry trade associations will be a useful source for this information. Such information is also commonly available in trade journals, at industry conferences, in industry newsletters, in the Chemical Safety Board's accident investigation reports, in reference publications (*e.g.,* Lees' Loss Prevention in the Process Industries [22]), and through other professional networks. EPA therefore believes that information about other potential failure scenarios that are potentially relevant to a covered process should not be costly for the owner or operator to conduct and will benefit both the regulated stationary sources and its surrounding community.

Regarding the comment that this provision will require the owner or operator to review findings from all incident investigations for the facility's entire history—EPA agrees that the owner or operator should review all available incident information, but notes that the rule does not require the owner or operator to retain incident investigation reports for more than five years. However, if the owner or operator has access to incident information beyond that period, they should incorporate it into their hazard review as appropriate.

d. Destroyed or Decommissioned Processes

EPA received various comments regarding the proposed rulemaking's requirement for investigation of incidents that resulted in destruction or decommissioning of a process. Several commenters, including local agencies, facilities, an advocacy group, and an association of government agencies, expressed support for the requirement that an incident investigation with a root cause analysis be performed for incidents involving processes units that were destroyed or will be decommissioned. A local agency and a facility explained that this information could improve safety for other processes at the same facility or at other facilities.

EPA also received comments opposing incident investigations for destroyed or decommissioned processes. A facility and industry trade associations commented that there is no benefit to requiring investigations in cases where a process is decommissioned or destroyed.

EPA also received comments in opposition to registration requirements for decommissioned processes. A facility and an industry trade association said that there is no incremental safety benefit to requiring a destroyed or decommissioned unit to remain registered under RMP until after the incident investigation is complete. The commenters argued that this requirement imposes additional paperwork burdens without any additional safety benefit.

EPA is finalizing this requirement as proposed. The Agency agrees with the commenters who support this requirement because it will ensure that when incidents occur, particularly incidents so severe that the owner or operator elects to decommission the process involved or where the process is destroyed in the incident, lessons are learned as a result, both for the benefit of the owner/operator, and potentially for other stationary sources with similar processes.

In response to the comments opposed to the registration requirements for decommissioned processes, EPA believes that the additional paperwork burden regarding such requirements is minimal, as the processes would have already been registered in the source's most recent RMP. New accident history information may be added to the RMP without performing a full update. Following that correction, if the affected process has been decommissioned or destroyed, and if the source has multiple covered processes, the owner or operator would update their RMP to reflect the loss of the affected process (this would be required whether or not the incident was investigated). If the affected process was the only process at the source, after completing the investigation and correcting the existing RMP, the owner or operator would submit a deregistration notice for the source to EPA. Deregistration is already required by § 68.190(c) when a source is no longer subject to Part 68. Therefore, from a paperwork standpoint, the primary effect of this change would be the timing of when deregistration occurs. EPA believes the potential benefits of the knowledge gained from the incident investigation warrant this delay in deregistering a source.

e. Near Misses

In the proposed rulemaking, EPA did not propose a definition for the term ''near miss,'' although EPA did include the term in proposed revisions to §§ 68.60 and 68.81, paragraph (a)(2), in the phrase: ''Could reasonably have resulted in a catastrophic release (*i.e.,* was a near miss).'' EPA also sought public comment on whether to include a formal definition for the term. EPA received comments both supporting and opposing a definition of ''near miss.''

Requests to define ''*near miss.*'' Several commenters, including government agencies, industry trade associations, facilities, and an advocacy group, recommended defining ''near miss'' to reduce vagueness, uncertainty around which incidents require investigation, and the reliance on owners and operators to define the term. A local agency and an industry trade association suggested providing examples of near misses in guidance. A local agency said that EPA should clarify whether a release is considered a ''near miss'' if it was a controlled release. Other commenters, including a state agency and an industry trade association, opposed a regulatory definition of the term, stating that facilities should be permitted to determine what qualifies as a ''near miss'' that requires investigation. A state agency also said that EPA should not define ''near miss'' because it would be challenging to provide a definition that is suitable for all industry sectors. An industry trade association stated that the rule raises constitutional due process concerns because the rule lacks specificity to define the ''near miss'' standard and fails to provide adequate notice to the regulated community as to what the RMP rule will require.

EPA is finalizing the language in paragraph (a)(2) of §§ 68.60 and 68.81 as proposed, and has elected not to finalize a regulatory definition of ''near miss'' to identify incidents that require investigation. The criteria for determining incidents that require investigation will continue to include events that ''could reasonably have resulted in a catastrophic release.''

[22] Lees, Frank P. 2012. Loss Prevention in the Process Industries, Fourth Edition. Butterworth-Heinemann. *http://www.sciencedirect.com/science/book/9780123971890.*

Under the final rule, this criterion, rather than a definition of ''near miss,'' applies to determine which incidents require investigation. However, the rule makes clear that a ''near miss'' is an example of an event that ''could reasonably have resulted in a catastrophic release.'' EPA agrees with commenters who said it would be difficult to address in a single definition the various types of incidents that may occur in RMP-regulated sectors that should be considered near misses, and therefore be investigated. Instead, facility owners or operators will need to decide which incidents ''could reasonably have resulted in a catastrophic release.'' This may be based on the seriousness of the incident, the process(es) involved, and the specific conditions and circumstances involved. In the 1996 Response to Comments on the original rule, EPA acknowledged that the range of incidents that reasonably could have resulted in a catastrophic release is very broad and cannot be specifically defined.[23] EPA decided to leave it up to the owner or operator to determine whether an incident could reasonably have resulted in a catastrophic release and to investigate such incidents.

EPA understands from the comments that there was some uncertainty about the term near miss. EPA's experiences with RMP facility inspections and incident investigations show there have been incidents that were not investigated, even though under slightly different circumstances, the incident could have resulted in a catastrophic release. While most of these events did not result in deaths, injuries, adverse health or environmental effects, or sheltering-in-place, the Agency believes that in some cases, if circumstances had been slightly different, a catastrophic release could reasonably have occurred.

As described in the preamble to the proposed rulemaking, and as noted by one commenter, there is a CCPS definition of ''near miss.'' CCPS defines a ''near miss'' as an event in which an accident causing injury, death, property damage, or environmental impact, could have plausibly resulted if circumstances had been slightly different.

For example, a runaway reaction that is brought under control by operators is a near miss that may need to be investigated to determine why the problem occurred, even if it does not directly involve a covered process both because it may have led to a release from a nearby covered process or because it may indicate a safety management failure that applies to a covered process at the facility. Similarly, fires and explosions near or within a covered process, any unanticipated release of a regulated substance, and some process upsets could potentially lead to a catastrophic release.

CCPS's ''Process Safety Leading and Lagging Metrics—You Don't Improve What You Don't Measure'' explains that a near miss has three essential elements.[24] These include:

- An event occurs, or a potentially unsafe situation is discovered;
- The event or unsafe situation had reasonable potential to escalate; and
- The potential escalation would have led to adverse impacts.

The CCPS document and the CCPS ''Guidelines for Investigating Chemical Process Incidents'' contain many examples of near misses, which can be an actual event or discovery of a potentially unsafe situation.[25] Examples of incidents that should be investigated include some process upsets, such as: excursions of process parameters beyond pre-established critical control limits; activation of layers of protection such as relief valves, interlocks, rupture discs, blowdown systems, halon systems, vapor release alarms, and fixed vapor spray systems; and activation of emergency shutdowns.

Near misses should also include any incidents at nearby processes or equipment outside of a regulated process if the incident had the potential to cause a catastrophic release from a nearby regulated process. An example would be a transformer explosion that could have impacted nearby regulated process equipment causing it to lose containment of a regulated substance. Near misses could also include process upsets such as activation of relief valves, interlocks, blowdown systems, or rupture disks.

The intent is not to include every minor incident or leak, but focus on serious incidents that could reasonably have resulted in a catastrophic release, although EPA acknowledges this will require subjective judgment. EPA will update existing RMP guidance to reflect the revised RMP requirements and will provide guidance to identify what types of incidents could be considered near misses.

The concept of ''near miss'' has a meaning in industry and in the chemical engineering profession. In this preamble and in guidance, EPA has explained the concept and has identified sources that explain the term, and EPA believes that this satisfies any due process concerns raised by commenters related to the definition of this term. These sources put the regulated community on notice of EPA's expectations under the rule and thus also address the due process concerns raised by commenters regarding notice to the regulated community as to what the RMP rule will require. EPA expects that by expanding the root cause analysis requirement to near misses that could have resulted in a catastrophic incident, some stationary sources will be able to take corrective actions before another similar, but catastrophic incident occurs in the future. For example, as discussed in the March 14, 2016 RMP proposed rulemaking (81 FR 13637), incidents at Tosco Refinery, Georgia Pacific, Shell Olefins, Morton International, BP Texas City Refinery and Millard Refrigerated Services all involved near-misses or less serious incidents involving the same cause as the later catastrophic release.

Industry suggestions for clarifying near misses. A few industry trade associations commented that the examples of near misses that EPA provided in the NPRM, such as excursions of process parameters and activation of protections devices such as relief valves, should not be considered ''near misses.'' The commenters said that many of these examples are safeguards that are designed to be used to prevent catastrophic releases. An industry trade association also proposed a definition of ''near miss'' that would be limited only to scenarios where the final safeguard or layer of protection is activated, such that a release would have occurred if not for that control.

In response to these comments, EPA agrees that not all excursions of process parameters outside control levels or all instances of protective device activation should necessarily be considered to be near misses. EPA expects that activation of protective devices should be investigated when the failure of such devices could have reasonably resulted in a catastrophic release. However, EPA does not agree that near miss investigations should only include situations that resulted in activation of a final safeguard or layer of protection. This may be appropriate in some cases, but in others, multiple layers of protection may quickly fail. EPA

[23] EPA. May 24, 1996. Risk Management Plan Rule, Summary and Response to Comments. Volume 1, p. 16–4. Docket No. A–91–73, Document No. IX–C–1.

[24] CCPS. January 2011. Process Safety Leading and Lagging Metrics—You Don't Improve What You Don't Measure, p. 36. CCPS, American Institute of Chemical Engineers, New York, NY. John Wiley and Sons. *http://www.aiche.org/sites/default/files/docs/pages/CCPS_ProcessSafety_Lagging_2011_2-24.pdf.*

[25] CCPS. March 2003. Guidelines for Investigating Chemical Process Incidents, 2nd ed., p. 68.

believes that owners and operators must use reasonable judgement to decide which incidents, if they had occurred under slightly different circumstances, could reasonably have resulted in a catastrophic release, and investigate those incidents.

f. Investigation Timeframe

EPA received many comments in support of a shorter investigation timeframe. Many commenters, including a local agency and a professional association, stated that 12 months is too long to complete most investigations, and some commenters said that the timeframe should be shortened to five or six months. Some commenters also stated there should be a shorter timeframe, but with the ability to request an extension.

Other commenters, including state and local agencies and industry trade associations, said that EPA should allow for 12 months to complete an investigation and also allow extensions for especially large or complex incidents. Some commenters also recommended requiring interim reports. An industry trade association asked EPA to clarify that the 12-month period is only for completing the investigation report, not for implementing the recommendations in the report.

Other commenters, including facilities and industry trade associations, said that EPA should not impose any deadline for completing incident investigations. A few commenters, including a facility and industry trade associations, commented that an arbitrary deadline does not account for the complexity of the incident, the types of process units involved, or the need to retain outside consultants or experts to complete the investigation.

After considering these comments, EPA has decided to finalize the requirement to complete incident investigations within twelve months as proposed. EPA believes that this timeframe will provide a reasonable amount of time to conduct most investigations, while also ensuring that investigation findings are available relatively quickly in order to assist in preventing future incidents. For very complex incident investigations that cannot be completed within 12 months, EPA is allowing an extension of time if the implementing agency approves such an extension, in writing. EPA encourages owners and operators to complete incident investigations as soon as practicable, and believes that 12 months is typically long enough to complete even complex incident investigations. However, EPA provided flexibility for facilities to request more time to complete investigations when they consult with their implementing agency and receive written approval for an extension.

g. Incident Investigation Team

Some commenters, including a Federal agency, local government agencies, an association of government agencies, and an industry trade association, supported the proposed requirements under § 68.60(c) for the owner or operator of a Program 2 process to establish an incident investigation team consisting of at least one person knowledgeable in the process involved and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident. Other commenters opposed these requirements. A facility commented that the incident investigation team requirements are unnecessary because they are already covered by the OSHA PSM standard. A private citizen commented that the requirement assumes that all investigations will be conducted by a team, when it is possible for a competent individual to perform all aspects of the investigation if given access and support by the facility owner or operator. The commenter also stated that although the proposed rulemaking provides significant information on who may perform a third-party audit, it does not specify the qualifications of persons who may perform investigations and certify investigation reports.

EPA is finalizing the Program 2 incident investigation requirements, as proposed. The Agency agrees with the commenters who support requiring at least one person on the investigation team to be knowledgeable in the process involved and other persons with appropriate knowledge and experience in incident investigation techniques, as EPA believes these provisions are necessary to ensure that facilities thoroughly investigate and analyze incidents and their root causes.

EPA disagrees that these incident investigation team requirements are already covered by the OSHA PSM standard. The requirements for Program 3 processes in the current rule already include a provision for incident investigation teams; however, the incident investigation team requirements in this rule apply to Program 2 processes, which by definition are not covered by the OSHA PSM standard. EPA agrees that the requirement assumes that all investigations will be conducted by a team. EPA believes that all incident investigations, whether conducted on Program 2 or Program 3 processes, should involve a team of at least two people, particularly given the requirement under the final rule for investigations to include analysis of root causes. However, beyond the requirements specified in the final rule (*i.e.,* to establish an investigation team consisting of at least one person knowledgeable in the process involved and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident), the Agency does not believe it is necessary to specify additional qualification criteria for incident investigation team members.

h. Root Causes

Support for root cause requirements. Many commenters, including government agencies, advocacy groups, a facility, and others, expressed support for the requirements to determine root causes through the use of a recognized method and to include information on root causes in investigation reports. The commenters supported these provisions as a way to prevent future incidents. Most of these commenters also expressed support for applying the root cause analysis requirement to both catastrophic release incidents and to incidents that could reasonably have resulted in a catastrophic release (*i.e.* near misses). These commenters stated that conducting root cause analysis on near misses would allow the owner or operator to identify and make corrective actions before a catastrophic incident occurs. Some commenters also supported EPA's proposal to allow the use of any recognized method to complete a root cause analysis.

EPA agrees with these comments and believes that requiring root cause analyses for catastrophic releases and near misses, and including root cause information in incident investigation reports is vital for understanding the nature of these events. EPA is finalizing, as proposed, the requirements that root causes must be determined through the use of a recognized method and that information on root causes must be included in investigation reports. As previously noted, however, the final rule includes a modified version of the proposed definition of the term ''root cause.'' The phrase ''that identifies a correctable failure(s) in management systems'' from the proposed definition has been deleted.

Opposition for root cause requirements. EPA also received many comments opposing the proposed root cause analysis requirements. Some commenters, including industry trade associations and Federal agencies, said

that requiring the owner or operator to conduct a root cause analysis versus other investigation methods is unnecessary. Some of these commenters also argued that root cause analysis assumes that there is an underlying management or system-related cause behind every incident, which may not be the case and which EPA has failed to prove. An industry trade association and a facility stated that EPA should not require facilities to select from a predetermined list of root causes so as to avoid forcing them to fit their findings into a category that may not be appropriate.

Regarding these comments, EPA agrees that root cause analysis may result in identifying causes that are not always an underlying management or system-related cause, but still believes that the analysis is necessary to understand why the accident occurred so that the causes can be addressed. Therefore, we have modified the definition of ''root cause'' to remove the phrase ''that typically identifies a correctable failure(s) in management systems'' in order to remove the implication that all incidents involve correctable management system failures. EPA also notes that the final rule does not require facilities to select from a predetermined list of root causes or force them to fit their findings into an inappropriate category.

Many commenters argued that EPA should not require root cause analyses for near misses. A Federal agency, industry trade associations, and some facilities stated that EPA should not require root cause analyses for near misses because the requirement would increase compliance burdens and costs on facilities and take attention away from other safety activities. A few industry trade associations also argued that the quality of safety reviews will be diluted by applying the requirement to low-consequence, high-frequency events. One industry trade association stated that requiring a root cause analysis for near misses creates a false equivalency between near misses and actual catastrophic releases.

While EPA acknowledges that requiring root cause analyses for near misses may impose some additional burden on facilities, the Agency disagrees that the burden is unwarranted or that it will take attention away from other safety activities. The Agency notes that catastrophic release near miss events are infrequent events, and therefore do not typically divert attention from other safety activities. However, EPA believes that investigation of such incidents, when they occur, should be a high priority safety activity for regulated stationary sources, because these investigations can lead to the correction of problems which could ultimately prevent much more serious and costly catastrophic release incidents.

EPA also disagrees that the final rule applies the root cause investigation requirement to low-consequence, high-frequency events. The final rule requires root cause investigations only for incidents that resulted in, or could reasonably have resulted in, a catastrophic release. Such incidents are unusual. Based on accident history information reported to EPA, most regulated sources have never experienced a catastrophic release incident, and the Agency also believes that near misses will also be relatively rare events. The final rule does not presume any ''equivalency'' between near misses and actual catastrophic releases. The Agency notes that actual catastrophic releases may be more difficult to investigate if the incident requires extensive cleanup, damage assessment, evidence collection, etc.—activities that are unlikely to be necessary for near miss events. However, lessons learned from catastrophic releases and near misses should both benefit the source and its surrounding community, whether or not such events are viewed as equivalent.

Root cause requirements for Program 2 facilities. Some commenters opposed requiring root cause analyses for Program 2 processes. An industry trade association said that since most incidents happen at facilities with Program 3 facilities, it is unnecessary to expand this requirement to Program 2 facilities. Another industry trade association said root cause analyses should only be required at Program 3 facilities because the methodology is most appropriate for complex incidents.

While it is true that most RMP-reportable incidents occur at Program 3 processes, EPA decided that there was little justification for limiting the root cause requirements to only Program 3 processes, because some serious accidents also occur at Program 2 processes. Also, the Agency notes that some of the accidents at Program 2 processes occur at publicly owned water and wastewater treatment facilities that are not in Program 3 only because they are not located in a state with an OSHA-approved State Plan. Unlike state and local government employees at facilities in states with OSHA-approved State Plans, state and local government employees at facilities in states under Federal OSHA authority are not covered by the OSHA PSM standard. This results in regulated processes at these sources being placed in Program 2, even though the processes generally pose the same risk as similar processes at publicly owned water or wastewater treatment processes that are located at sources in OSHA State Plan states.

Incident investigation methodology. One commenter argued that EPA does not have authority to specify a specific incident investigation and analysis methodology and should remove all references to or requirement for any named investigation or analysis method from its proposed rulemakings. The commenter cited various provisions of the CAA and the language within the Memorandum of Understanding between CSB and EPA and asserted that CSB is the lead entity for accident investigations and has the authority to specify a named investigation method. Other commenters, including a state agency and facilities, said that EPA has not provided examples of how to determine what is a recognized method or which consensus bodies are to be used to determine recognized methods.

EPA disagrees with these comments. While the final rule does not require use of a specific incident investigation or analysis method (the final rule allows the owner or operator to determine root causes using ''a recognized method''), nothing in the CAA precludes EPA from requiring sources to conduct incident investigations. Contrary to the commenter's suggestion, the legislative history specifically contemplates EPA requiring accident investigations (see Senate Report at 242–43 [26]). The Agency notes that the existing RMP rule already contains such a requirement applicable to Program 2 and Program 3 processes. Like other risk management provisions, CAA section 112(r)(7)(B)(i) requires investigation requirements to be reasonable, but nothing in the statute otherwise limits EPA from requiring the investigation to address the issue of the underlying root cause of the accident.

Nothing in this final rule interferes with the ability of the CSB to conduct its accident investigations. The incident investigation provision we adopt is designed to have the facility learn from its accidents and near misses in order to identify ways to improve the facility's prevention program. The root cause investigations in this rule serve a distinct purpose from the oversight purposes of the CSB.

EPA also disagrees that we should specify recognized investigation methods or point to specific governing

[26] Senate Committee on Environment and Public Works, Clean Air Act Amendments of 1989, Senate Report No. 228, 101st Congress, 1st Session (1989)—''Senate Report''.

bodies for such methods. Investigation methods evolve over time, and new methods may be developed, so any list promulgated by EPA in this rule may soon be obsolete. The Agency took a similar approach in the PHA requirements for the existing rule, where it listed several potential methods, but also included the option to use an appropriate equivalent methodology. EPA recommends that owners and operators consult available literature on root cause investigation. For example, CCPS has published Guidelines for Investigating Chemical Process Incidents, which provides extensive guidance on incident investigations, near miss identification, root cause analysis, and other related topics.[27]

i. Other Incident Investigation Report Requirements

A few commenters, including a Federal agency, expressed support for the proposal to require additional information to be included in incident investigation reports. Several other commenters expressed opposition to various proposed incident investigation report requirements. A facility said that EPA's proposed changes are unnecessary because each of the proposed items is already required under the OSHA PSM standard. Some industry trade associations opposed requiring facilities to include the results of the root cause analysis in the incident investigation report, saying this could increase the likelihood of lawsuits against the facility if those reports are made public, or could result in the release of confidential business information.

EPA believes that providing the additional required information is vital for understanding the nature of the incident and should be included in the incident investigation report. Some facility owners or operators may already voluntarily include root cause information and other elements required under this rule (*e.g.,* time and location of incident, name and amount of substance involved in the release, etc.) in incident investigation reports prepared to comply with the RMP rule. However, §§ 68.60 and 68.81 are being revised to require this information to ensure clarity and consistency among reports. While the OSHA PSM standard contains the same incident investigation reporting requirements as the existing RMP rule for Program 3 processes, prior to this rule, neither regulation required reporting of root cause information nor the other report elements required in this rule. EPA disagrees with the conjecture that there may be an increased possibility of lawsuits is a good reason not to include root causes and other factual incident information in incident investigation reports. We note that the current rule requires a report that discusses factors contributing to the incident and recommendations resulting from the investigation, so to the extent that litigants would seek to use reports to establish cause or preventability of an incident, the litigation risk is there already. To the extent that the root cause discussion contains CBI, the existing rule provides methods for asserting CBI claims. Identifying root causes can prevent future incidents, thereby reducing accidental release impacts.

B. Third-Party Audits

EPA proposed to require owners or operators of certain RMP facilities to perform third-party audits, in order to prevent accidents and ensure compliance with part 68 requirements. The third-party audits are similar to the compliance audits already required by §§ 68.58 and 68.79, but EPA expects that independent compliance audits will assist stationary sources to come fully into compliance with the applicable prevention program requirements. The details of these requirements are described further.

1. Summary of Proposed Rulemaking

a. Definitions

EPA proposed to define ''third-party audit'' in § 68.3 as a compliance audit conducted pursuant to the requirements of § 68.59 and/or § 68.80, by an entity (individual or firm) meeting the competency, independence and impartiality criteria in those sections.

b. Compliance Audit Requirements Under §§ 68.58 and 68.79

EPA proposed changes to §§ 68.58 and 68.79 to require third-party compliance audits for both Program 2 and Program 3 processes, under certain conditions and to clarify existing requirements for compliance audits. EPA proposed to edit §§ 68.58(a) and 68.79(a) to add the language ''for each covered process'' to clarify that all compliance audits, self and third-party, shall address compliance with the provisions of Subpart C or D for each covered process. EPA also added a sentence at the end of the paragraph to reference when a compliance audit must be a third-party audit.

EPA also proposed to add paragraphs (f) through (h) in §§ 68.58 and 68.79. Paragraph (f) identified third-party audit applicability. EPA proposed that the next required compliance audit for an RMP facility would be a third-party audit when one of the following conditions apply:

- An accidental release, meeting the criteria in § 68.42(a), from a covered process has occurred; or
- An implementing agency requires a third-party audit based on noncompliance with the requirements of this subpart, including when a previous third-party audit failed to meet the competency, independence, or impartiality criteria of § 68.59(b) or § 68.80(b).

Proposed paragraph (g) described the procedure when an implementing agency requires a third-party audit and proposed an internal appeals process. EPA proposed to require an implementing agency to provide written notice to the facility owner or operator stating the reasons for the implementing agency's preliminary determination that a third-party audit is necessary. The owner or operator would have an opportunity to respond by providing information to, and consulting with, the implementing agency. The implementing agency would then provide a final determination to the owner or operator. If the final determination requires a third-party audit, the owner or operator would have an opportunity to appeal the final determination. EPA proposed that the implementing agency would provide a written, final decision on the appeal to the owner or operator after considering the appeal.

Proposed paragraph (h) described the schedule for completing third-party audits. The proposed language required the audit and associated report to be completed, and submitted to the implementing agency within 12 months of when any third-party audit is required or within three years of completion of the previous compliance audit, whichever is sooner. The provision also allowed an implementing agency to specify a different schedule.

c. Third-Party Compliance Audit Requirements in §§ 68.59 and 68.80

EPA proposed new §§ 68.59 and 68.80, which included requirements for both third-party compliance audits and third-party auditors. In paragraph (a), EPA proposed that owners or operators engage a third-party auditor to evaluate compliance with the provisions of subpart C or D (as applicable) when the applicability criteria of § 68.58(f) or § 68.79(f) are met.

[27] CCPS 2003. Center for Chemical Process Safety, Guidelines for Investigating Chemical Process Incidents, 2nd Edition, NY: AIChE.

Auditor qualifications. In paragraph (b), EPA proposed third-party auditor qualifications and required facility owners and operators to document that the third-party auditor or audit team meets competency and independence criteria of the rule. Specifically, EPA proposed that facility owners or operators determine and document that the third-party auditors meet the competency criteria in paragraph (b)(1) and the independence criteria in paragraph (b)(2).

EPA proposed competency criteria for auditors, requiring third-party auditors to be:

- Knowledgeable with the requirements of part 68;
- Experienced with the facility type and processes being audited and the applicable recognized and generally accepted good engineering practices (RAGAGEP);
- Trained or certified in proper auditing techniques; and
- A licensed Professional Engineer (PE) or include a licensed PE on the audit.

EPA also proposed independence and impartiality criteria that would apply to the third-party auditor or auditing team, and to each audit team member, individually. Specifically, the criteria would have required the auditor/audit team to:

- Act impartially when performing all activities under this section;
- Receive no financial benefit from the outcome of the audit, apart from payment for the auditing services;
- Not have conducted past research, development, design, construction services, or consulting for the owner or operator within the last 3 years. For purposes of this requirement, consulting does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80;
- Not provide other business or consulting services to the owner or operator, including advice or assistance to implement the findings or recommendations in an audit report, for a period of at least 3 years following submission of the final audit report;
- Ensure that all personnel involved in the audit sign and date the conflict of interest statement in § 68.59(d)(8); and
- Ensure that all personnel involved in the audit do not accept future employment with the owner or operator of the stationary source for a period of at least 3 years following submission of the final audit report. For purposes of this requirement, employment does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80.

In addition, in paragraph (b)(3), the proposed rulemaking required the auditor to have written policies and procedures to ensure that all personnel comply with the applicable competency, independence, and impartiality requirements.

Audit report. EPA proposed requirements for the audit report in paragraph (c). In paragraph (c)(1) EPA specified the scope and content of these reports, including a statement to be signed by the third-party auditor certifying that the third-party audit was performed in accordance with the requirements of subpart C or D, as applicable. EPA also proposed to require that the final third-party audit reports identify any adjustments made by the third-party auditor to any draft third-party audit reports provided to the owners or operators for their review or comment.

Proposed paragraph (c)(2) included requirements for third-party auditors to retain reports and records. Proposed paragraph (c)(3) required the audit report to be submitted to the implementing agency at the same time, or before, it is provided it to the owner or operator. Proposed paragraph (c)(4) provided that the audit report and related records could not be claimed as attorney-client communications or as attorney work products, even if written for or reviewed by legal staff.

Third-party audit findings. EPA proposed in paragraph (d)(1), to require owners or operators, as soon as possible, but no later than 90 days after receiving the final audit report, to determine an appropriate response to each of the findings in the audit report, and develop and provide to the implementing agency a findings response report. EPA proposed that the findings response report would include:

- A copy of the final audit report;
- An appropriate response to each of the audit report findings;
- A schedule for promptly addressing deficiencies; and
- A statement, signed and dated by a senior corporate officer, certifying that appropriate responses to the findings in the audit report have been identified and deficiencies were corrected, or are being corrected, consistent with the requirements of subpart C or D of 40 CFR part 68.

EPA proposed in paragraph (d)(2), to require the owner or operator to implement the schedule to address deficiencies identified in the audit findings response report, and document the action taken to address each deficiency, along with the date completed.

Proposed paragraph (d)(3) required the owner or operator to provide a copy of documents required under paragraphs (d)(1) and (d)(2) to the owner or operator's audit committee of the Board of Directors, or other comparable committee, if one exists.

Recordkeeping. Finally, EPA proposed recordkeeping requirements for the owner or operator in paragraph (e). The proposal would have required the owner or operator to retain records at the stationary source, including: The two most recent third-party audit reports, related findings response reports, documentation of actions taken to address deficiencies, and related records; and copies of all draft third-party audit reports. Those sections would further have required the owner or operator to provide draft third-party audit reports, or other documents, to the implementing agency upon request. EPA proposed that requirements would not apply to any documents that are more than five years old.

2. Summary of Final Rule

Regulated entities must engage a third-party to conduct an independent compliance audit when they (1) have an RMP reportable accident or (2) have been notified by an implementing agency of a determination of either conditions that could lead to an accidental release or problems with a prior third-party audit.

EPA is finalizing the proposed requirements for third-party auditors with modifications that include:

- Revising the applicability criteria for third-party audits required by implementing agencies from noncompliance to conditions that could lead to an accidental release;
- Providing for a third-party audit team, led by an independent third-party, which may now include a wide variety of additional, non-independent personnel, including facility employees and other personnel;
- Eliminating the competency criterion that the auditor be a PE;
- Revising the third-party auditor independence criteria to increase the number and diversity of qualified and available auditors; and
- Removing the requirement that either or both draft and final audit reports be submitted to implementing agencies.

EPA believes these changes address many of the most significant public comments EPA received on the proposed third-party audit requirements.

a. Definitions

In the final rule, EPA revised the definition of ''third-party audit'' to reflect the changes in §§ 68.59 and 68.80, which, when applicable, require that an owner or operator must either engage a third-party auditor or assemble an auditing team led by a third-party auditor. EPA also deleted the reference to impartiality, because impartiality is a criterion under the independence criteria in §§ 68.59(c)(2) and 68.80(c)(2) and there is no need to highlight this term individually.

b. Compliance Audit Requirements Under §§ 68.58 and 68.79

EPA is finalizing paragraph (a) as proposed. This includes clarifying language ''for each covered process'' added to §§ 68.58(a) and 68.79(a).

EPA is finalizing the applicability requirements set forth in §§ 68.58(f)(1) and 68.79(f)(1) as proposed but modifies the criterion in §§ 68.58(f)(2) and 68.79(f)(2) to apply when an implementing agency requires a third-party audit due to conditions at the stationary source that could lead to an accidental release of a regulated substance, or when a previous third-party audit failed to meet the competency or independence criteria of § 68.59(c).

EPA is also finalizing the implementing agency notifications and appeals process in paragraph (g), as proposed. However, the final rule language includes minor editorial revisions. The language of subparagraph (g)(1) requires the implementing agency to provide written notice to the owner or operator that describes the basis for the determination. The language of §§ 68.58(g)(3) and 68.79(g)(3) was modified to delete the unnecessary phrase ''of this section.''

EPA has modified and clarified the schedule for completing a third-party audit in paragraph (h) as follows:

- EPA deleted the language requiring the auditor to submit the audit report to the implementing agency.
- The final rule requires a third-party audit to be completed within 12 months, unless a different timeframe is specified by the implementing agency. However, EPA made changes to simplify and clarify the schedule requirements.
  - Subparagraph (h)(1) requires a third-party audit to be completed within 12 months of an RMP reportable accident.
  - Subparagraph (h)(2) requires a third-party audit to be completed within 12 months of the date of the implementing agency's final determination, or if appealed, within 12 months of the date of the final decision on the appeal.

c. Third-Party Compliance Audit Requirements in §§ 68.59 and 68.80

EPA is finalizing paragraph (a) as proposed but modified the language slightly to clarify that the owner or operator shall engage a third-party to conduct an audit to evaluate compliance with subpart C or D as applicable.

Third-party auditors and auditing teams. In the final rule, EPA added paragraph (b) to provide options for assembling a third-party auditor or an audit team. In addition to engaging a fully independent third-party auditing firm, owners or operators may assemble auditing teams that include competent and independent third-party auditor team leaders and other qualifying, non-independent personnel. The owner or operator shall either:

- Engage a third-party auditor meeting all of the competency and independence criteria of the rule (subparagraph (b)(1)); or
- Assemble an auditing team, led by a third-party auditor meeting all of the competency and independence criteria. The team may include:
  - Other employees of the third-party auditor firm meeting the independence criteria of the rule; and
  - Other personnel not employed by the third-party auditor firm (subparagraph (b)(2)).[28]

Auditor qualifications. The final rule retains the third-party auditor qualification requirements in paragraph (b) of the proposed rulemaking but redesignated as paragraph (c). The qualification requirements set forth in this paragraph apply only to the third-party auditors. The third-party auditor qualifications are clarified and modified as described further in this preamble.

In the final rule, EPA simplified the introductory paragraph to indicate that the owner or operator shall determine and document that the third-party auditor(s) meets the competency and independence requirements set forth in the subparagraphs.

Subparagraph (c)(1) identifies competency criteria that apply to third-party auditors.[29] EPA is finalizing the competency criteria as proposed, except to delete the requirement for a licensed PE to conduct the audit or participate on the audit team.

Subparagraph (c)(2) identifies independence criteria that apply to third-party auditors. EPA is amending and finalizing the proposed independence criteria as follows:

- EPA is deleting the phrase ''and impartiality'' from the title because the impartiality requirement is listed as one of several criteria, and it is unnecessary to highlight the term separately.
- EPA clarified that retired employees qualify as third-party auditors when financial attachments are limited to retirement and/or health plans.
- EPA revised the timeframe that limits third-party auditors past and future research, development, design, construction services, or consulting services to two years. EPA further clarified that if the firm employs personnel that did conduct these services within the prescribed timeframe, then these personnel may not participate in the audit.
- The final rule requires third-party audit personnel to sign and date a conflict of interest statement documenting that they meet the independence criteria.
- The limitation regarding future employment with the owner or operator has been modified to apply to only third-party personnel involved in the audit and the timeframe decreased to two years.

EPA is finalizing subparagraph (c)(3), as proposed, to require auditors to have written policies and procedures to ensure that all personnel comply with the qualification criteria—except to delete the word impartiality from the criteria description.

Third-party auditor responsibilities. EPA is adding requirements for the owner or operator to provide certain responsibilities to the third-party auditor.[30] Paragraph (d) requires the

[28] ''Other personnel'' may be facility personnel, personnel from any other facilities owned or controlled by the owner or operator, and/or any non-independent second or third-party consultants or contractors the owners or operators choose to include on the auditing teams they assemble under subparagraph (b)(2). In addition, the auditing teams may include other employees of the third-party auditor firm who meet the independence criteria of subparagraph (c)(2). Such personnel need not individually meet the final rule's third-party auditor competency criteria as long as the independent third-party audit team leader, pursuant to his/her evaluation of audit team member competencies under subparagraph (d)(2), determines that the full audit team includes all of the competencies required to successfully complete the audit pursuant to the requirements in the final rule.

[29] The competency criteria do not apply to other personnel, not employed by the third-party auditor firm, that participate on the auditing team (*e.g.,* facility personnel).

[30] EPA is finalizing auditor responsibilities to ensure that third-party auditors maintain certain responsibilities when audit teams are comprised of both third-party auditor personnel and other personnel. EPA did not propose roles and responsibilities for independent third-party auditors because, in the proposed approach, independent third-party auditors were responsible for conducting all auditing activities.

owner or operator to ensure that the third-party auditor:

- Manages the audit and participates in audit initiation, design, implementation, and reporting;
- Determines appropriate roles and responsibilities for the audit team members based on the qualifications of each team member;
- Prepares the audit report and where there is a team, documents the full audit team's views in the final audit report;
- Certifies the final audit report and its contents as meeting the requirements of the rule; and
- Provides a copy of the audit report to the facility owner or operator.

Audit report. EPA is redesignating and finalizing audit report requirements under paragraph (e) of the final rule with modifications. EPA reorganized and added one report requirement to the proposed subparagraphs (c)(1)(i) to (c)(1)(v). These are subparagraphs (e)(1) to (e)(6) in the final rule.

EPA also amended the audit report provisions in the final rule to simplify the applicable provisions and simplify the requirements for preparing and handling the third-party audit reports:

- Subparagraph (e)(1) requires the report to identify all persons participating on the audit team, including their employers and/or affiliations. The report must also document that third-party auditors meet the competency criteria of the rule; [31]
- EPA added an additional requirement under subparagraph (e)(2) for the auditor to describe in the report, or incorporate by reference, policies and procedures to ensure all third-party personnel comply with the competency and independence criteria of the rule;
- Proposed subparagraphs (c)(ii) and (c)(iii) are finalized as proposed and redesignated as (e)(3) and (e)(4). The report must document the auditor's compliance evaluation for each covered process and document the findings of the audit, including any identified deficiencies;
- Subparagraph (e)(5) requires the report to summarize any significant revisions between draft and final versions of the report;
- Subparagraph (e)(6) requires the auditor or audit team leader to sign and date a certification. The certification is finalized as proposed except to remove the last sentence that acknowledges penalties for submitting false information;
- EPA deleted the provision that required the auditor to maintain copies of all reports and records; [32]
- EPA deleted the provision that required the auditor to submit the report to the implementing agency at the same time as it would be provided to the owner or operator; and
- EPA deleted the provision limiting attorney-client privilege.

Third-party audit findings. EPA is finalizing requirements for the owner or operator to prepare a findings response report; develop a schedule to address deficiencies; and submit the findings response report and schedule to the Board of Directors. These requirements are redesignated to paragraph (f) of the final rule with the following modifications to the findings response report:

- EPA deleted the proposed requirement to submit the findings response report to the implementing agency; and
- EPA amended the owner/operator certification in the findings response report to add a sentence indicating that the owner or operator has engaged a third-party to perform or lead an audit team to conduct a third-party audit in accordance with the requirements of 40 CFR 68.80. EPA also modified the final sentence of the certification to clarify that submitting false information includes making false material statements, representations, or certifications.[33]

EPA is finalizing requirements in subparagraph (f)(2) to develop a schedule to address deficiencies as proposed, except to modify the title of the provision to schedule implementation and correct citations to redesignated paragraphs.

EPA is also finalizing the requirement in subparagraph (f)(3) to submit the findings response report and implementation schedule to the board of directors as proposed with minor modifications to update citations to redesignated paragraphs, and capitalize Board of Directors in the title. In addition, the end of the last sentence was changed to reference a comparable committee, or individual, if applicable.

Recordkeeping. EPA is finalizing the recordkeeping requirements as proposed in paragraph (d) with the following modifications:

- The paragraph has been redesignated as paragraph (g) in the final rule;
- EPA eliminated the proposed subparagraphs and moved the language of proposed subparagraph (e)(1) into the main paragraph with edits to clarify that the owner or operator shall retain at the stationary source the two most recent final third-party audit reports;
- EPA eliminated the proposed requirement for owners or operators to retain copies of all draft third-party audit reports (subparagraph (e)(2) of the proposed rulemaking); and
- EPA amended the recordkeeping provision for Program 3 processes in § 68.80(e) to delete the sentence that applied the recordkeeping provisions to any documents that were five-years old or less. This revision is consistent with current recordkeeping compliance audits under § 68.79(e) and corrects an error in the proposed rulemaking text.

3. Discussion of Comments and Basis for Final Rule Provisions

Several comments supported the proposed third-party audit requirements, including one stating that the commenter found that internal audits often fail to identify systemic process safety deficiencies. However, many commenters opposed the proposed third-party compliance audit provisions, including some who expressed general opposition, reasoning that existing requirements and mechanisms are working. Some comments argued that the costs outweigh the benefits associated with this provision or that audits by internal resources are more cost-effective and less disruptive, while still providing adequate assessment and encouraging compliance.

EPA has retained a third-party audit requirement in the final rule. We continue to rely on the rationale expressed in the proposed rulemaking. However, in the final rule, we have modified the requirements for the audit team to expand the potential membership while still retaining the critical role of the independent auditor in the review of the compliance program. In the discussion that follows and in the Response to Comment document, we explain the modifications to our approach and the basis for these modifications.[34] While the RMP rule does not prohibit accidental releases, an accidental release can be an indication of a prevention program that both needs

[31] Note-only third-party auditors must meet the competency criteria of the rule-does not apply to other personnel on an audit team.

[32] EPA retains its authority under Section 114 of the CAA to require regulated entities to make such records available to the Agency, as appropriate, upon request or during inspections. EPA is finalizing recordkeeping requirements under paragraph (g) of the final rule.

[33] This change was made to track the language of Section 113(c)(2)(A) of the CAA which makes it illegal for regulated entities to ''make any false material statement, representation, or certification.''

[34] 2016. EPA Response to Comments on the 2016 Proposed Rulemaking Amending EPA's Risk Management Program Regulations. This document is available in the docket for this rulemaking.

improvement and that may benefit from an audit by someone independent from the source's historic program and the management of the source. The requirements finalized in this rule are not based on a wide finding that the original compliance audit requirement of the RMP rule does not have value; instead, we promulgate this requirement to target a subgroup that have had indications of potential problems not detected and addressed by the traditional audit structure.

EPA believes it is appropriate to require a subset of RMP-regulated facilities to engage competent and independent third-party auditors following an RMP-reportable accident or identification of conditions at the stationary source that could lead to an accidental release of a regulated substance. The purpose of the third-party audit is to assist the owners and operators in determining whether facility procedures and practices to comply with subparts C and/or D of the RMP rule (*i.e.,* the prevention program requirements) are adequate and being followed. Thus, EPA is finalizing requirements for third-party audits when required under § 68.58 and/or § 68.79, to require that owners and operators ensure that third-party auditors meet qualification criteria, audits are conducted and documented, and findings are addressed pursuant to the requirements of § 68.59 and/or § 68.80, as applicable. EPA notes that under part 68, sources with any Program 2 and/or Program 3 processes are already required to conduct compliance audits every three years. This rule does not change the requirement that RMP facilities regularly conduct RMP compliance audits but provides only that, in specific situations, those audits be performed by a third-party or a team led by a third-party, pursuant to the schedule in § 68.58(h) and/or § 68.79(h) of the rule.

EPA considered, but did not adopt, changes to the final rule that would establish additional processes or programs under which EPA or other regulatory agencies must first approve or credential third-party auditors before owners or operators can engage them. Nor did EPA modify the rule to establish or reference additional independent auditor accreditation programs or auditor accreditation oversight committees or otherwise require potential third-party auditors to be accredited by an independent auditing or accreditation body before owners or operators may engage the auditors under this rule. For some programs, external accreditation of third-party auditors adds additional rigor to the process of ensuring the competence and independence of the auditors but such external accreditation can be time-consuming and add financial costs. EPA believes that the level of effort and resources necessary to establish these programs would cause unnecessary delays in implementing third-party compliance audit requirements and are not warranted for the small universe of facilities that may be subject to these requirements. Comments on significant issues relating to third-party audits are summarized and discussed further in this preamble. The following also discusses EPA's basis for the third-party audit provisions adopted in this final rule.

a. Third-Party Auditing Constitutional Law and Agency Authority Issues

EPA's enforcement authority. Several commenters stated that EPA should rely on its existing enforcement authority, including the ability to require third-party audits in particular enforcement proceedings, rather than requiring third-party audits more generally. Another encouraged EPA to focus on enforcing existing audit requirements. Similarly, another recommended that EPA address facilities deemed to be incapable of performing objective self-auditing through EPA's enforcement authorities. One commenter argued that the proposed third-party audit requirements violate the U.S. Constitution's Fifth Amendment Due Process Clause because the proposal seeks to outsource EPA's inspectional duties to a third-party and force facility owners or operators to accept and implement the third-party's findings without processes to protect the due process rights of those subject to the audits. A few commenters stated that the proposed third-party auditing provisions are an unlawful and unconstitutional circumvention of Congressional appropriations limits on EPA's enforcement budget. Specifically, the commenters argued that the Anti-Deficiency Act prohibits EPA from augmenting its enforcement budget by mandating that third parties oversee the RMP program.

EPA disagrees with the commenters. Third-party audits do not constitute enforcement, nor do they substitute for inspections by implementing agencies, and as such, EPA believes that they do not violate either the Due Process Clause of the Fifth Amendment, or the Anti-Deficiency Act. In addition, as discussed further in this preamble, EPA believes that there is no violation of the Due Process Clause of the Fifth Amendment regarding implementation of third-party audit findings.

The third-party audits required in this final rule are compliance audits, similar to the current self-audit requirements, only conducted by a team led by a third-party auditor. The Senate Environment and Public Works Committee identified program audits ''by company personnel . . . or outside consultants'' as an element of prevention program rules within the range of authorities provided EPA. *See* Senate Report at 243.[35] The findings of a third-party audit are intended to identify noncompliance that was not discovered by facility personnel during self-audits, and are not intended primarily to bring such findings to the attention of government regulators. In fact, the audits are designed primarily to benefit owners or operators by assisting them to identify both actual noncompliance as well as operational or equipment deficiencies, previously unidentified risk factors, and accident release and/or regulatory noncompliance precursor conditions which, if uncorrected, could lead to releases and/or enforcement actions. Proactively addressing deficiencies, risk factors, and precursor conditions to accidental releases and regulatory noncompliance will provide financial, regulatory, and environmental benefits for facility owners and operators and communities. EPA has reasonably targeted third-party audit requirements at facilities that have had RMP reportable incidents that may demonstrate weaknesses in prior self-assessments and at facilities of heightened concern for implementing agencies.

Furthermore, third-party compliance audits in no way constitute regulatory inspections of, or enforcement at, RMP-regulated facilities. This rule is clear that third-party auditors' or third-party audit teams' findings are not, in and of themselves, determinations of regulatory violations. Nor are the audit reports or related documentation required to be automatically submitted to implementing agencies. EPA believes there is no violation of the Due Process Clause of the Fifth Amendment regarding implementation of third-party audit findings. Owners or operators must address all third-party audit findings, the rule provides that addressing the audit findings may include, where appropriate, determining that some specific findings were based on incorrect factual assumptions or were otherwise inappropriate to implement. Thus, as described further

[35] Senate Committee on Environment and Public Works, Clean Air Act Amendments of 1989, Senate Report No. 228, 101st Congress, 1st Session 211 (1989)—''Senate Report.''

in this preamble, the owner or operator of a stationary sources may determine an appropriate response to the findings in the audit report, and are not required to accept findings when they can justifiably decline to adopt them, and EPA believes that determining appropriate responses, and addressing of deficiencies, risk factors, and precursor conditions to accidental releases and regulatory noncompliance pursuant to the third-party audit regulatory requirements, do not constitute violations of the Due Process Clause of the Fifth Amendment.

Finally, nothing in this rule relieves the EPA of any of its responsibilities under the CAA or implies that EPA will not continue to use its enforcement authorities under the CAA or devote resources to monitoring and enforcing this rule. The third-party auditing regulatory requirements simply ensure that regulated entities will, in a carefully-defined subset of circumstances, take reasonable measures to assess and ensure their own compliance.

Security and CBI concerns. A few commenters expressed security concerns associated with third-party compliance audits. One commenter was concerned with ensuring proper treatment of confidential information by third-party auditors, and asserted that the proposed rulemaking does not address whether or not a facility will be able to limit the release of sensitive information once a third-party auditor is involved. Another comment was received stating that facility and process security are concerns for the commercial explosives industry, and recommended that EPA eliminate the third-party audit requirements. This commenter reasoned that internal staff at explosives sites would have undergone mandatory background checks but third-party auditors wouldn't necessarily be subject to the same security screening. A few commenters stated that attempts to find auditors with appropriate security clearances would further limit the pool of available qualified auditors. One commenter asserted that the third-party compliance audit requirements create legal concerns given that the third parties would be privy to potential CBI or information that should be protected under attorney-client privilege.

EPA acknowledges commenters concerns; however, facility owners or operators routinely obtain and review the internal policies, procedures, and qualifications of a wide range of consultants and contractors before engaging them in order to assess their qualifications to perform consulting or contractual services. EPA is confident owners and operators will be able to ensure that third-party auditor personnel meet applicable security criteria.

Regarding concerns that the third-party compliance audit requirements create legal concerns given that the third-parties would be privy to potential CBI, the contracts or other agreements between owner/operators and third-party auditors can address how any potential confidential business information is handled by the third-party.

With regard to information that arguably should be protected under evidentiary privileges, EPA's view is that the third-party audit reports and related records under this rule, like other documents prepared pursuant to part 68 requirements, such as process safety information, PHAs, operating procedures and others, are not documents produced in anticipation of litigation. With respect to the attorney-client communication privilege specifically, the third-party auditor is arms-length and independent of the stationary source being audited. The auditor lacks an attorney-client relationship with counsel for the audited entity. Therefore, in EPA's view, neither the audit report nor the records related to the audit report provided by the third-party auditor are attorney-client privileged (including documents originally prepared with assistance or under the direction of the audited source's attorney). Nevertheless, EPA recognizes that the ultimate decision maker on questions of evidentiary privileges are the courts. Therefore, this rule does not contain a specific regulatory provision prohibiting assertion of these privileges.

b. Requirement To Conduct Compliance Audit for Each Covered Process

EPA received several comments regarding the clarification in §§ 68.58(a) and 68.79(a) of the proposed rulemaking that all RMP audits must address ''each covered process'' at a facility. Some commenters opposed this clarification. A few commenters indicated that this would be a change, and asserted that EPA has endorsed guidance from the CCPS allowing facilities with a large number of covered processes to audit a representative sample of processes.

One commenter argued that it was punitive for an accidental release from one process to automatically trigger a third-party audit requirement for all covered processes. A few commenters stated that requiring that all RMP-covered processes at the facility be audited regardless of what process triggered the requirement to perform the third-party audit would result in duplication of efforts with little benefit where processes at multi-process facilities are on different auditing schedules and third-parties are required to audit processes that were recently audited and not related to the incident that triggered the third-party audit. One commenter stated that requiring audits of processes that are not part of an incident would tie-up plant resources for longer than needed, which was particularly notable to the commenter because these processes would very likely still be operating after the incident and at the time of the audit.

Finally, commenters asserted that it is unfair and more burdensome to require larger facilities with multiple processes to audit each covered process, arguing that they would essentially be auditing all the time, where small facilities with one or two processes would have a lesser auditing burden.

EPA disagrees with commenters that believe it is punitive or redundant to require an audit of all RMP-covered processes at the facility, including those not involved in an RMP-reportable accident. Under existing rules, each facility compliance audit must address each covered process at least every three years. The third-party audit required under this rule simply replaces the next scheduled self-compliance audit, which must address each covered process.

EPA has consistently maintained that, at least every three years, owners or operators must, under the RMP rule, certify that they have evaluated compliance with the prevention program requirements for *each covered process.* ''In EPA's General Risk Management Guidance, issued in 2004 and updated in 2009, in Chapter 6, ''Prevention Program (Program 2)'' Section 6.7 ''Compliance Audits (§ 68.58)'', under the heading ''What Do I Need to Do?'' it states ''At least every three years, you must certify that you have evaluated compliance with the prevention program requirements for *each covered process*'' [emphasis added]. In addition, Chapter 7 of this guidance, ''Prevention Program (Program 3)'' Section 7.9 ''Compliance Audits (§ 68.79),'' states ''You must conduct an audit of the process to evaluate compliance with the prevention program requirements at least once every three years.'' While EPA does list the 1993 edition of CCPS Guidelines for Auditing Process Safety Management Systems as a reference source within this guidance, EPA disagrees that the CCPS guidelines endorse allowing large facilities to audit a representative sample of covered processes.

EPA has also clearly stated its position within the Notice of Proposed Rulemaking preamble for the initial RMP regulation, and in the Response to Comments for that rule. In response to a question concerning whether facilities could stagger compliance audits where there are multiple processes at a facility, EPA stated, in the Response to Comments document, that a source ''may choose to audit different processes on different schedules (if) over each three-year period, all covered processes are audited.'' [36] Furthermore, while OSHA's original PSM compliance audit guidelines may have allowed for auditing a sample of processes, the current guidelines are consistent with EPA's General Risk Management Guidance. See OSHA's ''Appendix C to § 1910.119—Compliance Guidelines and Recommendations for Process Safety Management (Nonmandatory).'' EPA's decision to retain, in §§ 68.59(e)(3) and 68.80(e)(3) of the final rule, the requirements for the third-party audit reports to document the auditor's evaluation, for each covered process, of the owner or operator's compliance with the prevention program provisions is thus consistent with both the initial RMP rule and EPA's longstanding interpretation of the scope of the rule.

EPA also disagrees with commenters' burden argument for larger companies and facilities with a larger number of processes. These larger facilities typically also have more personnel and resources, where smaller facilities with fewer processes may have fewer employees, so the burden of auditing is proportionate for these facilities. Furthermore, larger facilities with more processes, in general, are likely to have more potential opportunities for accidental releases due to their size, complexity, and scale of operations. Therefore, it is appropriate for such facilities' auditing responsibilities to be commensurate to their size, complexity, and scale of operations.

c. Third-Party Audit Applicability

Some commenters generally supported the proposed applicability requirements. However, many commenters opposed the requirements, requesting that EPA narrow, limit, or eliminate these requirements.

RMP-reportable accident criterion. A commenter encouraged EPA to develop a narrower range of circumstances that can trigger a third-party audit to ensure they will not become an overwhelming compliance function, and detract from the performance-based aspects of RMP. Other commenters recommended limiting the requirements to: Releases that result in offsite impacts, such as offsite deaths, serious injuries, or significant environmental contamination; Program 3 facilities; facilities with multiple releases or multiple major accidents; or incidents that result in significant impacts to workers, or to the community. Another commenter stated that third-party audits should not be required automatically, but should only be required if the facility has experienced an accidental release that meets the criteria in § 68.42(a) and EPA makes the determination that there is good cause for the audit, in light of the particular circumstances and facts surrounding the release in question. One commenter stated that the accidental release trigger was not an effective way to improve public safety and urged EPA to adopt a more proactive and targeted approach.

EPA disagrees with commenters that third-party compliance audits will become an overwhelming compliance function. EPA has limited applicability of third-party audits to circumstances in which an RMP reportable accident has occurred or where conditions exist at the source that could lead to a release. In responding to the previous comments, it is necessary to provide context for how infrequently third-party auditing will, in practice, be necessary under the final rule, both in absolute numbers of such audits and their number relative to the full universe of RMP-regulated stationary sources already subject to the RMP rule's self-auditing requirements.

Currently, there are approximately 12,000 stationary sources with Program 2 and/or Program 3 processes. The final rule requires third-party compliance audits only under the following two conditions:

- If there has been an RMP reportable accident (*i.e.,* an accidental release from an RMP facility meeting the five-year accident history criteria as described in § 68.42(a)); or
- If an implementing agency makes a determination that a third-party audit at an RMP facility is necessary, based on conditions ''that could lead to an accidental release of a regulated substance'' or a prior third-party audit at the facility.

EPA does not expect these criteria to impact a large percentage of stationary sources with Program 2 and/or Program 3 processes. For example, comparing the number of facilities which in past years have had an RMP reportable accident (averages approximately 150/year), with the number of current stationary sources with Program 2 and/or Program 3 processes, would represent less than 2% of stationary sources subject to this requirement, due to an accident, on an annual basis. For more information on the number of RMP reportable accidents over a ten-year period see section IX.A of this preamble.

EPA also disagrees with suggestions to limit the applicability of third-party compliance audits to releases with offsite impacts, deaths, injuries, or significant environmental impacts. The purpose of the third-party audit is to help reduce the risk of future accidents by requiring an independent and objective audit to determine whether the owner or operator of the facility is effectively meeting the prevention program requirements of the RMP rule. Stationary sources that have had accidents and/or substantial noncompliance with Risk Management Program requirements may pose a greater risk to the surrounding communities. EPA agrees that releases with offsite impacts, deaths, injuries, or significant environmental impacts are potential indicators of noncompliance with RMP prevention program requirements. But so are accidental releases that involve significant property damage on-site, or known offsite evacuations, sheltering in place, property damage, or environmental damage of any degree.

The existing self-audit requirements under §§ 68.58 and 68.79 incorporate a proactive evaluation of prevention program requirements for Program 2 and Program 3 processes. However, when a facility has an accidental release or noncompliance that could lead to an accidental release of a regulated substance, EPA has determined that further self-auditing may be insufficient to prevent accidents and ensure safe operation. Therefore, we believe it is appropriate to require such stationary sources to undergo third-party auditing to better assist owners and operators and implementing agencies to determine whether the procedures and practices developed by the owner and/or operator under subparts C and/or D of the RMP rule (*i.e.,* the prevention program requirements) are adequate and being followed. EPA believes this approach will improve public safety overall by preventing future accidents at the source.

Overlap between incident investigations and third-party audits. Many commenters recommended that EPA focus on incident investigations after accidental releases rather than third-party audits. Some commenters reasoned that incident investigations are

[36] EPA. May 24, 1996. Risk Management Plan Rule, Summary and Response to Comments. Volume 1, p. 15–2. Docket No. A–91–73, Document No. IX–C–1.

the activities that are most likely to mitigate both the severity of future incidents and the potential for recurrence. Some commenters stated that third-party audits should not be required when an incident investigation is also required because both of these activities require substantial internal resources and the incident investigation is more responsive to health and safety concerns. Some commenters also stated that requiring a facility to conduct the third-party audit after an accidental release has the potential to dilute resources from the facility's efforts to complete a comprehensive incident investigation and implement associated improvements. One commenter suggested that an incident investigation be required immediately after a catastrophic release but not a third-party audit, and that EPA could then require the stationary source's next three-year compliance audit (after the completion of the incident investigation) to have some degree of independence to assess the effectiveness of the changes made in response to the incident investigation.

EPA disagrees with commenters. Following an accident, incident investigations often reveal that facilities have deficiencies in some prevention program requirements related to that process. Incident investigations generally only evaluate the affected process, and do not necessarily address all covered processes at a facility, or even all prevention program elements for the affected process. However, compliance audits entail a systematic evaluation of the full prevention program for all covered processes, and EPA expects that third-party audits should identify deficiencies in any other covered processes at such facilities.

EPA believes that conducting the third-party compliance audits immediately after an accidental release is necessary to identify and correct existing noncompliance at prevention program facilities that could lead to future releases. EPA acknowledges that conducting third-party audits at the same time as incident investigations may impact the availability of facility resources for these activities. However, this is not a sufficient argument to delay the independent audit. Facilities may hire personnel from different firms to conduct the two activities or, for some facilities with knowledgeable internal staff to conduct investigations, they may only need to hire the third-party.

Although we agree with the commenter that suggested that compliance audits assess the effectiveness of changes made in response to an incident investigation, we disagree that this assessment must be made by a third-party. The owner or operator will resume the three-year schedule to conduct self-compliance audits after the third-party audit and, at that time, the facility owner or operator may consider the findings of the incident investigation and the third-party compliance audit when assessing compliance with prevention program requirements.

Implementing agency criterion. Many commenters argued that the third-party audit trigger associated with implementing agency findings of noncompliance should either be eliminated or significantly revised. Commenters expressed concerns with allowing an implementing agency to require a third-party audit based on a noncompliance determination. Commenters were also concerned about the potential for inconsistent or arbitrary decisions by implementing agencies, and a few commenters were concerned about the potential for abuse of this mechanism by implementing agencies. One commenter expressed due process concerns related to the triggers for third-party compliance audits, stating that the proposed rulemaking fails to provide the regulated facility an opportunity to contest implementing agency allegations of noncompliance. Commenters also requested clarification on whether an implementing agency could require a third-party compliance audit following a site inspection by the implementing agency.

In response to comments, EPA has revised the third-party audit applicability criterion by requiring the implementing agency to base a determination on conditions at the stationary source that could lead to an accidental release of a regulated substance, rather than on noncompliance. An implementing agency may determine that a third-party audit is necessary following inspections, audits, or facility visits, if conditions are observed at the stationary source that could lead to an accidental release of a regulated substance. The implementing agency may choose to take other action following an inspection, as appropriate.

Conditions at a stationary source that could lead to an accidental release may include, but are not be limited to, significant deficiencies with process equipment containing regulated substances, such as unaddressed deterioration, rust, corrosion, inadequate support, and/or other lack of maintenance that could lead to an accidental release. The presence of small ''pinhole'' releases, that do not meet the criteria in § 68.42(a) for RMP-regulated accidental releases, could also constitute conditions that could lead to a larger accidental release of a regulated substance. The occurrence of several prior accidental releases that did not meet the reporting criteria in § 68.42(a) at or from a facility could also constitute conditions which could lead to potentially more severe accidental releases. These releases may be a potential indicator that an owner or operator is not complying with RMP prevention program requirements and would benefit from a third-party audit to prevent future accidental releases.

EPA believes that having the implementing agency evaluate whether conditions exist that could lead to an accidental release better addresses the types of situations where a third-party audit would be most effective and will minimize the potential for inconsistent or arbitrary decisions made by implementing agencies. EPA also believes that the revised criterion is responsive to commenters' requests to narrow the applicability of these requirements. The criterion focuses on conditions with the potential to lead to accidental releases, rather than authorizing implementing agencies to require third-party audits under a potentially wide range of circumstances, including minor noncompliance.

In the final rule, a facility owner or operator has an opportunity to challenge the underlying findings when an implementing agency requires a third-party audit. Sections 68.58(g) and 68.79(g) describe the notification and appeals process. The implementing agency must provide written notice to the facility owner or operator that describes the basis for the implementing agency's determination. Within 30 days, the owner or operator may consult with, and provide information and data to the implementing agency on the preliminary determination. The implementing agency will then consider this information and provide a final determination to the owner or operator. EPA believes this appeal process provides due process to the owner or operator and is sufficient to eliminate any potential inconsistent use or abuse of authority.

Previous third-party audit criterion. A few commenters suggested deleting the failure of a previous third-party audit to meet the competency, independence, or impartiality criteria as a criterion for potentially requiring a subsequent third-party audit. These commenters reasoned that EPA has not shown that the auditor criteria will necessarily lead to better outcomes. A commenter questioned whether it was reasonable for EPA to declare a previous audit that was otherwise conducted in good faith, to be null and void, arguing that stationary

sources could find it burdensome and difficult to track auditor qualification criteria.

EPA disagrees with commenters' assertions that stationary sources will find it burdensome or difficult to apply the third-party auditor competency and independence criteria in this rule to identify qualified third-party auditors. See sections IV.B.3.i and IV.B.3.j of this preamble for a discussion of auditor qualifications in the final rule as well as an explanation for why EPA believes that independent auditors can provide a fresh perspective on compliance audits that will enable an owner or operator to improve the source's risk management program.

If the implementing agency has concerns about a previous third-party audit, which involved an auditor that failed to meet the qualification criteria for competency and independence, and the agency is concerned about the quality and/or adequacy of the audit and/or its findings, then the implementing agency may choose to require that another third-party audit be conducted. The final rule establishes a procedure for owners or operators to challenge the regulators' determinations.

Regarding the comment concerning auditor criteria leading to better outcomes, this issue was addressed in the preamble to the proposed rulemaking, and is also discussed extensively in section IV.B.3.h of this preamble.

Alternative criteria suggestions. EPA received a comment recommending that EPA require third-party compliance audits for all Program 2 and Program 3 facilities every three years, reasoning that this alternative option is a more preventative measure than the proposed applicability.

A few commenters, including a state government agency, suggested that EPA consider limiting the requirement to perform third-party audits to specific NAICs codes. Some of these commenters further recommended that certain types of facilities be excluded from the requirement, including water and wastewater treatment facilities and retail anhydrous ammonia facilities. A local government agency commented that EPA should consider limiting the requirement to perform third-party audits to the petroleum manufacturing, chemical manufacturing, and paper manufacturing industries only.

As part of the SBAR panel process for the proposed rulemaking, SERs suggested that EPA consider excluding or exempting small businesses from the rule's third-party auditing requirements or providing small businesses with special flexibility to use less-than-fully-independent third-party auditors such as retired facility employees not otherwise meeting all of the proposed rulemaking's independence criteria. The SERs noted that the requirements in the proposed rulemaking for every member of the third-party auditing team to individually meet all of the proposed rulemaking's competency and independence criteria would be especially costly and burdensome to small businesses.

EPA disagrees with the suggestion to require all facilities with Program 2 and/or Program 3 processes conduct third-party compliance audits every three years, because the Agency believes that this would impose a very large economic burden on the regulated industry. EPA is also concerned that there may not be a sufficient number of independent auditors available to perform third-party audits at the frequency that this approach would demand.

Upon review of these comments in the context of EPA's overall approach to this rule, EPA has determined that it is unnecessary to add an exceptions or exemptions process for third-party auditor competency and independence to the final RMP rule, or to exempt small facilities or facilities within select industry sectors from the third-party auditing requirements. First, EPA expects that the current approach to require third-party audits following an RMP reportable accident, or based upon an implementing agency's determination, will impact approximately 150 facilities per year. In the Initial Regulatory Flexibility Assessment (IRFA) [37] for the proposed rulemaking, EPA determined that relatively few small businesses have reportable accidents and therefore this provision will typically not apply to small facilities. Therefore, it is unnecessary to exempt small facilities or revise the auditor qualifications for small facilities.

Additionally, EPA believes that the revised third-party auditor qualifications in this final rule will make it easier for owners and operators to find suitable third-party auditors and third-party audit team leaders to comply with the third-party audit provisions, making it unnecessary to add additional exceptions or an exception process to the final rule. EPA agrees with commenters' requests to provide additional flexibility to allow retired facility employees to conduct a third-party audit and has revised the auditor qualification criteria to address this request (see section IV.B.3.j of this preamble for more information).

Finally, EPA disagrees with commenters that request EPA exclude facilities within specific sectors from third-party applicability. EPA based applicability of third-party audits on whether a source had an RMP reportable accident or whether conditions exist that could lead to an accidental release. EPA believes that these criteria are potential indicators for noncompliance with prevention program requirements and therefore warrant an evaluation by a third-party. If a specific industry sector does not typically have accidental releases, then this provision will not likely apply. Furthermore, EPA modified the third-party auditor qualification criteria to make it simpler for all businesses, small, medium, and large and in all sectors, to find qualified third-party auditors. Therefore, it is unnecessary to exclude or limit third-party audit applicability to specific industry sectors.

d. Implementing Agency Notification and Appeals

A few commenters asserted that the appeals process associated with third-party compliance audits is insufficient. One commenter stated that the proposed appeals process does not preclude the excessive or baseless use of the claim by agency staff nor detail the quality or quantity of information that a facility could present to overcome an agency's determination and the requirement to perform a third-party audit. Commenters also recommended adding an additional independent party to the appeals process. One commenter stated that EPA should clearly provide for judicial review of decisions on appeals by including regulatory language specifying that EPA's decision ''constitutes final agency action for purposes of judicial review.'' Another commenter stated that EPA should make the deadline for appeals at least 60 days and should expressly provide for extensions.

EPA disagrees with the comments requesting an independent party be added to the appeals process. This approach would create unacceptable delays while the implementing agency and the facility identifies an appropriate third-party. EPA believes the appeals process set out in the final rule provides sufficient opportunities for the owner or operator to challenge an implementing agency's determination.

[37] The IRFA can be found in Chapter 7 of the *Regulatory Impact Analysis for Proposed Revisions to the Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7).* This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

Sections 68.58(g) and 68.79(g) describe the notification and appeals process for when an implementing agency requires a third-party audit. The implementing agency must provide written notice to the facility owner or operator that describes the basis for the implementing agency's determination. Within 30 days, the owner or operator may consult with, and provide information and data to, the implementing agency on the preliminary determination. The implementing agency will then consider this information and provide a final determination to the owner or operator. Then there is an appeals process, in which the owner or operator may appeal the final determination to the EPA Regional Administrator, or for determinations made by other implementing agencies, the administrator or director of such implementing agency.

It is important to note that the final determination regarding the applicability of these provisions is not an enforcement determination. It is a notification regarding the applicability of an existing regulatory requirement, a requirement that does not apply to all stationary sources, all the time, but when an agency determines that it would apply, the owner or operator is notified, given an opportunity to consult, and appeal further within the agency. Part 68 already includes final agency determinations regarding regulatory requirements in Section 68.220, and the process set out in this final rule for appeals of third-party audit determinations is similar.

In response to comments about the short time frames, EPA has determined that the 30-day timeframe to submit an appeal, which follows an initial 30-day time period for the owner or operator to provide information and data to, and consult with, the implementing agency, is adequate and will ensure timely consideration of the information presented. EPA believes there is sufficient time built into the initial notification and consultation process, and the subsequent appeals process, particularly considering that the provisions apply to third-party audits required due to accidents or conditions at the facility that could lead to an accidental release of a regulated substance, and taking into account the need, in these circumstances, to take prompt action to identify and correct deficiencies.

e. Schedule for Conducting a Third-Party Audit

One commenter supported the proposed 12-month timeframe to complete a third-party audit. However, a few commenters opposed the proposed schedule. One commenter said that it would not be reasonable or appropriate to require completion of an audit report within twelve months by default. Some comments suggested modifying the rule to allow extensions of time to conduct third-party audits. Some comments sought clarification concerning the timing of a third-party audit. One commenter stated that the proposal seems to include inconsistent requirements for the required timing of third-party audits. Another commenter stated that, although it seems that EPA intended to require the third-party audit to be completed within 12 months of a triggering event, the deadline would be even sooner if the next scheduled triennial compliance audit is fewer than 12 months away. A few commenters encouraged EPA to clarify that conducting a third-party audit would count as the scheduled compliance audit and reset the clock on the three-year compliance audit schedule.

In response to comments, EPA has revised the regulatory text to clarify that the schedule for conducting a third-party audit, unless a different timeframe is specified by the implementing agency, is within 12 months of an RMP reportable accident or within 12 months of the date of the implementing agency's final determination. If the final determination is appealed, the third-party audit is required within 12 months of the date of the final decision on the appeal. EPA believes that the 12-month timeframe in the final rule provides sufficient time for owners or operators to complete a third-party audit while avoiding unnecessary delays in identifying and addressing noncompliance. Additionally, the final rule allows the implementing agency to specify a different timeframe for conducting third-party audits. This allows flexibility for an implementing agency to grant an extension, or to specify a shorter timeframe, to complete the audit, as appropriate. For example, an implementing agency may grant an extension if a source can demonstrate that it has had difficulty finding a qualified third-party auditor to conduct or lead the audit team, or that the audit will require extra time due to the complexity or number of processes, due to extensive damage to the facility following an incident, or due to resource constraints. Alternatively, the implementing agency may specify a shorter timeframe to complete the audit after considering the severity of the release or determining that unsafe conditions exist at the source.

EPA acknowledges that in some cases, the default result of these timeframes may be that a gap of greater than three years may occur between completion of the previous compliance audit and a subsequent third-party audit (*e.g.,* if an accident triggering a third-party audit occurs shortly before the facility's next regular compliance audit is due). In these cases, the owner or operator will still have 12 months to complete the third-party audit unless a different timeframe is specified by the implementing agency. Finally, stationary sources are required to audit compliance at least every three years, and a third-party compliance audit counts toward meeting this recurring requirement for purposes of determining the timing of the stationary source's next compliance audit.

f. Process by Which Owners or Operators Select Third-Party Auditors

In the preamble to the proposed rulemaking, EPA sought comment on potential alternative approaches to determining auditor competency and independence, such as requiring third-party auditors to be accredited by EPA or an independent auditing or accreditation body or board. EPA received a range of public comments on this issue. Commenters disagreed about whether facility owners and operators should be responsible for determining and documenting third-party auditor qualifications for competence and independence. A few commenters, including local agencies and industry trade associations, supported having the facility, rather than a regulatory agency, determine their third-party auditors' qualifications. Another industry trade association agreed that auditor competency should be determined and documented by individual owners and operators but asserted that it should be the auditors' responsibility to determine whether they qualify as independent. Other commenters, however, including a state agency, facilities, and industry trade associations, asserted that it is burdensome to the owners and operators to require them to self-select qualified auditors that they determined to be competent and independent. One commenter stated that a facility cannot easily obtain and review a third-party auditing firm's internal policies and procedures each time it engages a third-party auditor. Two commenters further questioned whether facility owners and operators would be sufficiently able to assess a third-party's qualifications to perform the required audits.

A few commenters expressed support for establishing an accreditation program for auditing firms while others

stated that determinations of third-party auditor competency and independence are more properly performed by regulatory agencies. A state agency suggested, as an alternative, establishing an auditor oversight committee to include representatives from the facility, local agencies, and the community. Another state agency commented that an oversight committee would be needed to ensure that the process is truly independent if the auditor is hired by the owner or operator and not by the implementing agency. One commenter suggested that EPA approve third-party auditors based on technical and other qualifications and provide a list of those determined to be acceptable to industry. Some local agencies suggested that the implementing agency should approve or assist the facility in selecting a third-party auditor. One local agency stated that existing accreditation from a recognized auditing body should be allowed but not be the only prerequisite for being qualified to conduct a third-party audit. An advocacy group suggested that if an auditor failed to identify a crucial hazard that could have prevented a catastrophic event, the auditor should lose its accreditation until it corrects the problems that led to the failure.

EPA has considered these comments and believes that establishing an accreditation program for third-party auditors would add time and costs to the process of third-party auditor selection and engagement. Therefore, in this final rule EPA has elected, instead, to focus on streamlining the auditor competency and independence criteria. Owners and operators are responsible for determining and documenting that the third-party auditors are qualified pursuant to the rule's competency and independence criteria. EPA believes this approach is consistent with commenters' requests that the process for engaging the auditors should be straightforward and allow for reasonable judgement of the owner or operator in selecting third-party auditors. Owners and operators routinely obtain and review the internal policies, procedures, and qualifications of a wide range of consultants and contractors before engaging them in order to assess their qualifications to perform consulting or contractual services. EPA is confident that owners and operators will be able to assess third-party auditor qualifications in a similar manner.

g. Auditors and Audit Team Structure

In the preamble to the proposed rulemaking, EPA invited comment on how to determine the roles and responsibilities for third-party auditors and how to structure third-party audit teams. Many commenters, including a Federal government agency, a state government agency, facilities, and industry associations, stated that facilities should have the flexibility to utilize internal staff who are much more familiar with the facility and covered processes than outside consultants. A facility commented that in the past it has used third-party auditors and determined that the facility's existing internal audit process provided an audit of equal or greater value than that of the third-party. Industry trade associations also asserted that the use of facility staff was more effective than third-party auditors because crucial time is not lost in learning about the facility. Another industry trade association stated that, in addition to identifying deficiencies, the most effective audits identify opportunities for improvement, which the commenter asserted is why audits that are conducted by or overseen by corporate staff or staff from other facilities within a company with similar processes can be more effective than strictly third-party audits. A professional association stated that companies must determine their own policies, procedures, and programs for performing audits. Similarly, an industry trade association stated that owners and operators should be allowed to choose whether in-house personnel or a third-party auditor conduct the compliance audit, as long as the organization can demonstrate that the auditor is qualified.

Industry trade associations commented that EPA's proposed approach may have unintended consequences on the effectiveness of audits by setting up an adversarial relationship between the regulated facility and the third-party auditor and creating a scenario that discourages the free flow of information between the facility and the auditor. Furthermore, an industry trade association commented that this fundamental change to the RMP audit program will likely cause companies to separate RMP and PSM audits. The commenter argued that such a change would demonstrate that EPA had failed in this rulemaking to satisfy its statutory obligation to develop a coordinated approach with OSHA. An individual commenter recommended the Institute of Nuclear Power Operations evaluation team model, which is a hybrid of a self-audit and a third-party audit by well qualified individuals. An industry trade association suggested setting up an industry sharing option (similar to the Occupational Safety and Health Administration's Voluntary Protection Program, which uses qualified personnel from other regulated facilities or company employees from a different plant to perform audits at facilities being evaluated under the program) in lieu of third-party auditing firms.

A Federal government agency recommended that third-party auditors be required to consult with facility employees and their representatives when conducting audits, reasoning that this requirement would be consistent with the language in the CAA at 29 U.S.C. 651 *et seq.* and EPA guidance on worker participation during EPA audits and inspections. And although opposed to the proposed requirement for third-party audits, an industry trade association asserted that there can be value in having/adding a third-party individual on or in coordination with a self-audit team, reasoning that the addition of the third-party auditor contributes to the development of the internal experts and expertise.

In response to commenters' suggestions to allow more flexibility on the composition of the audit team, EPA is finalizing an approach that allows owners or operators to meet their third-party auditing obligations either by:

- Engaging third-party auditors meeting all applicable competency and independence criteria, as originally proposed, or
- By assembling an auditing team which is led by a third-party auditor but may include other audit team members. The audit team may be comprised of:
  - A team leader—this must be an employee of the third-party auditor firm who meets all of the competency and independence criteria of the rule;
  - Other employees of the third-party auditor firm—these personnel must meet the independence criteria of the rule; and
  - Other personnel not employed by the third-party auditor firm (*e.g.* facility personnel or employees of another consulting firm with specialized expertise). These personnel are not required to meet the competency and/or independence criteria of the rule.

EPA agrees with commenters who suggest that allowing facility personnel and other knowledgeable but non-independent contractors and consultants to participate in the audit would improve the audit teams' performance and outcomes. This change addresses, among other things, the commenters' concerns that requiring the audit team and all of its individual members to meet the full independence criteria would exclude too many potential team members with critical sector or facility-specific experience.

This approach allows qualified personnel from other regulated facilities or company employees to participate in the audit and enables facility personnel to provide input during the compliance audit.

Although some commenters suggested that facility's existing internal audit process provided an audit of equal or greater value than that of a third-party, EPA believes that an independent, third-party perspective can provide insight on the facility's risk management program that may not otherwise be identified during an internal compliance audit. EPA further disagrees that this change to the RMP audit program will cause companies to separate RMP and PSM audits. EPA believes that the flexible approach for assembling a third-party audit that includes both independent and facility personnel will allow facilities to continue to conduct RMP and PSM audits simultaneously, as appropriate.

h. Auditor Qualifications and Responsibilities

General comments on qualification criteria. Many commenters stated that the requirements in the proposed rulemaking for every member of the third-party auditing team to individually meet all of the proposed rulemaking's competency and independence criteria will severely reduce the number of qualified auditors available and raise the costs of auditing for facilities. One facility argued that the auditor qualification requirements are arbitrary and should be withdrawn. Specifically, the commenter described the findings from the EPA-Wharton pilot study and concluded that this study undermines EPA's assertion in the proposal that rigid qualifications are necessary for a successful RMP third-party audit program. A professional association recommended that EPA require companies to develop, implement, and maintain effective policies, procedures, and programs for performing RMP audits. Such policies, procedures, and programs could themselves establish basic third-party auditor competency and independence criteria.

EPA agrees with commenters that the proposed qualification criteria could limit availability of qualified auditors and raise costs of audits. Therefore, EPA is finalizing an approach that allows owners or operators to comply with third-party auditing requirements either by engaging third-party auditors that meet all applicable competency and independence criteria, as originally proposed; or by assembling an auditing team, led by a third-party auditor, that includes other personnel (*e.g.,* consultants or facility employees).

EPA disagrees with commenters who argue that auditor qualifications are unnecessary for a successful third-party audit program. EPA's goal, in proposing criteria for auditor qualifications, was to ensure clarity and objectivity as to the minimum expected standards third-party auditors must meet for competency and independence. Since EPA is not finalizing requirements for third-party auditors to be qualified or accredited by an outside independent accreditation board, nor to meet competency and independence criteria in external consensus standards or protocols, the final rule must necessarily specify third-party auditor competency and independence criteria. Such criteria are necessary to ensure that owners and operators are able to successfully identify and engage fully qualified, competent and independent third-party auditors.

Consensus standards. EPA did not propose that consensus standards apply to third-party audits or auditors. However, in the preamble to the proposed rulemaking, EPA sought comment regarding potentially relevant and applicable consensus standards and protocols that might apply to the third-party auditors or audits that could be incorporated into the rule. Some commenters recommended that EPA use existing guidelines and standards including the CCPS ''Guidelines for Auditing Process Safety Management Systems'' and National Fire Protection Association codes and standards. One commenter stated that establishing protocols for auditing would assist in ensuring that a third-party audit is being performed to some type of recognized standard. However, the commenter stated that it is not aware of the establishment of such a standard at this time and noted that EPA might be required to work with a standard setting organization to develop the standard, if such a standard was to be provided to facilities and auditors. One commenter stated that the International Code Council (ICC) administers exams for building, fire, plumbing, and many other trade inspectors. An industry trade association commented that it opposed a requirement that consensus standards and protocols be incorporated into compliance audits and asserted that such a requirement was not within the scope of Executive Order 13650.

A few commenters, including a local government agency, noted that consensus standards may result in the bar for acceptable procedures being set low. Although noting that consensus standards could offer some minimum criteria to follow, a commenter stated that applying consensus standards to third-party compliance audits could be problematic because they are the lowest high-bar industry has agreed to, which runs the risk of lowering the bar for select companies or the consultants hired to perform the audit.

EPA acknowledges that consensus standards and protocols are referenced in a range of Federal and state regulations and can play useful roles in third-party verification programs. California's Underground Storage Tank program is an example of a program that relies on consensus standards in which designated operators are required to pass an exam administered by the ICC in order to be certified to conduct audits.[38] However, EPA has determined that reference to such standards and protocols is unnecessary for third-party compliance audits conducted under this rule because the final rule identifies qualification criteria for competency and independence for third-party auditors and third-party auditor team leaders.

EPA is also finalizing third-party auditor responsibilities in §§ 68.59(d) and 68.80(d). This provides the third-party auditor with minimum expectations for conducting the compliance audit. The owner or operator shall ensure that the third-party auditor:

- Manages the audit and participates in audit activities including: Initiation, design, implementation, and reporting;
- Determines appropriate roles and responsibilities for the audit team members;
- Prepares the audit report and ensures all audit team members' views are reflected in the final audit report;
- Certifies the final audit report and its contents as meeting the requirements of the rule and
- Provides a copy of the audit report to the facility owner or operator.

Third-party auditors must evaluate the audit team members' qualifications to determine appropriate audit roles and responsibilities in order to produce audit outcomes and final audit reports meeting the applicable rule requirements. This approach recognizes that audit team members may have varying levels of knowledge and experience with the RMP rule requirements, the stationary source being audited, the applicable or relevant

[38] *See, e.g.,* CA UST Regulations (CCR, Title 23, Division 3, Chapter 16), Amended and Effective July 1, 2012) at § 2715 (Certification, Licensing, and Training Requirements for Underground Storage Tank Owners, Operators, Installers, Service Technicians, and Inspectors). *http://www.swrcb.ca.gov/ust/regulatory/docs/title23_d3_c16.pdf*

engineering practices, and proper auditing techniques. EPA believes it is appropriate for the third-party auditor to be responsible for these determinations and that this approach allows the owners or operators and the third-party audit team leader to successfully collaborate to assemble an effective auditing team.

i. Third-Party Auditor Competency Criteria

Almost all of the public comments on the proposed third-party auditor competency criteria focused on the requirement for the auditor to be a licensed Professional Engineer (PE) or include a licensed PE on the audit team. PE organizations supported the proposed requirement arguing that many facilities that would require third-party audits are designed, constructed, and maintained by PEs, who are subject to professional ethical standards that require objectivity. Some of these commenters described the supply of PEs as being sufficient to meet the demand for the third-party auditors under the approach in the proposed RMP rule.

However, a large number of commenters opposed the proposed PE competency criterion. Many commenters stated that they saw no value in requiring a PE because PEs do not specifically have process safety or auditing skills. Several commenters questioned whether there are a sufficient number of PEs with appropriate experience to meet the need for RMP audits. As an industry trade association observed, even though the number of PEs may be large, there may be an insufficient number of PEs that have third-party audits as an area of expertise. A facility asserted that every PE cannot practice in every state, and if a PE is part of the audit team, he or she must be licensed in the state affected by the RMP incident.

As part of the feedback for the SBAR Panel for the proposed rulemaking, SERs suggested that EPA consider allowing other qualified, credentialed personnel besides PEs to qualify as third-party auditors. Such other personnel could, SERs suggested, be degreed chemists, degreed chemical engineers, Certified Safety Professionals (CSP), Certified Industrial Hygienists (CIH), Certified Fire Protection Specialists (CFPS), Certified Hazardous Materials Managers (CHMM), Certified Professional Environmental Auditors (CPEA) or Certified Process Safety Auditors (CPSA). SERs indicated that these credentials also include ethical obligations to provide sound independent advice. Many other commenters also suggested that professionals with process safety management experience who have other credentials subject to ethical standards should also be allowed to give facilities a larger choice for their third-party auditors. Another facility and an industry trade association commented argued that the owner or operator is in the best position to assess who is qualified to perform the audit. Two commenters characterized the EPA-Wharton Pilot Study on Third-Party Audits [39] as suggesting that relevant industry and process specific experience, training, and regulatory knowledge are the essential qualifications of RMP auditors and that the PE requirement should be withdrawn.

EPA agrees with commenters that stated it is unnecessary for third-party auditors to be PEs and that a variety of qualified personnel can potentially be effective third-party auditors or third-party audit team leaders. Consequently, EPA deleted the PE requirement from the final rule. EPA believes it is sufficient for the third-party auditor or third-party audit team leader to be:

- Knowledgeable with the requirements of the RMP rule;
- Experienced with the stationary source type and processes being audited and applicable recognized and generally accepted good engineering practices; and
- Trained or certified in proper auditing techniques.

Third-party auditors can meet the requirement to be knowledgeable with the RMP rule requirements, and the requirement to be experienced with the stationary source type and processes being audited and applicable recognized and generally accepted good engineering practices through a variety of ways, including prior experience and training. Third-party auditors can meet the requirement to be trained or certified in proper auditing techniques by completing courses in environmental or safety auditing, obtaining certifications from recognized professional bodies, or having prior process safety auditing experience.

EPA has also established third-party auditor responsibilities in §§ 68.59(d) and 68.80(d). If the third-party auditor believes that a necessary skill or expertise is lacking in the auditing team, the owner or operator and third-party auditor are responsible for augmenting the audit team with the additional team members needed to supply the missing skill or expertise. For example, an owner or operator may choose to designate an employee competent in using an infrared camera to participate on a third-party auditing team. Such an audit team member would be acceptable, even though the individual does not meet the independence criteria and lacks specific knowledge of the stationary source type and processes being audited, as long as the third-party audit team leader evaluates the employee's qualifications to perform the specific role the employee will perform in the audit. The same standard would also apply to the participation of any other personnel the owner or operator might choose to include when assembling the third-party audit team.

j. Third-Party Auditor Independence Criteria

A few commenters, including a Federal and two local government agencies, supported the proposed provisions for ensuring auditor independence. Some local government agencies agreed that the proposed requirement for auditors to have written policies and procedures to ensure that personnel comply with the proposed competency, independence, and impartiality requirements is appropriate. Several commenters, however, warned that the independence criteria would be difficult to monitor and enforce. Conversely, many commenters opposed the third-party auditor independence criteria, arguing that the criteria are too restricted and will limit the availability of third-party auditors and the quality of the audits.

Availability of third-party auditors. Some commenters warned that the proposed auditor independence criteria would have the unintended consequence of reducing the quality of the audits and/or the availability of sufficiently qualified auditors. A few commenters suggested that the lack of ability for employees to participate on the audit team could lead to an adversarial relationship, inhibiting the impartial fact-finding an audit is supposed to facilitate. Some commenters stated that the independence criteria would, in practice, discourage open and productive auditor-source dialog, that auditor unfamiliarity with the audited facilities could turn the audits into ''check-the-box'' exercises, and that new and unfamiliar auditors will feel

[39] EPA conducted a pilot study with the Wharton School of the University of Pennsylvania on the efficacy of voluntary third-party RMP audits. For relevant reports from this pilot, see R. Barrish, R. Antoff, & J. Brabson, Dep't of Natural Resources & Env. Control, Third Party Audit Pilot Project in the State of Delaware, Final Report (June 6, 2000) *http://opim.wharton.upenn.edu/risk/library/2000_RAB,RA,JB_3rdPartyAudit_Delaware.pdf* and EPA Region 3, Third-Party Pilot Project in the Commonwealth of Pennsylvania, Final Report (February 2001).

pressure to be ''trigger happy'' on finding deficiencies. An industry trade association suggested that facilities should be allowed to petition for a relaxation of these requirements if auditors cannot be identified.

As part of the SBAR Panel process, some SERs raised concerns about the extent of the independence criteria and suggested this would limit the availability of qualified auditors. Specifically, these SERs were concerned that the independence criteria would rule out, as third-party auditors, all of the members of any auditing firm employing any personnel who previously worked for or otherwise engaged in consulting services with the owner or operator. This was deemed problematic because, in the SERs' experience, many, if not most, otherwise qualifying audit firms hire retired personnel specifically because the personnel have sector, company, and/or facility-specific experience with firms subject to the RMP rule. Numerous other commenters observed that consulting firms perform a wide variety of work for RMP facilities of which only a fraction is auditing but the new restrictions could cause those firms to exit the auditing market rather than risk losing their other business lines.

In order to address concerns about the availability of auditors, EPA modified the third-party auditor independence criteria in the final rule to enable more firms and individuals to qualify as third-party auditors or third-party audit team leaders. The final rule modifications provide additional flexibility while still ensuring that audit teams are managed and operated independently to produce the types of enhanced audit outcomes commonly associated with independent auditors per the literature and evidence described in the preamble to the proposed rulemaking and in this document.

EPA made many significant changes to the third-party independence criteria. The most significant modification to the third-party audit requirements is that only employees of the independent third-party audit firm must meet the independence criteria of § 68.59(c)(2) and/or § 68.80(c)(2). For third-party audit teams, the team leader must meet both the competency and independence criteria of § 68.59(c) and/or § 68.80(c) and all other employees of the third-party auditor firm that participate on the team need only meet the independence criteria. Third-party audit teams may also include other personnel, such as consultants or facility employees and these personnel are not subject to the third-party qualification criteria of the final rule.

EPA also revised the timeframe within which third-party auditors cannot provide business or consulting services to two years. EPA also added language indicating that if a third-party-firm employs personnel who have provided business or consulting services to the facility within the prescribed timeframe (*i.e.* within two years of the audit) then the third-party audit firm must ensure that these personnel do not participate on the audit team. Additionally, EPA clarified in regulatory language the circumstances in which a retired employee may participate in a third-party audit. Viewed as a whole, these changes serve to increase the types of personnel who may potentially serve as independent third-party auditors. Therefore, EPA believes it will be unnecessary for facility owners or operators to petition for a relaxation of auditor qualifications.

Criteria limiting past and future business or consulting services and future employment. A large number of commenters specifically opposed the proposed independence provisions, particularly the requirement that an auditor cannot have provided other consulting services to the owner or operator in the prior three years and cannot accept future employment for three years following submission of the final audit report. Some commenters stated that third-party auditing is entirely unnecessary for RMP facilities because there is no evidence to believe that internal auditors working for, or employed by, facility owners or operators would deliberately fail to conduct honest and complete audits because of their prior, current, or future financial or employment ties to the owners or operators. Many commenters stated that to disqualify auditors who have performed certain services for the owner or operator of a facility within the past three years would disqualify those auditors who are most familiar with a source's operations, and facilities would be forced to select auditors who are unfamiliar with the facility and its processes. Many commenters emphasized that audit teams should include personnel with direct, personal familiarity with the facility (including facility employees) to ensure effective RMP compliance audits. Commenters stated that this could be of concern particularly for plants with complex engineered processes requiring site-specific expertise.

In response to these comments, in the final rule EPA has modified the three-year prohibition on auditors providing prior consulting services to (other than auditing services) or subsequently being employed by the owner or operator to a two-year prohibition. This prohibition applies only to employees of the third-party auditor firm. Owners or operators can assemble a third-party audit team led by a third-party auditor that meets both the competency and independence criteria of the final rule. The third-party audit team can also include other non-independent personnel such as current or former employees of the facility or other persons with prior site-specific experience. This revision, itself, will enable a much broader and more diverse set of auditors to serve on the audit teams, including knowledgeable facility personnel, other personnel employed at different facilities owned by the regulated company, and a variety of second or third-party personnel such as consultants and contractors. Only employees of the third-party auditor firm leading the audit team are subject to the independence criteria of the final rule and only the individual leading the third-party audit team is subject to both the competency and independence criteria of the final rule.

Retired employees. Commenters and SERs supported allowing company retirees to participate on audit teams.

EPA agrees with commenters. EPA modified the final rule to clearly identify that retired employees who otherwise satisfy the third-party auditor independence criteria may still qualify as independent if their sole continuing financial attachments to the owner or operator are employer-financed or managed retirement and/or health plans. This revision clarifies that owners or operators can hire retired employees with specialized knowledge or experience with the source type or facility to participate in third-party audits.

Effectiveness of self-audits. Three trade associations stated that EPA failed to adequately demonstrate through statistical or other analyses that the RMP rule's self-auditing requirement was deficient or that independent auditor certification is necessary. Some commenters stated that the proposed third-party auditing requirements and criteria are unnecessary because the record does not demonstrate widespread RMP self-auditing-related fraud. One association referenced the CSB's report on the Texas City refinery accident as suggesting that management's failure to implement prior self-audit recommendations is of greater concern than self-audit inadequacy, per se.

While third-party auditing is useful for minimizing the potential for fraudulent behavior or reporting, EPA believes that helping to prevent or

minimize fraud is but one positive independent third-party auditing outcome. In fact, the third-party auditing requirements are intended to improve auditing practices and outcomes by also correcting biases shown by the literature to be associated with self-auditing. These biases are compelling precisely because they are not the hallmark solely of fraudulent firms but are exhibited commonly by entities with no overt or covert malicious intent to be inaccurate or unfair in their auditing or reporting.[40]

EPA's recent experience demonstrates that in some cases self-auditing is deficient. In the preamble to the proposed rulemaking, EPA referenced enforcement settlements requiring third-party auditing of settlement agreement implementation and compliance at facilities handling CAA section 112(r) chemicals. One such settlement is the administrative order on consent issued by Region 1, in 2015, to Mann Distribution LLC and 3134 Post Road LLC (Respondents) to address Resource Conservation and Recovery Act (RCRA) and CAA section 112(r)(1) (the ''general duty clause'') violations found during an April 4, 2013 inspection at a chemical distribution facility in Warwick, Rhode Island. Like the Risk Management Program requirements, section 112(r)(1) of the CAA addresses safe operation and prevention of accidental releases. Unsafe conditions found during the inspection included, among other things, failure to have a fire suppression system, failure to inspect a fire alarm, co-location of incompatible chemicals, and many RCRA generator violations. The facility also had a prior history of noncompliance. The order required Respondents to, among other things, implement an independent third-party inspection program. The Respondents agreed to the program because they wanted to maximize the benefits of implementing the administrative order on consent by accelerating the improvement of the culture of compliance and safety at the facility.

Since the proposed rulemaking was published, EPA has received and reviewed the Mann independent third-party inspection team's audit reports. These reports state that the third-party team found several compliance and safety issues the facility owner and operator had not independently found or corrected. The suite of audits uncovered and tracked the correction of these deficiencies. EPA has also received feedback from a facility representative and its third-party auditor about the program. All of the involved parties—EPA, facility representative, and the third-party auditor—agreed that the new and independent third-party auditing required pursuant to the enforcement order was beneficial for both correcting specific deficiencies and improving a culture of compliance. The suite of four third-party inspections improved the company's hazardous materials management plan, plan implementation, and emergency response program. As of March 2016, corrections to issues identified by the third-party auditors produced results including safer storage of chemicals that are oxidizers, improved integrity testing and maintenance of chemical storage tanks; better emergency egress, training, and coordination with the fire department; and improvements in container storage (such as better labeling and more aisle space). After a year of audits, the audit team leader provided some constructive suggestions about how EPA could modify third-party audit requirements in the future. For example, she felt that one of the order's auditor independence criterion (a five-year ban on future work with the company) was excessive as such a requirement, in light of New England's contracting manufacturing/industrial market, might serve as a disincentive to the participation as third-party auditors by highly qualified professionals and firms. Also, although this order did not require that the audit team include a PE, the auditor said she was aware that EPA was considering requiring PEs for future audits and believed that such a requirement would be unnecessary because good practice suggests that team make-up and qualifications should be determined on a case-by-case basis.

EPA agrees with the commenters stating that auditors with facility-specific experience can contribute insights that independent auditors lacking such experience would be unlikely to contribute. EPA addressed this comment in the final rule by, among other things, modifying the final rule to allow owners or operators to include non-independent employees, contractors, or consultants with facility-specific experience on the third-party auditing teams.

EPA continues, however, to believe that the ''fresh eyes'' and perspectives that third-parties contribute to audit teams support the approach in this rule to third-party auditing for the small subset of RMP facilities that have RMP reportable accidents or conditions at their stationary sources that could lead to an accidental release of a regulated substance. In this context, EPA has assessed available empirical research suggesting why independent auditors lacking prior facility-specific experience can actually produce better audit outcomes than personnel with prior site-specific experience. This research suggests independent personnel can audit the facilities they monitor with ''fresh eyes'' and thus be more likely to identify issues of concern. While the research that follows primarily involves government inspectors, EPA believes that the findings correlate to designing effective third-party auditing programs.

One such study concerns the relationship of inspector experience and product recalls in the medical device industry.[41] The study's authors explain:

> Plant inspections enable supply chain partners to manage quality risk in global supply chains. However, surprisingly little research examines the behavioral aspects of inspectors' work. Drawing on insights from the experience, learning, and complacency literatures, we examine the how well plant inspection outcomes predict future recalls and analyze the effect of inspector experience on both the information content of plant inspections as well as the prevalence of product recalls. Using secondary data spanning a 7-year period in the medical device industry and a recurrent event Cox Proportional Hazard model, our results show that inspection outcomes contain information and hence predict future product recalls, and that this relationship is moderated by inspector experience. . . . [T]he hazard of recalls at a plant increases if the same inspector continues to inspect the plant, independent of the inspection outcome. Recall hazard increases by 48% the second time an inspector visits a plant, and 63% by the third visit. These results indicate the need to rotate inspectors among plants and have important implications for managers, regulatory agencies, and theory.

The authors' views on the drivers for these outcomes are informative. Although significant literature exists indicating that sending the same auditor or inspector to repeatedly inspect a facility can lead to familiarity, that

[40] *See, e.g.:* (1) Short, Jodi L., and Michael W. Toffel, *The Integrity of Private Third-party Compliance Monitoring,* Harvard Kennedy School Regulatory Policy Program Working Paper, No. RPP–2015–20, November 2015. (Revised December 2015) *http://www.hbs.edu/faculty/Pages/item.aspx?num=50186*; (2) Lesley K. McAllister, *Regulation by Third-Party Verification,* 53 B.C. L. Rev. 1 (2012). *http://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=3182&context=bclr*; (3) Esther Duflo et al., Truth-Telling by Third-Party Auditors and the Response of Polluting Firms: Experimental Evidence From India, 128 Q.J. Econ. 1499, 1499 (2013) *http://qje.oxfordjournals.org/content/128/4/1499.abstract.*

[41] Ball, George and Siemsen, Enno and Shah, Rachna; *Inspector Experience and Product Recalls in the Medical Device Industry* (June 2, 2014). Available at *http://ssrn.com/abstract=2445022*, *http://dx.doi.org/10.2139/ssrn.2445022*, or *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2445022.*

weakens an auditor's independence and compromises audit outcomes,[42] these were not the above study's primary findings. Rather, the authors found that the worsening inspection outcomes over time were likely primarily due to inspector complacency. In the authors' words,

> The stale, routine nature of the job, and the familiarity which comes from repeat visits to a site, can lead to complacency and lower the information contained in an inspection, even when the investigator has no clear incentive to 'go easier' on an inspection site.

These complacency effects ''may outweigh the benefits [such repeat visits have on inspector] learning.'' Another analysis of 426,831 unannounced inspections by state government inspectors from July 2003 through March 2010 found that new inspectors tend to have ''fresher eyes'' in their first visit to a restaurant, reporting 12.7–17.5% more violations than the second visit of a repeat inspector, and that this effect is more pronounced when the previous inspector had a longer relationship with the restaurant.[43]

Findings such as these, and the policy implications that flow from such studies, address human behavioral and psychological influences that appear to be common to inspection and auditing regimes. Thus, although not expressly required by this rule, EPA encourages owners or operators, when assembling both third-party audit teams and conducting self-audits under the RMP rule, to include on their teams a mix of personnel previously familiar, and unfamiliar, with the specific facilities they are tasked with auditing.

Finally, EPA agrees with commenters that it is critical that facility owners and operators implement corrective actions to address findings from compliance audits. Therefore, the final rule requires the owner or operator to certify in the findings response report that deficiencies are being corrected. As an additional measure to ensure accountability, EPA is also requiring a copy of the findings response report and schedule to implement deficiencies to be submitted to the auditing committee of the Board of Directors or other comparable committee or individual, if applicable.

Validity of examples of third-party audits. Commenters sought to criticize the many examples of third-party auditing provided by EPA in the preamble to the proposed rulemaking, including mandatory and voluntary programs by regulators and industry trade associations, on the grounds that these other regulations and programs operate in a different context from that of the RMP rule (*i.e.,* that the literature and empirical data on the effectiveness of third-party auditing cited by EPA do not specifically address regulatory compliance auditing at RMP facilities). These commenters stated that most or all of EPA's examples of other Federal, state, and voluntary or industry independent auditing do not relate to RMP rule compliance, and therefore limit the transferability of these programs' design features and outcomes to the RMP context. The associations further stated that there is no evidence showing:

- A systemic problem with RMP facilities' self-audits or that employees or contractors act unethically or are biased;
- A lack of auditor independence creates bias leading to accidents;
- Third-party audits would have successfully prevented past accidental releases; or
- The root causes of a significant number of past accidents at RMP facilities were deficient self-audits.

EPA disagrees with commenters. Because RMP facilities were not previously required to have third-party compliance audits, statistically valid outcome data specifically on RMP rule third-party auditing does not currently exist. As EPA has described, however, there is a considerable and growing body of literature and empirical data on the effectiveness of third-party auditing, generally. These literature and data occur in many contexts that involve a diverse set of statutes and voluntary standards. In fact, some of these contexts are similar to RMP auditing.

In the preamble to the proposed rulemaking, EPA presented many examples of Federal and state agencies and trade association third-party verification programs. Like the RMP rule, some of those programs are expressly described by their managers as designed to improve regulatory compliance, prevent or reduce risks, or improve safety at the same or similar facility types and operations as are regulated by the RMP rule. These programs reflect industry recognition that third-party auditing does, in fact, produce better outcomes relative to self-auditing in a variety of settings. Such programs include:[44]

- *Responsible Care.* This program is described by ACC as identifying, and acting to address potential hazards and risks associated with their products, processes, distribution and other operations.[45] Responsible Care's Guiding Principles include ''mak[ing] continual progress toward a goal of no accidents, injuries or harm to human health and the environment from products and operations and openly report health, safety, environmental and security performance.''[46] The Responsible Care management system process includes mandatory certification, by auditors described by ACC as accredited and independent, to ensure the program participants have a structure and system in place to measure, manage and verify performance.[47] The Responsible Care Web site provides, ''A key part of the Responsible Care Management System process is mandatory certification by an independent, accredited auditor.''[48]
- *The API Process Safety Site Assessment Program (PSSAP).* According to API, the PSSAP ''is focused on higher risk activities in petroleum refining and petrochemical facilities. This program primarily involves the assessment of a site's process safety systems by independent and credible third-party teams of industry-qualified process safety expert assessors.''[49] Using industry-developed protocols, API describes the process safety site assessments as evaluating the quality of written programs and effectiveness of field implementation for the following process safety areas that

[42] *See, e.g.,* Abigail Brown, *The Economics of Auditor Capture,* Edmond J. Safra Center for Ethics, Harvard University (Nov. 8, 2011) at *https://abigailbrown.files.wordpress.com/2009/08/auditor-capture-111108.pdf* (''[T]here does not need to be an explicit exchange of bribes to sustain a collusive equilibrium, suggesting that social norms and psychological biases reinforce rational action and allow profitable collusion to occur with little conscious intent.'' Id. at Abstract).

[43] Ginger Zhe Jin & Jungmin Lee, *A Tale of Repetition: Lessons from Florida Restaurant Inspections,* National Bureau of Eco. Research Working Paper No. 20596 (Oct. 2014). *http://www.nber.org/papers/w20596.*

[44] EPA has not formally evaluated these programs and standards or their outcomes. This discussion is not a formal Agency review or endorsement.

[45] ACC. 2012. Responsible Care Product Safety Code. *https://responsiblecare.americanchemistry.com/Product-Safety-Code/.*

[46] ACC Responsible Care Guiding Principles. *https://responsiblecare.americanchemistry.com/ResponsibleCare/Responsible-Care-Program-Elements/Guiding-Principles/.*

[47] Certification must be renewed every three years, and companies can choose one of two certification options. RCMS® certification is intended to verify that a company has implemented the Responsible Care Management System. RC14001® certification combines Responsible Care and ISO 14001 certification. See *http://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Management-System-and-Certification* and *http://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Process-Safety-Code/Responsible-Care-Process-Safety-Code-PDF.pdf.*

[48] ACC Responsible Care Management System. *https://responsiblecare.americanchemistry.com/Management-System-and-Certification/.*

[49] API. 2015. PSSAP. *http://www.api.org/~/media/Files/Certification/PSSAP/PSSAP-Brochure.pdf?la=en.*

will be evaluated: Process Safety Leadership; MOC; Mechanical Integrity (focused on fixed equipment); Safe Work Practices; Operating Practices; Facility Siting; Process Safety Hazards; and HF Alkylation/RP 751.[50]

• *Center for Offshore Safety (COS).* This strategy for promoting safety and protection of the environment includes third-party auditing and certification of the COS member company's SEMS and accreditation of the organizations (Audit Service Providers) providing the audit services. The Center serves the U.S. offshore oil and gas industry with the purpose of adopting standards of excellence to ensure continuous improvement in safety and offshore operational integrity. The third-party audits are intended to ensure that COS member companies are implementing and maintaining Safety and Environmental Management Systems (SEMS) throughout their deepwater operations.[51] COS states expressly that ''the highest level of safety for offshore drilling, completions, and operations [is promoted through] independent third-party auditing and certification.'' [52]

• *ChemStewards®.* ChemStewards is a SOCMA program intended to promote continuous performance improvement in batch chemical manufacturing. The program offers a three-tiered approach to participation. Each tier includes a third-party verified management system.[53] On its Web site, SOCMA describes the environmental benefits of the program as including improving environmental performance, decrease releases and waste disposal costs, and positioning members to meet current and future compliance requirements.[54] The associated training materials explain the on-site audit elements of the third-party verification program.[55]

Additionally, the supporting literature and data described by EPA in the proposed rulemaking preamble remain relevant to RMP compliance auditing, notwithstanding the varied contexts they describe, because such literature addresses cross-cutting human biases and behaviors, common to all auditor and audit types, that can be addressed or corrected through independent third-party auditing.[56] EPA thus finds that the state of the science, evidence, and data on the effectiveness of independent third-party auditing programs supports requiring independent third-party audits for RMP facilities with accidental releases or conditions that could lead to an accidental release of a regulated substance.

k. Third-Party Audit Report

Draft reports. EPA received numerous comments regarding the proposed third-party audit reporting requirements. While no commenters objected to the requirement to prepare an audit report, most commenters opposed the proposed requirements to submit draft and final reports to the implementing agency. Many commenters felt that a requirement to submit draft reports before they have been vetted by internal operations and management teams could have the unintended consequence of incomplete or inaccurate information being distributed. Some of the commenters added that the owner or operator should be able to ensure that the audit report does not contain confidential business information. Finally, some commenters stated that the proposed requirement to document all changes made by the owner or operator to audit report drafts would chill communications and information exchange during audits.

EPA agrees with commenters. The final rule requires the third-party auditor to prepare an audit report and provide it to the owner or operator, but does not require that the draft or final reports be submitted to the implementing agency. However, the third-party auditor must summarize in the audit report any significant revisions between draft and final versions of the report.

Submitting reports to the implementing agency. Many commenters, including industry trade associations and facilities, objected to the proposed requirement that third parties submit their reports to the implementing agency at the same time, or before, the reports are sent to the source. These commenters felt that this would prevent facilities from being allowed to correct factual errors or present evidence that the auditors either missed or were not aware of, which could markedly change the audit's recommendations. Some commenters who opposed distribution of audit reports to the implementing agency warned of the potential release of confidential business information.

EPA agrees with commenters and deleted provisions that require the third-party auditor to submit audit reports to the implementing agency.

Attorney-client communications. EPA received several comments regarding the proposed limitation on claiming the audit report and related records as attorney-client communications or attorney work products. One commenter agreed with EPA that the audit report should not be protected from disclosure under the attorney-client privilege. Many commenters opposed EPA's proposal to prohibit companies from asserting attorney-client privilege and attorney work product privilege over third-party audits and related documents. The commenters argued that EPA lacked authority to do this and that these privileges are essential for purposes of legal representation. One commenter stated that attorney-client privilege is a long-established common-law rule of evidence, and asserted that any attempt to abrogate it across the board is likely a violation of the Sixth Amendment. Similarly, another commenter stated that the proposed limitations on attorney-client privilege seem contrary to due process and legal rights that should be afforded the owner or operators of the facility.

It remains EPA's position, as stated in the preamble to the proposed rulemaking, that with respect to the attorney work product privilege, the audit report and related records are produced to document compliance. Audit reports and related records are similar to other documents prepared pursuant to RMP rule requirements (*e.g.,* process safety information, PHAs, operating procedures) and are not produced in anticipation of litigation. They are analogous to work or management practice records that show a regulated operation was performed. With respect to the attorney-client communication privilege, the third-party auditor is arms-length and independent of the stationary source being audited. The auditor lacks an attorney-client relationship with counsel for the audited entity. Therefore, in EPA's view, neither the audit report nor the records related to the audit report provided to the third-

[50] API. 2015. PSSAP. *http://www.api.org/certification-programs/process-safety-site-assessment-programs.*

[51] COS. 2013. *See http://www.centerforoffshoresafety.org/auditInfo.html.*

[52] COS. 2015. *See http://www.centerforoffshoresafety.org/About.*

[53] SOCMA. 2015. *See http://www.socma.com/ChemStewards/.*

[54] SOCMA, 2016. *See* Benefits of Implementing ChemStewards®. *http://www.socma.com/chemstewards/about/benefits.*

[55] SOCMA. *See http://www.socma.com/Portals/0/Files/ChemStewards/ChemStewards_101_Training.pdf.*

[56] *See, esp.:* (1) Short, Jodi L., and Michael W. Toffel, *The Integrity of Private Third-party Compliance Monitoring,* Harvard Kennedy School Regulatory Policy Program Working Paper, No. RPP–2015–20, November 2015. (Revised December 2015) *http://www.hbs.edu/faculty/Pages/item.aspx?num=50186*; (2) Lesley K. McAllister, *Regulation by Third-Party Verification,* 53 B.C. L. Rev. 1 (2012). *http://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=3182&context=bclr*; (3) Esther Duflo et al., Truth-Telling by Third-Party Auditors and the Response of Polluting Firms: Experimental Evidence From India, 128 Q.J. Econ. 1499, 1499 (2013) *http://qje.oxfordjournals.org/content/128/4/1499.abstract.*

party auditor, including documents originally prepared with assistance or under the direction of the audited source's attorney, should be considered attorney-client privileged. Nevertheless, EPA recognizes that the ultimate decision makers on questions of evidentiary privileges are the courts. Therefore, this rule does not contain a specific regulatory provision prohibiting assertion of these privileges.

l. Findings Response Report, Timeframe, and Response to Audit Findings

EPA received several comments relating to the proposed requirement for the owner or operator to develop a findings response report within 90 days of receiving the final audit report, and to provide the report to the implementing agency and the owner or operator's audit committee of the Board of Directors. EPA also received comments opposing various aspects of the proposed requirements for findings response reports.

Timeframe. Some commenters supported these proposed requirements. One commenter urged EPA to shorten the required reporting from 90 days to 30 days, arguing that deficiencies in compliance indicate a risk of a catastrophic release that could harm the facility, its employees, and the community. The commenter reasoned that 30 days is enough time to review the audit report and develop a schedule to address deficiencies.

Other commenters objected to the proposed timeframe for preparing and submitting the findings response report, stating that 90 days provides for an insufficient timeframe for preparing the report. A few commenters recommended a six-month timeframe. One commenter asserted that EPA has not demonstrated that a 90-day period to develop a findings response report is achievable. As an alternative to extending the timeframe for all facilities, a few commenters urged EPA to consider allowing facilities to obtain extensions as needed to adequately address the concerns raised by third-party auditors.

EPA is finalizing the requirement that the owner or operator prepare a findings response report as soon as possible, but no later than 90 days after receiving the final audit report as proposed. EPA believes this timeframe is appropriate for the owner or operator to consider the findings of the audit report and determine a response to each of the audit's findings. This approach allows the owner or operator an opportunity to establish a schedule to implement corrective actions that can extend beyond the 90-day period for developing the findings response report and balances the need to promptly respond to the audit findings. EPA notes that, in many instances, an owner or operator may receive prior information about the audit's findings before receiving a final audit report, particularly when the third-party audit team includes facility personnel. This will give the owner or operator additional time to consider its responses.

Submitting findings response report to implementing agency. Some commenters opposed the proposed requirement to submit a findings response report to the implementing agency. One such commenter stated that EPA has not demonstrated a need for universal submission of an action plan to respond to audit findings and schedule. Commenters also expressed legal concerns about the findings response report. These commenters raised concerns about not being able to dispute purported violations or deficiencies identified by third-party auditors. Some commenters asserted that refusing to afford companies the opportunity to dispute audit findings raises fundamental due process concerns.

EPA agrees with the commenters and has eliminated the requirement to submit findings response reports to the implementing agency in the final rule. The audit report, findings response report and related records must be retained at the stationary source in accordance with the recordkeeping requirements in §§ 68.59(g) and 68.80(g).

Eliminating the requirement to submit the findings response report to the implementing agency also responds to commenters legal concerns. The owner or operator can determine an appropriate response to each of the audit report findings. This is similar to existing self-compliance audit requirements for the owner or operator to promptly determine and document an appropriate response to each of the findings of the compliance audit.

In addition, there is no need for a process to dispute findings as the relevant requirement in the final rule for each of the findings in the audit report is to determine an appropriate response. In determining an appropriate response, owners or operators may follow EPA's existing guidance for addressing PHA team findings and recommendations, which is based on OSHA's *29 CFR 1910.119, Process Safety Management of Highly Hazardous Chemicals—Compliance Guidelines and Enforcement Procedures* for resolving such findings.[57] Under these guidelines, EPA considers an owner or operator to have resolved a finding or deficiency when the owner or operator either has adopted or implemented the associated recommendations or has justifiably declined to do so. An owner or operator can justifiably decline to adopt a recommendation where the owner or operator can document, in writing and based upon adequate evidence, that one or more of the following conditions is true:

- The analysis upon which the recommendation is based contains material factual errors;
- The recommendation is unnecessary to protect public health and safety or the health and safety of the owner or operator's employees, or the employees of contractors;
- An alternative measure would provide a sufficient level of protection; or
- The recommendation is infeasible.

Where a recommendation is rejected, the owner or operator must communicate this to the audit team and expeditiously resolve any subsequent recommendations of the team. Provided that the owner or operator addresses the audit report's findings by implementing the findings or by justifiably declining to do so, the owner or operator complies with the requirement. If an implementing agency concludes that a justification is inadequate and brings an enforcement action regarding this requirement, then the owner or operator may dispute the enforcement action through the normal adjudication process.

m. Owner or Operator Certification to Findings Response Report

Certification burden. EPA received comments regarding the certification to the findings response report. A few commenters opposed the proposed certification requirement. Some commenters argued that the certification requirement increases the regulated community's burden, but provides no corresponding benefit. Other comments urged EPA to incorporate the ''reasonable inquiry'' concept from Title V compliance certifications into the proposed certification framework. These commenters described the ''reasonable

[57] See page 7–7 of EPA's General Guidance on Risk Management Programs for Chemical Accident Prevention (40 CFR part 68), EPA–550–B–04–001, April 2004 *https://www.epa.gov/rmp/guidance-facilities-risk-management-programs-rmp*; and replacement pages B–21 and B–22 of OSHA 29 CFR 1910.119, Process Safety Management of Highly Hazardous Chemicals—Compliance Guidelines and Enforcement Procedures CPL 2–2.45A CH–1, September 13, 1994 *https://www.osha.gov/OshDoc/Directive_pdf/CPL02-02-045_CH-1_20150901.pdf.*

inquiry'' concept as requiring certification based on ''information and belief formed after reasonable inquiry.'' The commenters argued that this was necessary because a senior official signing a certification could not be expected to have or obtain personal knowledge of all the facts potentially relevant to the findings response report. Similarly, a facility encouraged EPA to coordinate the certification statement in this rule with the certification statement that is already required under CAA Title V. One commenter stated that EPA's rules regarding self-audits impose a less stringent certification requirement, and recommended that a less stringent standard may be appropriate here, too, if the third-party compliance audit provisions are finalized.

In this rule, EPA is requiring a senior corporate officer, or an official in an equivalent position, to certify in the findings response report that:

- He or she engaged a third-party to perform or lead an audit team to conduct a third-party audit in accordance with the requirements of 40 CFR 68.59 or 68.80,
- The attached RMP compliance audit report was received, reviewed, and responded to under the senior officer's direction or supervision by qualified personnel, and
- Appropriate responses to the findings have been identified and deficiencies were corrected, or are being corrected, consistent with the requirements of subparts C or D of 40 CFR part 68.

EPA believes these requirements and the associated certification are consistent with equivalent certification requirements in many EPA regulations, including in the CAA Title V regulations (40 CFR 70.5(d).[58])

EPA agrees that senior corporate officials do not necessarily have high levels of technical expertise; however, these officials and entities include key managers responsible for establishing internal corporate accountability and overseeing corporate prioritization, budgeting, and operations. Indeed, the Security and Exchange Commission (SEC) requires other specified documents to be provided to such individuals, committees, and boards for similar reasons.[59] Finally, EPA believes that the certification will minimize corporate failures to properly address and implement compliance audit findings and recommendations. Adopting a less stringent standard would not be appropriate. EPA expects that the senior corporate official certification of the audit findings will improve facility and public confidence that third-party audit report findings and recommendations are promptly and properly addressed.

Senior corporate officer or equivalent official. Comments were received requesting clarification of the terms ''senior corporate officer, or official in an equivalent position.'' Some commenters recommended that EPA incorporate the ''responsible official'' definition from the CAA's Title V operating permit program for major stationary sources which allows for certification by corporate leadership or a ''duly authorized representative'' appointed by corporate officials.

One commenter stated that the certification requirement risks infringing on the senior corporate official's Fifth Amendment privilege against self-incrimination. The commenter stated that the Supreme Court has held that the privilege protects against compulsory disclosures to the government when those disclosures have ''the direct and unmistakable consequences of incriminating'' the disclosing party, and concluded that the proposed certification requirement may compel precisely those sorts of disclosures. The commenter went on to state that the certification necessarily admits the existence of ''deficiencies'' which can only be interpreted as violations of the CAA and which could certainly be a significant link in a chain of evidence tending to establish guilt in a criminal case. One commenter also argued that the certification requirement raises First Amendment concerns by compelling speech that does not serve a sufficient government interest to avoid running afoul of the right to free speech because it is unclear what government interest the certification advances and the relevant section of the rule is not narrowly tailored to that interest.

EPA disagrees with this recommendation to allow delegation of the certification to a duly authorized representative. The certification indicates that the compliance audit report was received, reviewed, and responded to under the senior corporate officer's direction or supervision by qualified personnel. Similar to the requirement to submit the findings response report to the audit committees of the Board of Directors, a senior corporate official ensures accountability and overseeing corporate prioritization, budgeting, and operations.

Furthermore, the language of the certification cites the actions that are taken by the owner or operator pursuant to these requirements, and includes, among other things, a statement that based on personnel knowledge and experience, or inquiry of personnel involved in evaluating the report findings and or inquiry of personnel involved in evaluating the report findings and determining appropriate responses to the findings, the information submitted herein is true, accurate, and complete. This language is equivalent to the language in certifications that support submissions under Title V of the CAA. EPA continues to believe that it is important for a senior corporate official, or an official in an equivalent position, sign such a certification, ensuring that the owner or operator is aware of the findings and responses, and will be correcting the deficiencies, pursuant to these requirements. For smaller entities without corporate officials, the official in an equivalent position for purposes of this requirement may include the owner or operator, or designated representatives of the owner or operator, including facility manager, operations manager, or another official at or above that level. Regarding comments concerning self-incrimination in connection with the certification requirement, the certification does not contain an acknowledgement of a violation. It merely describes the actions taken by the owner or operator pursuant to the third-party audit requirements, and states that the information submitted is true, accurate, and complete. The certification and report are not required to be automatically submitted to the implementing agency.

n. Schedule Implementation

EPA received comments supporting the proposed requirement for owners and operators to ''promptly'' address deficiencies noted in audit reports. A few commenters stated that there should be no specific timeframe for addressing deficiencies identified during a third-

[58] ''(d) Any application form, report, or compliance certification submitted pursuant to these regulations shall contain certification by a responsible official of truth, accuracy, and completeness. This certification and any other certification required under this part shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.''

[59] Under Section 3(a)(58) of the Exchange Act as added by Section 205 of the Sarbanes-Oxley Act, the term audit committee is defined as ''[a] committee (or equivalent body) established by and amongst the board of directors of an issuer for the purpose of overseeing the accounting and financial reporting processes of the issuer and audits of the financial statements of the issuer'' (if no such committee exists with respect to an issuer, the entire board of directors of the issuer). *See* Securities and Exchange Commission, 17 CFR 240.10A–3—Listing standards relating to audit committees (68 FR 18818, April 16, 2003, as amended at 70 FR 1620, January 7, 2005; 73 FR 973, January 4, 2008).

party audit, reasoning that there will be a wide variety of possible site-specific actions that an owner or operator may take to address audit findings. Another commenter believed it was appropriate to require ''prompt'' correction of deficiencies, but encouraged EPA to provide guidelines on what would be considered ''prompt'' action.

Some commenters recommended specific timeframes for addressing deficiencies. One commenter recommended that deficiencies be corrected ''promptly'' and no later than six months absent a written extension from EPA. A few commenters recommended that facilities be required to promptly implement corrective actions and that deficiencies be addressed within 18 months. However, some of these commenters stated that facilities should be given the opportunity to request an extension, if needed, from the implementing agency. Another commenter recommended that facilities be given 24 months to correct deficiencies after the facility has identified an appropriate response, with the deficiencies presenting the highest risk of injury being addressed first.

One commenter recommended that EPA allow stationary sources to develop a reasonable schedule for correcting audit findings that would be based on the types of audit findings and the resulting efforts to implement them appropriately, rather than at a pace that may impede sound and sustainable implementation processes. One commenter stated that the proposal does not account for the likelihood that plans and schedules for addressing deficiencies may need to change. To account for needed changes, the commenter recommended that EPA should clarify that the details of the schedule are not binding.

EPA disagrees with commenters that suggested incorporating a prescribed schedule for addressing findings in the final rule and we are finalizing the schedule implementation provision of §§ 68.59(f)(2) and 68.80(f)(2) as proposed. The owner or operator's third-party audit findings response report must include ''a schedule for promptly addressing deficiencies'' but does not prescribe a specific timeframe or due dates by which the deficiencies must be addressed. Thus, under the final rule, the owner or operator must exercise best judgement to determine how, and when, to prioritize and address actions, consistent with the normal definition of ''promptly'' as meaning quickly, without delay.[60] EPA finds that this approach best provides the flexibility owners or operators will need to address a potentially very wide range of deficiencies and other findings noted in third-party audit reports. This allows the facility owner or operator to develop a reasonable schedule for correcting audit findings that would be based on the types of audit findings and the resulting efforts to implement them appropriately.

EPA also disagrees with commenters' suggestions to request a schedule extension from the implementing agency. The implementing agency will not receive a copy of the final audit report or findings response report and therefore it is inappropriate to request an extension to address deficiencies identified in the findings response report. In the event that a schedule must change due to unforeseen circumstances, EPA recommends that the owner or operator document the reasons for the change and update the schedule to reflect revised dates.

o. Submitting Reports to the Board of Directors

EPA received comments both supporting and opposing the proposed requirement to submit the audit report to the audit committee of the Board of Directors. Those in support reasoned that it will make the Board of Directors aware of the deficiencies, and noted that the requirement will allow the Board of Directors the opportunity to properly budget for corrective actions.

Several commenters, including facilities and industry trade associations, opposed the proposed requirement to submit the audit report to the Board of Directors, arguing that it is generally unnecessary or inappropriate to do so. These commenters stated that the requirement would unduly constrain facilities that may have other processes to involve facility leadership in responding to findings from third-party audits. Similarly, an industry trade association reasoned that this requirement subverts company policy established under the rule's management provisions and that the program would be most effective if each company is allowed to determine the most appropriate chain of command and reporting. The commenter also warned that such a requirement could set a precedent for other regulatory programs, which could result in Boards of Directors receiving a deluge of technical information that they do not have time to address and that they are in no position to interpret.

One commenter recommended that EPA provide definitions for Board of Directors and audit committee to avoid ambiguity. The commenter also recommended that EPA specify a timeframe for this report to be submitted to the Board's audit committee. Furthermore, the commenter urged EPA to address how this requirement would be documented as completed or what documentation would be required to demonstrate that the owner or operator does not have an audit committee or comparable committee.

Boards of Directors and their audit committees play an important role in establishing internal corporate accountability and overseeing corporate prioritization, budgeting, and operations. EPA believes that providing the audit committee of the Board of Directors with third-party audit findings will ensure the committees and their Boards of Directors are aware of any deficiencies and have the opportunity to properly budget for any required corrective actions in a timely manner. EPA expects that this approach will improve facility and public confidence that third-party audit report findings and recommendations are promptly and properly addressed.

Therefore, the final rule requires the owner or operator to immediately, upon its completion, provide to the audit committee of the Board of Directors, or other comparable committee or individual, if applicable a copy of the:

- Findings response report; and
- Implementation schedule to address deficiencies identified in the audit findings response report.

EPA does not agree that we should define ''Board of Directors'' and ''audit committee.'' Facility owners or operators should consider their corporate structure to determine if there is, in fact, a committee or individual that may serve to oversee auditing and compliance oversight. The closing clause in §§ 68.59(e)(3) and 68.80(e)(3), ''if applicable,'' replaces the corresponding language in the proposed rulemaking, ''if one exists.'' ''If applicable,'' in this context, is intended to clarify that owners or operators not otherwise required by law to have an audit committee of the Board of Directors or that have not, otherwise, established or designated a comparable committee or individual, are not subject to the requirements in §§ 68.59(e)(3) and 68.80(e)(3).

Finally, in response to concerns about demonstrating compliance with this requirement, EPA recommends that the facility document how the owner or

[60] *See* definition of ''promptly,'' Cambridge English Dictionary, at *http://dictionary.cambridge.org/us/dictionary/english/promptly.*

operator complied with this requirement and maintain that documentation with the findings response report. This may include identifying who received a copy of the report and the date it was provided. If there is no audit committee of the Board of Directors or a comparable committee or individual, then the owner or operator should consider documenting that no committee or individual exists.

p. Third-Party Audit Recordkeeping

Some commenters supported the proposed third-party audit recordkeeping requirements. However, some commenters opposed the requirement to retain copies of the draft audit report. A few commenters opposed the requirement that records be retained at the stationary source.

EPA agrees with commenters that opposed maintaining draft audit reports. Therefore, EPA is not finalizing the proposed requirement in §§ 68.59(e)(2) and 68.80(e)(2) for owners or operators to retain copies of all draft third-party audit reports. The final rule requires that the owner or operator retain as records certain documents at the stationary source, including the two most recent final third-party audit reports, related findings response reports, documentation of actions taken to address deficiencies, and related records. The final audit report must include a summary of any significant revisions between draft (if any) and final versions of the report.

The final rule also requires the owner or operator to retain records at the stationary source in order to ensure that records are readily available to stationary source staff to review and utilize and for implementing agency inspectors to access during site inspections. These documents may be retained electronically as long as they are immediately and easily accessible to the owner or operator and the owner or operator retains the signed original documents, where appropriate.

q. Other Comments

One commenter encouraged EPA to correct what it described as a grammatical error within §§ 68.58(a) and 68.79(a). Specifically, the commenter urged EPA to correct the plural reference to the owner or operator by changing the word ''they'' to ''it'' to make it clear that only one of the entities needs to conduct an audit.

EPA is not making this recommended revision. Both the owner and operator are responsible to evaluate compliance with the prevention program requirements of the rule and we do not believe that this language has been confusing. However, to clarify, we do agree that as long as the audit is performed, only one of the entities needs to have conducted the audit.

C. Safer Technology and Alternatives Analysis (STAA)

1. Summary of Proposed Rulemaking

EPA proposed to modify the PHA provisions in § 68.67 by adding paragraph (c)(8) to require certain industry sectors to conduct a safer technology and alternatives analysis (STAA) and to evaluate the feasibility of any inherently safer technology (IST) identified. EPA proposed to limit the requirement to owners or operators of facilities with Program 3 regulated processes in North American Industrial Classification System (NAICS) codes 322 (paper manufacturing), 324 (petroleum and coal products manufacturing), and 325 (chemical manufacturing).

In the proposed rulemaking, EPA specified that the STAA would consider, in the following order of preference:

- IST or inherently safer design (ISD),
- Passive measures,
- Active measures, and
- Procedural measures.

EPA further indicated that the owner or operator would be able to evaluate a combination of these risk management measures to reduce risk at the process.

EPA also proposed to add several definitions that relate to an STAA in § 68.3. EPA proposed active measures to mean risk management measures or engineering controls that rely on mechanical, or other energy input to detect and respond to process deviations. Some examples of active measures included alarms, safety instrumented systems, and detection hardware (such as hydrocarbon sensors).

EPA proposed feasible to mean capable of being successfully accomplished within a reasonable time, accounting for economic, environmental, legal, social, and technological factors. EPA further clarified in the definition that environmental factors would include consideration of potential transferred risks for new risk reduction measures.

For inherently safer technology or design, the proposed definition meant risk management measures that:

- Minimize the use of regulated substances,
- Substitute less hazardous substances,
- Moderate the use of regulated substances, or
- Simplify covered processes in order to make accidental releases less likely or the impacts of such releases less severe.

The proposed definition of ''passive measures'' meant risk management measures that use design features that reduce the hazard without human, mechanical, or other energy input. EPA provided examples of passive measures that included pressure vessel designs, dikes, berms, and blast walls.

Finally, EPA proposed procedural measures to mean risk management measures such as policies, operating procedures, training, administrative controls, and emergency response actions to prevent or minimize incidents. EPA sought comment on these proposed revisions.

2. Summary of Final Rule

After review and consideration of public comments, EPA is finalizing the STAA provision in § 68.67(c)(8), and related definitions in § 68.3, as proposed, with the following modifications:

- EPA is substituting the term ''practicability'' for ''feasibility'' in proposed § 68.67(c)(8)(ii) of the PHA requirements;
- EPA is substituting the term ''practicability'' for ''feasible'' in the definition in § 68.3 and substituting the phrase ''the capability'' for ''capable,'' while retaining the remaining definition as proposed; and
- EPA is revising the definition of ''passive measures'' by clarifying that these measures not only reduce a hazard but reduce the frequency or consequence of a hazard.

Significant comments on the proposed STAA provisions and related definitions are discussed in section IV.C.3 of this preamble.

3. Discussion of Comments and Basis for Final Rule Provisions

Many commenters from environmental advocacy groups and some state agencies expressed support for the proposal to require an STAA to improve process safety. However, some believed that implementation of feasible safer alternatives, particularly IST, should be required and that STAA requirements should apply to a greater universe of facilities and not just those in the chemical manufacturing, petroleum refining and paper manufacturing industries. Many commenters, mostly from industry, requested that EPA remove IST and design requirements from the rule entirely for a variety of reasons, or requested significant clarifications to applicability if the STAA provision is finalized.

As noted previously, except for substituting the term ''practicable'' for ''feasible'' and some other definition changes, EPA is finalizing the STAA provisions as proposed. We continue to rely on the rationale expressed in the proposed rulemaking. In the discussion that follows and in the Response to Comment document, we explain our consideration of the comments and our analysis and response.[61]

We recognize there may be multiple, rational approaches to STAA. We determined that it was reasonable to require STAA for sectors that have had a high per facility incidence of reportable accidental releases and where the complexity and variety of methods of chemical handling demonstrate the potential for process safety revisions. We do this in part to balance potential accidental release rate reduction and cost. There are some sectors, such as water treatment, with known ISTs that we do not require to evaluate or implement ISTs under this rule. In the water treatment sector in particular, the sector's lower accidental release rates do not demonstrate that requiring thousands of facilities to conduct STAA would result in a significant drop in accidental releases.[62] In contrast, even if some of the sectors we have identified for the STAA requirement already may have voluntarily undertaken an STAA approach (at least at new facilities), accidental release rates remain higher for these industries, technologies advance over time, and ensuring a minimum level of application of the STAA approach limits the disincentives for sector members to be leaders in adoption of safer technologies. We do not mandate the adoption of any IST found to be practicable in part because we recognize that a passive measure or other approach on the STAA hierarchy may also be effective at risk reduction; we continue to leave the adoption of particular accident prevention approaches to owners' and operators' reasonable judgment. We discuss other factors that have led us to select particular industries for STAA and particular requirements in our STAA approach in response to particular comments.

a. Legal Issues

Various commenters raised potential legal issues or challenges regarding the STAA requirements based on CAA authority, Congressional intent, deficient analysis or substantiation, vagueness of requirements, and jurisdiction.

Several industry associations and individual companies commented that EPA lacked the legal authority to require assessment of STAA in general and IST/ISD in particular. One argued that the authority for RMPs rests in subparagraph (B) of CAA section 112(r)(7), while the authority for design and equipment changes rests in subparagraph (A). Several argued that EPA did not adequately explain its change of position from the one adopted in the 1996 final RMP rule, which did not require the assessment or implementation of IST. In light of EPA's position that the 1996 final RMP rule and EPA's program implementation provided incentives to adopt IST, some argued that requiring STAA analysis without requiring implementation of changes would offer no new benefit to public health and safety; these commenters suggested that IST had been informally used already for decades where it was feasible. Another commenter said the STAA requirement could effectively ban certain chemicals without the authority to do so. Others noted that IST consideration would lead to increased liability issues for facilities because, even if a source was not required to implement IST by rule, should an accident happen, plaintiffs could cite the failure to adopt the IST in a court case. A commenter criticized the requirement as too amorphous to be meaningfully implemented and enforced in a non-arbitrary manner. Other commenters said IST is more properly within the authority of OSHA, that EPA's record did not reveal consultations and coordination with OSHA as required by CAA section 112(r)(7)(D), and that subsequent to the enactment of the 1990 CAA Amendments, Congress had denied both EPA and DHS the authority to require IST when it rejected bills requiring or authorizing IST.

In contrast to the comments discussed previously, a coalition of environmental, labor, community and other public groups, as well as a mass mail campaign, commented that EPA must adopt STAA in its final rule not only for NAICS codes we proposed but for all facilities where STAA is feasible. In the commenters' view, the proposed amendments are inconsistent with the statute's prevention objectives and its preference for measures that completely eliminate potential hazards because only certain sectors are required to undertake STAA while others only have requirements imposed after accidental releases. Additionally, the commenters argue that the authority to ''make distinctions'' among classes of facilities in CAA section 112(r)(7)(A) and to ''recognize differences'' among types of sources in CAA section 112(r)(7)(B) does not include the authority to exempt entire sectors from STAA; even if the statute gave such authority, EPA failed to explain how it is relying on that authority. Finally, the commenters contended EPA's action was arbitrary and capricious by failing to account for the significant value STAA could provide to facilities, workers, and communities by not only removing hazards but by saving money through removing potential liability and sometimes improving industrial efficiency.

EPA disagrees with the comments that the CAA does not authorize the STAA provisions of this final rule. Both subparagraphs (A) and (B) of CAA section 112(r)(7) authorize STAA and IST in particular. EPA cited all of paragraph (7) as authority for ''[e]ach of the portions of the Risk Management Program rule we propose to modify.'' 81 FR 13646, March 14, 2016.[63] The authority section for 40 CFR part 68 references CAA section 112(r) and is not limited to particular paragraphs and subparagraphs. The proposed rulemaking also noted that subparagraph (A) had been invoked in the rulemaking petition on IST. Therefore, EPA provided sufficient notice that we contemplated action under any authority under CAA section 112(r)(7). Nevertheless, we also view that our authority to require STAA assessments or an IST review is consistent with subparagraph (B). Under subparagraph (B), EPA has broad authority to develop ''reasonable regulations . . . for the prevention of accidental releases.''

Further support for IST can be found in both the Conference Report accompanying the 1990 CAA Amendments and the Senate Report explaining the provisions of the Senate bill that closely mirrors enacted provisions. In discussing the ''Hazard Assessments'' required by section

[61] 2016. EPA Response to Comments on the 2016 Proposed Rulemaking Amending EPA's Risk Management Program Regulations. This document is available in the docket for this rulemaking.

[62] An intentionally-caused release through the criminal act of a third-party would be an accidental release because the emission would be unanticipated from the perspective of the owner or operator of the stationary source. Where the location of a water treatment source could expose large populations to regulated substances, we believe it is appropriate for such sources to work with local emergency planners and homeland security officials to reduce the risk. Nevertheless, such isolated cases do not justify a mandate across the industry in place of a case-specific review.

[63] We note that our more extensive discussion of authority for the RMP rule provided in the 1993 proposal focused on CAA 112(r)(7)(B)(i) and (ii), 58 FR 54191–93 (October 20, 1993), which the proposal for the Modernization rule referenced for additional authority discussion.

112(r)(7)(B), the Conference Report specifies that such assessments ''shall include . . . a review of the efficacy of various release prevention and control measures, including process changes or substitution of materials.'' [64] Conference Report at 340–41. The STAA analysis is such a review.[65] The Senate Report identifies as ''release prevention measures'' many of the techniques that are now known as IST—substitution of less hazardous materials, reduction in the severity of the conditions of processing and complexity of the process, and decreasing volumes of chemicals in storage.[66] Senate Report at 242. That subsequent Congresses did not enact additional legislation on IST is irrelevant to what was enacted and intended at the time of enactment.

The proposed rulemaking, 81 FR 13646, March 14, 2016, provided an extensive discussion of developments concerning IST since the 1996 final RMP rule. As we explained, EPA adopted a rule in 1996 that provided incentives for IST without a specific mandate to either conduct studies of IST or implement IST measures. From 1996 on, EPA has recognized that good PHA techniques will often identify opportunities to make new and existing processes and operation inherently safer. However, in the 1996 rule and thereafter, we also recognized that IST is not the only way to prevent accidents, and that sometimes IST can be impractical, especially for existing sources.

The STAA approach we adopt in this action places IST in a hierarchy that allows for sources to choose non-IST approaches to accident prevention, such as passive mitigation, active mitigation, and administrative controls. While the EPA did not, in 1996, expressly require facilities to analyze and implement IST specifically, this rule places IST in a set of options to be studied. EPA relies on sources making rational decisions once presented with STAA studies and selecting prevention approaches that optimize the cost of the measures taken and costs avoided (*e.g.,* liability, operational efficiency, image). Such an approach is similar to the approach to energy assessments recently taken in the major source and area source boiler rules under CAA section 112(d) and affirmed in *U.S. Sugar Corp* v. *EPA.*[67]

We acknowledge that many sources have conducted STAA analyses already. For these sources, the cost of implementing the new STAA requirement should be lessened. The requirement we promulgate in this rule captures those slower in considering IST in high accident industries rather than harms leaders. There are no specific chemicals banned by this final rule. While we recognize that companies have moved away from certain processes, such as those that involve the storage of large quantities of methyl isocyanate, in order to make facilities safer, we leave process design decisions to the reasonable judgment of owners and operators under this action.

EPA disagrees with the comments concerning IST being more properly within the authority of OSHA. It is plain from the history of the 1990 Amendments that both agencies were given authority to prevent accidents, and that Congress contemplated EPA adopting some IST measures as appropriate. Furthermore, EPA has a history of prior coordination with OSHA to define and promote STAA when developing the EPA and OSHA, Chemical Safety Alert: Safer Technology and Alternatives (EPA 550–F–15–003; June 2015).[68]

Not only for STAA, but also for other provisions of this final rule, the record adequately reflects EPA's coordination and consultation with Department of Labor (DOL)/OSHA and DOT. As an initial matter, both DOL and DOT were part of the Working Group under Executive Order 13650. That order and report of the Working Group reflect consultation and direction regarding the development of the this final rule. Second, we note that EPA's decision to not consider the regulation of AN at this time explicitly is based on an effort to coordinate any potential regulatory requirements for this substance with actions contemplated by other agencies, including OSHA. Third, while the content of interagency deliberations are not for the record for judicial review under CAA section 307(d), multiple agencies have an opportunity to review a draft rule under Executive Order 12866 *Regulatory Planning and Review.* Finally, OSHA had representatives attend the SBAR panel which discussed the development of the proposed rulemaking. All of this is a matter of public record in the docket for this rulemaking.

Consistent with the structure of the RMP rule, EPA has placed IST among the methods a facility may choose to adopt to prevent accidents. Commenters who argue that we have failed to require accident prevention by not mandating the adoption of IST measures for all facilities wherever feasible fail to acknowledge that non-IST methods for preventing accidents may be reasonable in some circumstances. To the extent that these regulations are imposed under subparagraph (B), these regulations have an overriding requirement to be reasonable. While it is true that similar quantities of chemicals under the same conditions present similar hazards regardless of sector, various sectors present different likelihood of release. Some sectors handle chemicals differently under conditions that are more likely to lead to severe releases. The record reflects that the likelihood of severe accidents is greater in the sectors that must conduct STAA analysis under this final rule. Thus, it is reasonable to have different requirements for these sectors than for others. Independent of whether any new IST/ISD is adopted, there is a cost to conducting an STAA analysis. EPA has reasonably limited STAA analysis requirements to sectors that we view as most likely to likely to have more frequent, severe releases that are most likely to be benefit from STAA review. Inherent in our approach is distinguishing among classes and types of facilities. We expect that the adoption of STAA analysis requirements in this final rule will advance IST not only in the sectors targeted by the rule, but also more generally as experience is gained and opportunities for technology transfer are developed.

b. Applicability

Limiting applicability of STAA provisions. While some commenters supported EPA's proposal to limit applicability of STAA provisions to the petroleum refining, chemical manufacturing, and paper manufacturing sectors, other commenters objected to this aspect of the proposal. Many commenters, including a mass mail campaign joined by approximately 300 commenters, expressed concern that the proposed rulemaking arbitrarily determined which industries have feasible and worthwhile alternatives, and which communities and facilities would benefit from STAAs. These commenters

[64] H. Rep. 101–952, Clean Air Act Amendments of 1990 Conference Report to Accompany S. 1630, 101st Cong., 2d Session, 340–41. October 26, 1990.

[65] EPA chose to incorporate into the prevention program provisions several of the hazard assessment elements mentioned in the conference report and to limit the hazard assessment portions of 40 CFR subpart B to the offsite consequence analysis and accident history in order to better conform the RMP rule to the format of the PSM rule. 58 FR 54194 (October 20, 1993).

[66] Clean Air Act Amendments of 1989, Report of the Committee on Environment and Public Works, U.S. Senate together with Additional and Minority Views to Accompany S. 1630. S. Report No. 101–228. 101st Congress, 1st Session, p. 242, December 20, 1989.

[67] *United States Sugar Corp.* v. *EPA,* 830 F.3d 579 (D.C. Cir. 2016).

[68] *https://www.epa.gov/sites/production/files/2015-06/documents/alert_safer_tech_alts.pdf.*

asserted that limiting the requirement to certain industry sectors would exempt other sectors that pose a significant threat to the public. Commenters argue that focusing on accident rate to target sectors for STAA was not a credible way to forecast and prevent rare catastrophic events that tend to fall out of existing patterns.

Some commenters urged EPA to apply the STAA requirement to all sources, or all Program 3 sources. Other commenters, including another mass mail campaign joined by approximately 17,250 commenters, recommended that EPA require assessment and implementation of STAA for industries where safer alternatives are feasible or well demonstrated, such as water supply, wastewater treatment, power generation, food and beverage manufacturing, and others. Several other commenters indicated that EPA should apply the STAA provisions to facilities with the largest worst case scenario populations, or to the 2,000 high-risk facilities cited in EPA's 2017–2019 National Enforcement Initiative (NEI). A few commenters suggested that EPA implement a pilot program requiring IST implementation for a subset of sectors considered extremely high risk, such as wastewater or drinking water treatment plants, bleach plants, refineries using hydrogen fluoride and for those facilities among the 2,000 high-risk facilities cited in the EPA's NEI 2017–2019 proposal. A few commenters believe that the proposed STAA requirements have failed to address the disproportionate health and safety threats in communities of color and low-income communities, and want the STAA provisions to apply to all RMP facilities.

In this rule, EPA is finalizing the STAA provisions as proposed, which limits applicability of the STAA requirements to Program 3 processes in the petroleum refining, chemical manufacturing, and paper manufacturing sectors. EPA does not believe that the final provisions have been limited arbitrarily, or that the Agency's decision to limit applicability of the STAA provisions to the petroleum refining, chemical manufacturing, and paper manufacturing sectors implies that other sectors do not have viable safer technology alternatives. In the proposed rulemaking, EPA acknowledged that most RMP-regulated sectors could identify safer technologies and alternatives. However, the Agency proposed to limit the applicability of the STAA provisions to facilities in complex manufacturing sectors with high accident rates. EPA took this approach in order to target these provisions to the industrial sectors with the potential to achieve the greatest safety improvements through consideration of safer technology alternatives. EPA explained that sources involved in complex manufacturing operations have the greatest range of opportunities to identify and implement safer technology, particularly in the area of inherent safety, because these sources generally produce, transform, and consume large quantities of regulated substances under sometimes extreme process conditions and using a wide range of complex technologies. Therefore, such sources can often consider the full range of inherent safety options, including minimization, substitution, moderation, and simplification, as well as passive, active, and procedural measures. Further, EPA noted that RMP facilities in the three selected sectors have been responsible for a relatively large number of accidents, deaths, and injuries, and the most costly property damage.[69] Facilities in these sectors also have significantly higher accidents rates as compared to other sectors.[70] EPA agrees that there is no way to forecast rare catastrophic events; however, we believe it is appropriate to target sectors that have had a large number of accidents and have the greatest opportunity to identify safer technologies.

While EPA does not believe it is necessary to require all sources, all Program 3 sources, or all sources in industry sectors where feasible safer technology alternatives have been identified to perform an STAA, the Agency encourages such sources to consider performing an STAA, and to determine practicability of IST or ISD considered, even if they are not subject to the STAA provisions of the final rule.

EPA does not agree that only sources with large worst-case scenario populations, or only sources on EPA's high risk facility list should be required to comply with the STAA provisions. EPA believes it is not appropriate to apply the STAA provisions only to sources with specified worst case scenario populations for several reasons. First, EPA's OCA requirements allow regulated facilities to use any commercially or publicly available air dispersion modeling techniques, provided the techniques account for the modeling conditions specified in the rule and are recognized by industry as applicable as part of current practices. This flexibility can result in two similar facilities obtaining significantly different endpoint distances (and vulnerable zone populations) simply through choosing different modeling techniques. By linking the STAA requirement to the worst case scenario, EPA could inadvertently cause some facilities to recalculate their OCA using a different modeling approach, simply to avoid the STAA requirement, and without actually implementing process changes that might reduce the facility's worst case scenario. Second, linking the STAA requirement to large worst case scenario populations would effectively bias the applicability of the requirement to facilities in densely populated areas, and potentially exempt equally hazardous facilities in or near less densely populated communities. Third, this application of the STAA requirement would disregard the criteria that EPA has used in the proposed rulemaking—accident history and facility complexity, which EPA believes provide a stronger rationale for limiting the applicability of the requirement. In addition, EPA believes that targeting the STAA requirements to the larger and more complex processes will benefit minority communities, who are located closer to larger facilities with more complex chemical processes and who bear a larger portion of risk from chemical accidents. Lastly, distribution of worst-case scenario population information is restricted under the CAA, and this would effectively prohibit the public from knowing which facilities are required to perform an STAA.

For similar reasons, EPA does not agree with commenters' suggestions to develop a pilot program to apply to a subset of high risk facilities or to apply the STAA requirement to facilities on EPA's high risk facility list. This list is generated, in part, using worst case scenario population information (chemical quantities and accident history are also considered, although sector accident frequency is not), and therefore the list may not be publicized by EPA.

Apply to facilities using different incident rate methodology. Several commenters objected to EPA's methodology for selecting industrial sectors subject to STAA requirements using an incident rate based on the

[69] For more information, see Chapter 6 of the *Regulatory Impact Analysis—Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7).* This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

[70] For more information, see EPA, January 27, 2016. Technical Background Document for Notice of Proposed Rulemaking: Risk Management Programs under the Clean Air Act, Section 112(r)(7). This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

number of RMP-reportable accidents per facility in the industry sector. These commenters expressed concern that the proposal to require STAAs from only three NAICS codes is based on an incorrect approach to, and interpretation of, incident rates. An industry trade association commented that looking at the number of accidents per facility does not allow for direct comparisons as it does not account for the relative number of employees at a facility. This commenter argued that EPA should recalculate this value using the number of accidents per hours worked or the number of accidents per full time worker, and reasoned that such a calculation would be more consistent with the incident rate calculations conducted by the Occupational Safety and Health Administration (OSHA) and the Bureau of Labor Statistics (BLS). Another industry trade association remarked that EPA's methodology ignores not only the size of the facility but also the quantity of chemicals and the number of covered process units at a given facility. According to this commenter, upon normalizing the petroleum refining sector's accident rate to account for the number of process units and the diversity of facilities being compared, the accident rate for this sector is lower than for most other sectors. The commenter also expressed concern that EPA's proposal to subject this sector to the STAA requirement ignores the industry's significant recent safety improvements that EPA itself has noted in the NPRM, and that industries such as poultry processing have higher incident rates than petroleum refining or chemical manufacturing, even though these industries are not subject to the STAA requirement.

A trade association representing the paper manufacturing industry urged EPA to remove the STAA requirement for that sector. The industry trade association stated that paper manufacturing should not be considered a ''complex'' manufacturing process, and cited EPA's Technical Background Document [71] which, according to the commenter, does not categorize paper manufacturing facilities as ''complex.'' Additionally, the commenter remarked that the paper manufacturing industry has a much lower level incident risk than other sectors based on injuries offsite, and stated that of the roughly 15,000 offsite injuries mentioned by EPA, the paper manufacturing industry was responsible for only two. Citing Exhibit 6–4 of EPA's Regulatory Impact Analysis for the proposed rulemaking, the commenter asserted that the entire U.S. paper manufacturing sector has been responsible for the fewest offsite injuries out of any industrial sector over the ten-year study period. This commenter concluded that implementing the requirement for the paper industry would not enhance public safety, and that the industry has made significant strides to increase safety procedures in recent years.

Another commenter stated that EPA's use of routine incident rates in selecting industry sectors to conduct STAAs was faulty because frequent smaller incidents cannot be used to reliably predict infrequent catastrophic events.

EPA acknowledges that there were other possible methods of selecting industry sectors that would be subject to STAA requirements. All of the methods offered by commenters—normalizing accident rates by FTE, number of process units, chemical quantities, etc.—were considered but ultimately rejected by the Agency. EPA does not believe normalizing accident rates by FTE or chemical quantity is appropriate because prior research has shown that the interaction between these factors and incident rates is complex, and that none of these variables, by itself, is a suitable proxy for the relative risk of a catastrophic chemical release incident at a facility.[72] Likewise, selecting industry sectors for applicability of the rule's STAA provisions using an approach similar to that used for OSHA personal injury statistics (*e.g.,* OSHA lost workday injury and illness rates) would not identify sectors with higher chemical process risks. These OSHA rate data generally scale directly with the number of employees because most of the incidents measured in these metrics involve single-person injuries (*e.g.,* overexertion, sprains and strains, slips, trips, falls, injuries due to contact with objects and equipment, etc.).[73] In other words, facilities with more employees are more likely to suffer higher amounts of these ''lost workday'' injuries, but not necessarily higher numbers of chemical release incidents.

Furthermore, EPA chose not to normalize accident rates by the number of process units for two reasons. First, regulated sources have significant discretion in determining covered process boundaries—some petroleum refineries and large chemical manufacturing facilities containing numerous unit process operations have chosen to consider their entire plant as a single covered process, while other similar plants have divided their stationary source into dozens of different covered processes. Therefore, normalizing accident rates by the number of processes could result in a less accurate reflection of a sector's historical accident propensity. More importantly, even if a higher accident rate at a large facility is due, in part, to the facility having more covered processes, that fact does not reduce its risk to the surrounding community. For the community, it is the frequency of accidents at its neighbor that matters, not the rate per process. In fact, the relatively higher likelihood of accidental releases at such sources further warrants their consideration, and potential application, of safer alternative technologies.

EPA disagrees that its approach ignores recent safety improvements on the part of the petroleum refining sector. The Agency views the application of safer technology alternatives as an approach to hazard control that can be applied throughout the life-cycle of a facility. A facility's recent implementation of a safer technology alternative does not foreclose consideration of additional safer technologies in the future. Facilities that have already implemented safer technology alternatives should document their implementation in their next PHA, determine whether there is additional information that should be considered in their STAA, and continue to consider additional safer alternatives during subsequent PHA re-validation cycles.

EPA agrees that the poultry processing sector, when that sector is considered separately from other food and beverage industry sectors, has a slightly higher RMP facility incident rate than the petroleum refining sector. However, EPA did not include the poultry processing sector under the final rule STAA provision because the poultry processing sector, by itself, does not delineate a meaningful technological subgrouping of RMP facilities. Poultry processing facilities are just one of many different types of food and beverage manufacturing and processing facilities covered under the RMP regulation. The common technology among these facilities that results in their coverage under the RMP

[71] EPA. January 27, 2016. Technical Background Document for Notice of Proposed Rulemaking: Risk Management Programs under the Clean Air Act, Section 112(r)(7). This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

[72] Elliott, M.R., Kleindorfer, P.R., and Lowe, R.A., The Role of Hazardousness and Regulatory Practice in the Accidental Release of Chemicals at U.S. Industrial Facilities, Risk Analysis, Vol. 23, No. 5, 2003.

[73] See, *e.g.,* ''Nonfatal Occupational Injuries and Illnesses Requiring Days Away from Work, 2014,'' U.S. Department of Labor, Bureau of Labor Statistics, November 19, 2015. Available at *http://www.bls.gov/news.release/osh2.nr0.htm.*

regulation is ammonia refrigeration. While EPA is aware that some RMP facilities in the poultry processing sector have had serious chemical accidents, the Agency does not believe that these accidents are usually related to the fact that these facilities process poultry. Rather, they generally relate to the design, maintenance, or operation of the ammonia refrigeration system at the facility, and are similar to the causes of accidents involving ammonia refrigeration systems at other types of food and beverage processing facilities. Therefore, when considering the accident rates of RMP-covered poultry processing facilities, EPA believes the proper approach is to combine RMP facilities in this sector with RMP facilities in all other sectors in the food and beverage industry, as indicated in the RIA for the final rule.[74] When this is done, the accident frequency for the food and beverage manufacturing sector is significantly lower than the accident frequency for the petroleum refining sector.

EPA disagrees with the commenter that argued the paper manufacturing sector should be exempt from the STAA provision of the final rule because the sector has had fewer accidents with offsite injuries, or because the sector was not characterized as ''complex'' by EPA's economic analysis. While it is true that the paper manufacturing sector has had fewer accidents with offsite injuries than other sectors, this is partly due to the relatively small number of RMP facilities (70) in the paper manufacturing sector. Additionally, the great majority of the offsite injuries reported by RMP facilities resulted from a single accident at the Chevron Richmond refinery, therefore it is inappropriate to compare offsite injuries from the paper manufacturing sector to the total of all offsite injuries that occurred during the ten-year period analyzed.[75]

More importantly, offsite injury is only one of several types of accident consequences that require reporting under the RMP rule. Other reportable consequences include deaths, injuries, and significant property damage on-site, and known offsite deaths, evacuations, sheltering-in-place, property damage and environmental damage. When all RMP-reportable accident consequences for a sector are considered, and normalized by the number of sources in the sector, the paper manufacturing sector has the second highest accident rate among all sectors regulated under the RMP rule. EPA believes this approach is a better gauge of the historical accident propensity for a sector than considering only accidents with offsite injuries.

While it is also true that EPA did not characterize the paper manufacturing sector as ''complex'' in the Technical Background Document[76] and for estimating the costs of most rule provisions within the RIA, it did do so for purposes of the STAA provision, and arguably could have done so for all rule provisions. Paper manufacturing facilities, and particularly large integrated pulp and paper mills, are clearly more complex than most other RMP facilities, which only involve chemical storage (*e.g.,* agricultural ammonia distribution facilities) or simple chemical processes (*e.g.,* water treatment). The main purpose for EPA's broad characterization of certain sectors as ''complex'' and all others as ''simple'' for certain rule provisions within the RIA was because the Agency judged that the cost of implementing those rule provisions would vary primarily by the complexity of the processes involved, and that a rough two-tier division of regulated sources (*e.g.,* simple vs. complex) would suffice to establish cost estimates for those rule provisions. However, EPA did not use this two-tier division for purposes of estimating the costs of the rule's STAA provision. For the STAA provision, EPA included paper manufacturing as a sector that involves ''complex manufacturing operations.'' EPA chose to apply the STAA requirement to sources involved in complex manufacturing operations because these sources have the greatest range of opportunities to identify and implement safer technology, particularly in the area of inherent safety. These sources generally produce, transform, and consume large quantities of regulated substances under sometimes extreme process conditions and using a wide range of complex technologies. For more information, see the preamble discussion in the proposed rulemaking at 81 FR 13688, March 14, 2016.

EPA disagrees that the agency used ''routine'' incident rates to select industry sectors covered by the STAA provision. Accidents meeting EPA reporting criteria include accidental releases from covered processes that result in deaths, injuries, and significant property damage on-site, and known offsite deaths, injuries, evacuations, sheltering-in-place, property damage and environmental damage. EPA believe that such accidents generally either resulted in, or could reasonably have resulted in, a catastrophic release of a regulated substance, and are therefore an appropriate criterion to consider when identifying industrial sectors that may benefit public safety the most by analyzing safer alternative technologies.

Eliminate or exempt batch toll chemical manufacturers. In the context of exempting batch toll processors from the STAA provision, some commenters recommended that processes governed by government agency specifications or through a contractual relationship with a customer should not be subject to the STAA provision because in these cases, the customer specifies the manufacturing process. According to one commenter, the customer is subject to regulation, often from the FDA or EPA. An industry trade association requested that EPA explicitly state in the body of the regulation that the STAA requirement would not apply to processes in whole or in part specified by a government agency or through any contractual obligation.

EPA disagrees with the suggestion to exempt batch toll manufacturers from the STAA requirement. Safer technology alternatives include many options beyond chemical substitution. For example, IST could involve minimization of stored raw material chemicals, making process changes that make it less likely to release the chemical (moderation), or reducing complexity in the process in order to make accidents less likely (simplification). Therefore, even where a contractual relationship or regulation requires a regulated batch toll manufacturing facility to use a particular regulated substance in specified quantities, owners and operators of batch toll manufacturing facilities should still consider other potential IST measures besides chemical substitution. The facility must also consider potential safer alternatives beyond IST, such as passive measures instead of or in combination with active

[74] *Regulatory Impact Analysis—Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7).* This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

[75] According to the CSB, ''approximately 15,000 people from the surrounding communities sought medical treatment at nearby medical facilities for ailments including breathing problems, chest pain, shortness of breath, sore throat, and headaches. Approximately 20 of these people were admitted to local hospitals as inpatients for treatment.'' CSB, January 2015, Final Investigation Report: Chevron Richmond Refinery Pipe Rupture and Fire, Chevron Richmond Refinery #4 Crude Unit, Richmond, California, August 6, 2012, Report No. 2012–03–I–CA, *http://www.csb.gov/assets/1/16/Chevron_Final_Investigation_Report_2015-01-28.pdf.*

[76] EPA. January 27, 2016. Technical Background Document for Notice of Proposed Rulemaking: Risk Management Programs under the Clean Air Act, Section 112(r)(7). This document is available in the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

measures, or active measures instead of procedural measures. Toll manufacturers may use RMP chemicals for purposes in addition to making a formulated product, such as for cleaning equipment, wastewater treatment or refrigeration, for which chemical substitution may not be prohibited by regulation or contractual relationship. Also, the final rule does not require regulated sources to implement IST or ISD considered, so there is no conflict between this final rule and other regulations that may apply to RMP-regulated facilities subject to STAA requirements. For example, an owner or operator would be in compliance with the STAA requirement to consider potential chemical substitution as part of the analysis if he or she determines that a chemical substitution is not practicable because the substitution is prohibited by another regulation The owner or operator would still need to consider other types of IST (minimization, moderation, or simplification), and passive, active, and procedural measures in the analysis.

Applicability to water treatment facilities. Some commenters, including professionals and a mass mail campaign joined by approximately 300 commenters, urged that water supply and wastewater treatment facilities should be subject to the proposed STAA provision. A number of commenters expressed concern about threats posed by water and wastewater facilities and related operations. Several commenters asserted that technologically and economically feasible alternatives are available for water supply and wastewater treatment facilities, and suggested that exploring the implementation of these alternatives would be beneficial for the safety of workers, personnel, and communities associated with the facilities. One commenter stated that the costs for water facilities to convert to safer alternatives are feasible, and remarked that it is possible to adopt IST without disrupting operations.

Alternatively, a few industry trade associations and government organizations stated that STAA should not be applied to water facilities citing that any STAA requirement would be repetitive and counterproductive and that drinking water utilities already have to consider a variety of public health and safety factors under the Safe Drinking Water Act (SDWA).

EPA disagrees with commenters who suggest subjecting water and wastewater treatment facilities to STAA requirements. EPA's approach to applying the STAA requirement was to identify industry sectors with the greatest accident frequency at RMP-regulated facilities within the sector, and with the greatest opportunity to apply STAA risk management measures. While EPA agrees that water supply and wastewater treatment facilities often have feasible alternatives available, according to RMP accident history data, the sector is among the least accident-prone sectors covered under the risk management program. Therefore, the final rule does not apply the STAA requirement to the water and wastewater treatment sector. EPA acknowledges that drinking water utilities already may have considered alternative technologies for their disinfection process while addressing safety and health considerations, risk tradeoffs and compliance with the SDWA.

Limit applicability to major process changes or after accidents. A few commenters want EPA to consider having a requirement similar to that required by Contra Costa County for facilities to conduct an STAA whenever major process changes are proposed and in the aftermath of accidents, when there are often significant opportunities for making process improvements as equipment is rebuilt or repaired. One commenter noted that the CCHS program requires an ISS analysis during the design of new processes, for PHA recommendations, or for major changes resulting from incident investigation recommendations, root cause analysis or MOC review that could reasonably result in a major chemical accident or release. This commenter noted that California's proposed refinery regulations are following the same requirements as the CCHS program. Other commenters recommended that instead of requiring STAA analyses at least every five years in conjunction with the a PHA revalidation, EPA should require the analysis only after accidents.

Another commenter recommended modifying the wording in section 68.67(c)(8) to limit the provisions to new processes or major modifications to existing processes. The commenter also remarked that stationary sources' management of change (MOC) programs should be updated to account for process changes and allow for reassessment of the IST analysis. The commenter concluded that this will ensure that existing IST components are not removed, replaced, or changed without revalidating the IST feasibility criteria.

EPA disagrees that the STAA requirement should be triggered only by a major process change. While the Agency acknowledges that a major process change could be an opportune time to evaluate safer technology alternatives, the Agency is concerned that requiring STAA reviews only after major process changes could result in some processes rarely or never being evaluated for safer technology alternatives. This could occur if few or no major changes occurred during the life of the process. Also, limiting the STAA to only major process changes could create a disincentive to upgrading processes if facilities chose not to make improvements to avoid having to perform an STAA. EPA is also concerned that there is no common definition or understanding of the term ''major process change'' that could easily be applied to the wide range of processes affected by the STAA requirement. Therefore, while EPA agrees that integrating STAA reviews into a facility's MOC program (and other prevention programs) may often be beneficial, the Agency believes it is appropriate to incorporate the STAA provision into the PHA section of § 68.67, rather than the MOC section of § 68.75. Nevertheless, EPA encourages owners and operator to also consider safer technology alternatives whenever major process changes are planned.

EPA is revising the PHA requirements in § 68.67 to require that the PHA address findings from incident investigations as well as any other potential failure scenarios. Other potential failure scenarios may include those introduced from major process changes or new designs or those discovered as a result of an accident investigation. Thus, EPA believes that the PHA with its requirement to encompass IST review as part of the PHA process, would cover the same process changes whether they result from an incident investigation, MOC action or other process change.

Finally, EPA disagrees that the STAA requirement should be triggered only by accidental releases. Although the Agency agrees that accidental releases may indeed signal to the owner or operator that safer technology alternatives should be considered, the Agency prefers that owners and operators evaluate safer technologies before accidents occur, with the aim of ultimately preventing such accidents. Also, similar to the Agency's objection to requiring STAA reviews only after major process changes, requiring an STAA only after an accident would mean that many processes subject to this provision may never undergo an STAA.

Limit applicability of STAA requirements to the design phase of a process. Several commenters, including

industry trade associations suggested that EPA should not require STAAs for existing facilities or processes. Numerous commenters, including facilities, industry trade associations, local agencies, and a Federal agency, stated that an STAA is more appropriate during the design phase of a new process or facility, or during significant modifications. Some commenters, including a local agency, encouraged EPA to require STAAs to consider the highest level of hazard control (referring to the ''hierarchy of controls'') that is feasible during the design phase or whenever a facility makes a change. Another commenter stated that adding a new regulatory requirement, particularly for existing operations, is unnecessary to address inherently safer design, and that safer technology reviews should not be part of a PHA.

In contrast, other commenters urged that safer technologies analyses are an ongoing need and should not be limited to new facilities. A state agency and an individual urged that IST should be performed for all new projects, processes, or stationary sources throughout various phases of a project's life cycle. According to the commenter, performing a separate IST analysis for the entire existing process approximately every five years allows evaluators to see the big picture rather than just the minute details associated with a typical PHA process.

EPA disagrees that STAA analyses should only be required during the initial design phase of a facility. While the greatest potential opportunities for using IST occur early in process design and development, many IST options may still be practicable after the initial design phase. Furthermore, STAA involves more than just IST. Safer technology alternatives also include passive measures, active measures, and procedural measures, and these measures can be modified and improved after the initial design of a facility. EPA notes that many RMP-regulated facilities were originally constructed decades ago, yet major enhancements have been reported in some plants that have been operating for many years.[77] CCPS explains that inherently safer strategies can be evaluated throughout the lifecycle of a process, including operations, maintenance and modification, and EPA agrees with this approach.

Lastly, EPA disagrees that the PHA is not an appropriate risk management program element in which to integrate the STAA. EPA believes that safer technologies can and should be evaluated during the full life-cycle of a covered process, and the PHA is the fundamental and recurring risk management program element concerned with overall analysis and control of process hazards. By integrating the STAA with the PHA, every process subject to the provision will undergo an STAA, every five years. EPA believes that five-year revalidation will give the owner or operator the opportunity to identify new risk reduction strategies, as well as revisit strategies that were previously evaluated to determine whether they are now practicable.

Owners and operators of new construction facilities that will be subject to the RMP rule should consider performing the STAA portion of their initial PHA well enough in advance of facility construction so that the full range of inherently safer designs is considered, and include this evaluation in the initial PHA for the process.

c. Definitions

Feasible definition. Many commenters, including a facility, several trade associations and an environmental advocacy group, remarked that EPA did not sufficiently explain any of the five factors (''economic, environmental, legal, social and technological'') for facilities to consider in the proposed definition of ''feasible,'' and asserted that the examples provided by EPA are unhelpful and vague. The commenters argue that the proposed rulemaking does not provide sufficient guidance on the feasibility component of the STAA review. As such, the commenters conclude that these factors are so expansive and vague that they do not provide any clear guidance as to how feasibility of IST should be determined, and therefore have no place in the RMP rule. According to one commenter, even if the five measures are properly defined, they do not address the full range of issues in the operational life of a project rather than just the processing phase.

A mass mail campaign joined by approximately 300 commenters warned that ''accounting for'' these factors could be used as an excuse to avoid necessary implementation measures.

An industry trade association said that it does not want EPA to elaborate further on the proposed STAA requirement. One commenter stated that it would be very subjective and difficult to prescribe in regulations what is ''feasible'' for a facility and that any ''one-size fits all'' approach to process safety would limit employers' ability to react to real facts on the ground. In regards to incorporating ISTs into safety programs, the commenter asserted that only facility operators know whether IST is appropriate given the complexities of their unique operating environments, and no one program will work for all facilities.

EPA believes that the same tools and methods that facilities currently use for their PHA can be used to identify and measure hazards and risks of any safer alternative options. Further explanation of the economic, environmental, legal, social and technological factors included in the ''practicability'' definition of this final rule can be found in NJDEP's Guidance for Toxic Catastrophe Prevention Act (TCPA)-Inherently Safer Technology (IST) Review, Attachment 1 Feasibility guidance.[78]

EPA did not define the various factors, such as ''economic'' or ''social'' used in the proposed definition of ''feasible'' or in the revised term ''practicability.'' The examples in the proposed rulemaking preamble are taken from the guidelines provided by CCPS, and are not exclusive of other situations. EPA believes that the definition of ''practicability'' in the final rule provides sufficient flexibility for the owner or operator to determine whether an IST or ISD considered could be successfully accomplished. EPA does not believe that we should further define ''economic or social factors'' in the rule because further specificity of these terms would likely be too prescriptive and would not encompass all the possible conditions and outcomes that might be encountered when determining the practicability of an IST or ISD considered in the STAA. EPA expects that facility owners and operators will use their expertise and make reasonable judgements when considering the appropriate meaning of economic or social factors so that any decisions regarding possible implementation of IST is not driven towards changes that would cause unintended adverse consequences.

Finally, EPA disagrees with commenters' assertion that accounting for the factors in the definition of ''practicability'' could be used as an excuse to avoid necessary implementation measures. EPA is not requiring IST or ISD implementation in the final rule and, therefore, further clarifying the practicability definition will not impact IST or ISD implementation.

[77] CCPS. 2009. Inherently Safer Chemical Processes: A Life Cycle Approach, 2nd ed., American Institute of Chemical Engineers, CCPS New York, Wiley, p. 25.

[78] *http://www.nj.gov/dep/enforcement/tcpa/downloads/IST_guidance.pdf.*

Consistency of feasible definition with other programs. A commenter encouraged EPA to incorporate the definition of ''feasibility'' provided in the Contra Costa County Safety Program Guidance Document. Another commenter stated that the proposed definition of ''feasibility'' is consistent with California's proposed California Accidental Release Prevention (CalARP) regulations and the Contra Costa County and the City of Richmond's Industrial Safety Ordinances. However, a state agency, commented that there is an inconsistency with CalARP's definition of ''feasible'' in that the proposed EPA definition omits the terms ''health'' and ''safety,'' and the commenter encouraged EPA to add these terms to the list of factors to consider in a determination of feasibility.

EPA based the feasible definition on the CCHS definition of ''feasible'' but modified the definition to add language acknowledging that environmental factors include a consideration of the potential to transfer risks or introduce new risks to a process or source. The practicability definition in the final rule maintains this language.

EPA disagrees with the suggestion to add the terms ''health'' and ''safety'' to the definition. The primary reason for EPA to consider ISTs in a STAA is to reduce risks to health and safety of the public by mitigating the frequency and severity of accidental releases. EPA believes this is adequately addressed in the definition of ''inherently safer technology or design'' of this final rule and including these factors in the definition of ''practicability'' would be redundant.

Suggested revisions to feasible definition. One commenter argued that the term ''within a reasonable time'' in the definition of ''feasible'' could allow facilities to avoid implementation, and urged EPA to exclude a time based factor from the final definition. This commenter also argued that EPA should not make any level of cost, no matter how minimal, an excuse to not implement any IST measures, but rather should recognize that IST measures should be implemented unless doing so would cause an extremely serious adverse economic effect, such as a facility shutdown. A facility noted that the proposed feasibility analysis does not allow sufficient time to complete the necessary work and recommended that the timeframe be determined on a case by case basis. A state agency commented that the feasibility of an IST must consider factors such as timeliness of implementation and costs. This commenter expressed concern that the definition of ''feasible'' would allow for the implementation of IST options that may not be economically justifiable compared to other equally protective options.

Some commenters recommended deleting the explanation of environmental factors in the feasible definition. These commenters warned that this language is too specific in comparison with the general terms included in the definition. One commenter expressed concern that the language shows an industry bias and suggested using the following alternative definition: ''Feasible means capable of being successfully accomplished within a reasonable time, accounting for economic, environmental, legal, social, and technological factors weighed against the immediate and long-term benefits to safety and health. A claim of infeasibility shall not be based solely on evidence of reduced profits.''

EPA disagrees with the commenters. Cost is a consideration when determining whether a risk management measure can be successfully accomplished and because EPA is not requiring implementation of any IST, we see no reason to exclude this factor from a practicability determination. EPA also disagrees with the suggestion to limit consideration of reduced profits when assessing a risk management measure because the Agency believes that cost is a valid consideration for practicability. Identifying an amount of an allowable cost for an IST is not something that can be prescribed in the regulation because cost decisions are highly dependent on the economics involving a particular process, facility and industry.

EPA also disagrees that incorporating consideration of a reasonable timeframe will allow facilities to avoid implementation. EPA is not requiring IST implementation and we acknowledge that there may exist practical limits on whether some projects or process designs can be done to enhance safety. If a risk management measure cannot be accomplished within a reasonable time, then the facility should ensure that other safeguards are in place to prevent accidents instead of relying on the uncertainty of completing a long-term project that is dependent on future conditions such as process design, operating budgets, etc.

Finally, as other commenters have noted, some ISTs involving chemical substitution or significant process redesign can result in new hazards or risks being introduced, and these should be considered when deciding the practicability of an IST. Thus, EPA is retaining the explanation of environmental factors in the practicability definition in this final rule.

Definition should be stronger than OSHA definition of ''feasible.'' One commenter urged EPA to adopt a definition that is stronger than or at least as protective of health and safety as the OSHA definition of ''feasible'' to provide an appropriate minimum level of protection under CAA—42 U.S.C. 7412(r)(7) that EPA should not go below. The commenter states that under the OSHA standard, a protective measure is technologically feasible if, using existing technology or technology that is reasonably expected to be developed, a typical facility could achieve the standard in most operations most of the time. Additionally, the protective measure is economically feasible if its costs do not threaten the existence or competitive structure of an industry. The commenter contends that OSHA's definition has been interpreted by courts to mean that the mere expense of a measure, alone, cannot trump the implementation of safety measures that are ''capable of being done.'' The commenter believes that EPA should not set a weaker definition that would make it less likely that IST or other prevention measures would be implemented under § 7412(r) than under OSHA's definition. Doing so would be both inconsistent with the objectives of § 7412(r) to protect the public and with the existing framework facilities follow under OSHA requirements, could lead to confusion for facilities and in the courts, and result in an overall reduction in safety measures.

EPA disagrees with the commenter and believes the approach in the final rule to consider the practicability of IST or ISD considered is consistent with the intent of CAA and will not lead to an overall reduction in safety measures. The current rule already requires the PHA to consider active, passive and procedural risk management measures in § 68.67; however, the requirements do not prescribe exactly which type or exactly what engineering and administrative controls must be implemented. The regulations allow facilities to use their specific knowledge and expertise of the process to meet the PHA requirement to ''identify, evaluate and *control* the hazard'' [emphasis added]. EPA is finalizing a requirement for certain sectors to conduct a STAA that also considers IST in the hierarchy of controls. However, requiring facilities to implement IST instead of using passive, active or procedural safeguards can involve extensive and very expensive changes to a facility's

process, depending on the IST, especially if it involves substitution of alternative chemicals and/or major process redesign. EPA believes that a practicability consideration should address whether an IST or ISD can be accomplished technologically, is economically possible, does not result in an increase in hazards or other risks that cannot be controlled, or cannot be successfully accomplished because of other considerations. Therefore, EPA disagrees that the practicability definition should be stronger than (or even similar to) OSHA's interpretation of feasible.

Harmonize feasible definition with OSHA. A facility noted that the proposed definition of ''feasible'' in § 68.3 could cause the potential for confusion because the proposed rulemaking preamble states that OSHA has indicated that it would be unable to adopt the term feasible, as defined in this notice, under its PSM standard if OSHA considers similar revisions involving IST. This is an illustration of the need to harmonize the requirements of EPA RMP requirements with that of OSHA PSM.

A few commenters, including facilities and industry associations, urged harmonization with OSHA's definition of ''feasibility'' and requirements. A facility and an industry trade association warned of the confusion that could ensue if ''feasibility'' is defined inconsistently between EPA and OSHA, and encouraged EPA to use the term ''practicability'' instead. Similarly, an industry trade association urged EPA to use the term ''practical'' in place of ''feasible.'' The industry trade association argued that what is deemed feasible is often not practical for a number of reasons, and asserted that any decision to alter a technology involves a complex variety of factors such as operating costs, associated risk, energy consumption and greenhouse gas emissions. The commenter concluded that only facility owners should ultimately be able to define what is feasible or practical for their facility. In contrast, a state agency encouraged use of the term ''feasible'' rather than ''practical.'' An industry trade association asserted that neither term should be the basis for the analysis.

EPA agrees with commenters and is revising the rule to replace the term ''feasible'' with ''practicability.'' EPA proposed to use the term ''feasibility'' as part of the STAA analysis as it is already widely used in the technical literature discussing IST. However, because OSHA is considering similar revisions to its PSM standard involving IST and in order to eliminate the potential for confusion of different meanings of the term ''feasible,'' [79] EPA has decided to use the term ''practicability'' while retaining the same definition and meaning used for ''feasible'' in the proposed rulemaking.

Hierarchy of controls. A commenter noted that California's proposed regulations for refineries and EPA's proposed regulations would require that the facility look for inherently safer means to reduce the hazards, but if there is not a means to reduce the hazard, the facility would go through a hierarchy of prevention methods and select the highest level of prevention. This commenter and another requested that EPA use the term ''Hierarchy of Control,'' which is a term that is already understood, instead of adding a brand new term.

EPA does not use the term hierarchy of control (nor substitutes a new term for it) but instead explicitly explains the concept in the regulation by stating that the owner or operator shall consider risk management measures in the following order of preference:

- Inherently safer technology or design,
- Passive measures,
- Active measures, and
- Procedural measures.

EPA believes this is consistent with proposed CalARP regulations [80] for Hierarchy for Hazard Control Analysis, which require refineries to eliminate hazards using first order inherent safety measures; to reduce any remaining hazards using second order inherent safety measures; and to address any remaining risks in the following sequence and priority by using passive safeguards, active safeguards, and procedural safeguards.

Passive measures. A commenter recommended revising the definition of ''passive measures'' to ''mean risk reduction measures designed to reduce the probability or the consequences of an accidental regulated chemical release without human intervention'' to better reflect that EPA probably meant ''reducing the hazard'' as an aspect of risk management. The commenter views ''hazard'' as the inherent capacity of a substance to cause an adverse effect, while ''risk'' is the probability that an adverse effect will occur, if one uses OSHA's definition of the terms. In addition, the commenter said that the definition of ''other energy inputs'' needs revision, and suggested replacing the phrase ''energy inputs'' with ''human intervention'' to meet the intent of the definition. This commenter expressed concern that the word ''other'' in the phrase ''other energy input'' mischaracterizes pressure vessel designs, dikes, etc. as energy inputs. This commenter also suggested that passive ''design features'' could include mechanical or energy intervention measures and the commenter cited examples such as automatic fire suppression systems and automatic vapor ignition.

EPA agrees with the commenter's suggestion to revise the definition of ''passive measures'' to address the frequency and consequence of the hazard. EPA based the proposed definition of ''passive measures'' on the definition used by CCPS, which defined ''passive'' as ''minimizing the hazard through process and equipment design features that reduce either the frequency or consequence of the hazard without the active functioning of any device, *i.e.,* providing a dike wall around a storage tank of flammable liquids.'' [81] Thus the intent of the CCPS definition appears to be on aspects of both hazard and risk reduction. EPA is modifying the ''passive measures'' definition in the final rule to clarify that passive measures reduce the frequency or consequence of the hazard.

EPA disagrees that the word ''other'' in ''other energy inputs'' characterizes pressure vessel designs and dikes as energy inputs and also disagrees that passive design features would include automatic fire suppression systems or automatic vapor ignition (in which a flare is ignited). These types of measures would most likely be considered to be active measures. CCPS, in their Guidelines for Hazard Evaluation Procedures,[82] cites a fire protection system as an active safeguard because a fusible link or other engineered device must function to successfully trip the system.

IST/ISD. A number of commenters, requested clarification on the definition of IST, ISD or Inherently Safer Measures. A few wanted clarification as to what would qualify as ''safer'' in this context. One labor union expressed general support for the proposed definition of IST. One commenter asked

[79] 81 FR 13667, March 14, 2016.

[80] Draft California Accidental Release Prevention Program (ARP) Regulations, California Governor's Office of Emergency Services. July 5, 2016, p. 83 *http://www.caloes.ca.gov/FireRescueSite/Documents/CalARP%20Proposed%20Regs%202016.pdf.*

[81] CCPS. 2009, Inherently Safer Chemical Processes: A Life Cycle Approach. 2nd ed., p. 10. *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0253.*

[82] CCPS. 2008, Guidelines for Hazard Evaluation Procedures. 3rd ed., p. 234. *http://www.aiche.org/ccps/publications/books/guidelines-hazard-evaluation-procedures-3rd-edition.*

EPA to ensure that there is a distinction between IST and less effective controls and management methods. This commenter argued that chemical substitution and process changes are the most effective methods to protect workers and the public from incidents and that these ''inherently'' safer options should be distinguished from less effective controls and management methods. The commenter cited lesser effective controls from the NJDEP IST compliance, such as safer extremely hazardous substance risk location, protection of storage vessels from weather conditions, changes in truck traffic patterns, addition of EHS leak detectors, use of closed circuit television systems, labeling of valves and equipment, revising procedures, installing a simulation training station, and adding light towers for EHS leak alarms. The commenter requested that EPA develop a precise definition for IST and Inherently Safer Design (ISD).

EPA disagrees with the commenters' suggestions to provide a distinction between IST and other controls and management methods. EPA believes that determining effective risk management strategies for a facility is a site-specific determination and EPA encourages any improvement that will could lead to inherently safer conditions. Therefore, EPA is finalizing the definition of IST/ISD as proposed.

EPA based its definition of inherently safer technologies (IST) or design (ISD) on the four inherently safer strategies as explained in the Inherently Safer Chemical Processes: A Life Cycle Approach by CCPS.[83] These four types of strategies have been widely recognized by the industry and best encompass the concepts and principles of applying inherent safety, which focuses on eliminating or reducing the hazards associated with a set of conditions.

As the 2010 CCPS Final Report: Definition for Inherently Safer Technology (IST) in Production, Transportation, Storage and Use[84] states:

> IST (Inherently Safer Technology), also known as Inherently Safer Design (ISD), permanently eliminates or reduces hazards to avoid or reduce the consequences of incidents. IST is a philosophy, applied to the design and operation life cycle, including manufacture, transport, storage, use, and disposal. IST is an iterative process that considers such options, including *eliminating a hazard, reducing a hazard, substituting a less hazardous material, using less hazardous process conditions, and designing a process to reduce the potential for, or consequences of, human error, equipment failure, or intentional harm.* [emphasis added]

The CCPS guidance is organized by these four strategies and provides many examples of each type of strategy. NJDEP also uses descriptions of the four strategies to identify available IST alternatives in their inherently safer technology review requirements.[85] Although some NJ facilities may have reported some controls that others might not strictly view as IST, EPA does not believe that IST should be limited only to chemical substitution and process changes. Some changes such as better labeling of equipment are cited as examples of process simplification in CCPS' IST Checklist. Changes involving transportation of chemicals and storage location are also cited in the checklist because inherent safety can involve reduction of hazard, and does not require complete elimination of a hazard.

d. General Comments on STAA Requirements

Suggestions for minimal elements for STAA methodology. An environmental advocacy group noted that in the proposed rulemaking, EPA states that owners and operators may use ''any available methodology or guidance'' to conduct their STAA, but urged EPA to define the minimum basic elements that owners or operators must include in their STAA. The commenter believed the STAA should include an analysis of the technical, economic, legal/regulatory, social, and hazards implications of each major technology option, and noted that the sample methodologies and guidance listed in the proposed rulemaking may not include all of these elements. The commenter urged EPA to require the economic analysis to include potential liabilities, costs, avoided costs, and savings associated with each major STAA option evaluated.

EPA does not believe it should specify factors other than those already present in the PHA and STAA requirements, including the definition of ''practicability.'' EPA believes that various resources and guidance exist (as well as existing PHA methodologies, such as HAZOP, What-If? Method, or checklists or a combination of these as discussed in Chapter 8 of CCPS' book, *Inherently Safer Chemical Processes: A Life Cycle Approach*[86]) that can assist facilities in understanding how IST can reduce hazards and risk and in determining practicability of IST or ISD considered in the STAA. Facilities can follow, for example, guidance for IS Review Documentation found in CCPS's Inherently Safer Chemical Processes, which suggests documenting the summary of the approach used for the IS review (*i.e.,* methodology, checklist, etc.), names and qualifications of the review team, IS alternatives considered, as well as those already implemented or included in the design, results of each consideration including those not considered and why, documentation of feasibility and rationale for rejection of IS opportunities.

While some facilities may choose to conduct an economic analysis of potential liabilities, costs, avoided costs, and savings associated with each major STAA option evaluated, EPA is only requiring facilities to determine whether IST is practicable and document this determination. It may not be always be possible to estimate avoided costs and savings for a particular IST.

STAA is not a suitable replacement for other prevention program measures. An association of governments expressed concern that analyses will not prevent accidents because human factors such as operational bias towards production rather than safety, failures to manage changes, failures to provide adequate training for employees and failures to follow standards cannot be eliminated by a safer technology analysis. The association warned that the analysis could be used as a substitute for appropriate emergency preparedness and accident prevention programs. The commenter also believed that adoption of safer technology without a holistic review of risk transfers might be dangerous.

EPA does not believe or intend that a safer technology analysis as part of the exiting PHA would negate the need or requirements for facilities to follow other RMP rule provisions, such as training, managing change, and following RAGAGEP. Rather this analysis is designed to supplement or enhance the ways that hazards or risks of an accidental release can be eliminated or reduced by possibly more rigorous risk reduction measures.

[83] CCPS. 2009, Inherently Safer Chemical Processes: A Life Cycle Approach. 2nd ed., *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0253.*

[84] CCPS. July 2010. Final Report: Definition for Inherently Safer Technology in Production, Transportation, Storage, and Use, *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0274.*

[85] NJDEP TCPA. March 29, 2012. NJ Title 7, Chapter 31 TCPA Program Consolidated Rule Document, *http://www.nj.gov/dep/rules/rules/njac7_31.pdf.*

[86] CCPS. 2009. Inherently Safer Chemical Processes: A Life Cycle Approach, 2nd ed., American Institute of Chemical Engineers, CCPS New York, Wiley.

Facilities can evaluate the feasibility of potential safer technologies and this evaluation can and should take into account any known transfers of risk, as well as other considerations. For this reason, EPA is not prescribing that facilities adopt any particular safer alternative and is allowing any decision on implementation of IST to be made based upon a facility's judgement using accepted hazard analysis and their knowledge of their processes, hazards, risks and methods to control hazards. EPA does not believe the analysis could be used as a substitute for appropriate emergency preparedness and accident prevention programs—existing requirements in these areas are still in place and this final rule also provides more emphasis on emergency coordination and response (for more information see section V of this preamble).

STAA guidance, regulatory incentives and voluntary partnership programs. An industry trade association suggested the establishment of a working group to develop decision framework and guidance materials for STAAs. The commenter remarked that creation of a working group would be more effective than mandating RMP facilities to conduct STAAs with insufficient guidance. A commenter recommended that the working group should consider existing voluntary programs that include a safer alternatives assessment, and should consider the possibility of establishing a public-private partnership. The commenter further explained that the working group should explore how EPA could leverage these programs by providing regulatory incentives to those who participate in and fulfill the requirements of the voluntary programs. The commenter also suggested that a partnership could be created based on the core principles adopted by industry (*i.e.,* stewardship) programs and the lessons learned from existing and past voluntary partnership programs. The commenter stated that such a program could provide technical assistance and tools to help create awareness and instill a quality culture of safety and security. The commenter provided a white paper with more detailed discussion on the potential purposes, components, incentives and requirements for a voluntary partnership program to improve chemical safety and security.

EPA appreciates the commenters' suggestions for developing guidance, regulatory incentives and partnership programs for STAAs. EPA is finalizing a regulatory provision requiring Program 3 industry sectors in NAICS codes 322, 324, and 325 to conduct an STAA as part of the PHA and determine the practicability of IST or ISD considered. EPA disagrees that STAA should be limited to a voluntary partnership program; however, EPA will further consider the merits of a potential voluntary partnership program with industry to engage in improved process safety practices.

EPA believes the STAA requirements are flexible and allow the use of industry expertise to best decide which safer technologies and alternatives to consider, and to determine the practicability of IST or ISD considered in the STAA. EPA will develop guidance for complying with RMP PHA and STAA requirements before sources must comply with the STAA provision required in this action. A draft of this guidance will be available for public comment.

Making STAA information available to LEPCs. A facility is concerned that the proposed requirement to share information pertaining to inherently safer technology or design with the local LEPC would require specific detailed information that the LEPC may not consider relevant. While the facility expressed willingness to share appropriate information with the LEPC, the facility does not believe the LEPC would be interested in the minute details of the changes in process units. An industry trade association stated that not requiring implementation while requiring facilities to provide LEPCs the date of implementation or planned implementation could cause confusion.

EPA agrees that providing LEPCs with detailed information regarding process changes involving IST or ISD may not always be relevant or necessary to community emergency preparedness or can be confusing. The final rule eliminates the proposed requirements under § 68.205 to provide information to the LEPC, upon request (including IST information). For more information about how the final rule addresses sharing information with LEPCs or emergency response officials, see section VI.A. of this preamble.

e. Including STAA as a PHA Requirement

Appropriateness of PHA techniques or process for STAA. A few local agencies expressed support for STAA measures being used as a method of addressing PHA recommendations. Commenters, including a local agency, encouraged the review of the STAA at least every five years.

However, several commenters opposed including STAA in the PHA. Two trade associations commented that requiring PHA teams to evaluate the feasibility of IST has the potential to undermine the effectiveness of the PHA process. The commenters argued that regulating IST is infeasible because there is no simple answer when it comes to managing risk. The same two trade associations and one facility asserted that a PHA review of an existing process considers the adequacy of the existing controls for that process while an IST review is entirely different. The commenters believe an IST review involves a comparison to a different technology and an operation-specific and site-specific evaluation based on engineering judgment, in which many variables are considered that include hazards, the location of the facility, surrounding populations, exposures, technical feasibility and economic feasibility. A state agency and an industry trade association warned that requiring STAA during the PHA would be inappropriate because the structure of a PHA does not facilitate such an analysis.

A facility expressed concern that none of the PHA methodologies described in the NPRM require this type of comparison, arguing that IST/ISD methodologies are similar, but not identical, to PHA analysis techniques. The facility stated that it would be wrong to assume that STAA can be directly incorporated into existing PHA methodologies. A trade association commented that in order to have PHA team members perform a comparative analysis on alternatives, the PHA team would be required to compile relevant process safety information for the alternatives in order to perform the IST analysis.

One commenter believes that IST needs to be evaluated outside of the PHA process because the node-to-node hazard and operability study (HAZOP) approach is minutely focused, does not look at the bigger picture and reduces the impact of IST to localized risk reduction measures rather than making the whole process inherently safer. The commenter stated that a separate IST analysis for the entire existing process is needed and could be performed every five years but separately from the PHA since different team participants (such as technical experts) are usually needed.

One trade association and a facility believed that IST analyses are not practical to conduct as part of a PHA for a defined process with defined chemicals. The commenters claimed that to consider a substitute, a facility operator would need to design the new process before being able to conduct the analysis. Some facility commenters reasoned that design and hazard reviews for new facilities can take place years

before any PHA. An industry trade agency suggested that EPA should include appropriate lead-time and grandfathering provisions so as not to disrupt projects already in the design or construction phase. Finally, an industry trade association asserted that IST decisions are very complex and should not be determined by any government agency, and recommended that EPA delete the proposed STAA provisions.

EPA believes that IST analysis can be incorporated in the existing RMP PHAs by using PHA techniques such as HAZOP, What-If? Method, or checklists or a combination of these as discussed in Chapter 8 of CCPS' book, *Inherently Safer Chemical Processes: A Life Cycle Approach.*[87] These techniques themselves are not requirements, but tools available to help the facility owner or operator to identify, evaluate and control the hazards involved in the process.

While developing the original RMP rule, EPA noted some commenters strongly opposed any requirement for safer technology analyses because PHA teams regularly suggest viable, effective (and inherently safer) alternatives for risk reduction. In the preamble to the original RMP rule, EPA agreed with these commenters, indicating that ''application of good PHA techniques often reveals opportunities for continuous improvement of existing processes and operations without a separate analysis of alternatives.'' [88] While these comments in 1996 led us to not require STAA in the original rule, further developments in STAA, and EPA's own experience with implementation of the rule, now indicate that a specific mandate to conduct STAA reviews as part of the PHA will encourage facilities who were performing PHAs that were of lower quality but legally compliant with the old rule, to perform better PHAs.

Therefore, EPA disagrees with commenters that argue it is not appropriate to include an STAA in the PHA. In fact, the RMP PHA requirements include other aspects of an analysis that is typically associated with process design. For example, the PHA must also address stationary source siting issues which involve the location and proximity of the source to local population and their numbers.

Nevertheless, EPA agrees that for situations where an IST would involve a new process that is entirely different from the current process, the process design would have to exist or be developed, and process safety information be compiled, to conduct a PHA for this new process. EPA does not expect facility owners or operators to research and create new process designs or conduct research into all possibilities for the use of new chemicals. Instead, the STAA should focus on the known and existing substitute processes and chemicals that have been demonstrated to be in use commercially.

If a facility is considering a chemical substitution or process change that involves a significant redesign of their process, such efforts involved with redesign and its evaluation may need to be undertaken as part of a practicability study.[89] The definition of ''practicability'' allows for consideration of technological factors, which could include whether the potential safer alternative can be designed and operated to meet the process functions needed. However, not all IST involves substituting a chemical or an entirely new process and there are other types of other IST measures (minimization, moderation or simplification) that can be considered to address various points within the current process where hazards and risks exist. Furthermore, the final rule does not require the facility to implement IST measures.

Facilities may, if desired, conduct a separate IST analysis of each covered process, outside of the PHA, if desired, as long as it is done in same timeframe as the PHA and the results are documented. If a facility does not have staff capable to identify and evaluate alternatives, the facility owner or operator may require outside assistance from engineering firms or consultants.

The RMP PHA requirements require the facility owner or operator to identify risk management measures that eliminate or reduce the risks from the process hazards. If the facility has already performed such IST analysis in the past, then the owner or operator should consider these analyses when updating or revalidating their PHAs and determine whether there is new information that should be considered as part of conducting the current STAA.

Involvement and training of employees and team members. An industry trade association expressed concern about the potential experience limitations of the PHA team. The commenter stated that team members may lack the expertise required to assess all alternative technologies, and said that in the case of inadequate experience the STAA should be considered within the management of change element of the RMP and the facility's ongoing risk assessment analysis. Two trade associations commented that a PHA and an IST analysis serve two entirely different engineering functions and the teams that conduct these reviews are staffed differently. The two associations further commented that small facilities do not have staff design engineers to conduct an IST review, which means the facility would be required to absorb the cost of retaining them even though there is no requirement that their findings be implemented.

One Federal agency commented that throughout the SBAR panel process, SERs noted that this analysis would require additional staffing such as design engineers, in addition to the chemical and mechanical engineers already staffed for PHA analyses. The SERs added that most small facilities do not have design engineers on staff and as a result, would need to incur additional expenses to retain them.

Another commenter stated that conducting a full IST/ISD review based on yet-unproven technologies typically is an extremely complex endeavor (particularly for a chemical production process), and would require very different PHA teams that could adequately assess IST/ISD (*e.g.,* to adequately study how the hypothetical use of new IST/ISD might create additional, unanticipated hazards throughout a process).

Another commenter suggested that the PHA/hazard review team should be properly educated in inherent safety analysis. A professional organization encouraged the participation of workers in the STAA process, but urged that these employees must have proper training and education to participate. Some commenters recommended engaging workers in the alternatives and feasibility assessment process and making sure they have the ability to report anonymously and hold whistleblower authority. One commenter urged EPA to explicitly state that union representatives and workers can participate fully in the STAA.

EPA believes that limiting the applicability of the STAA requirement to only those facilities in Program 3 in the petroleum and coal products manufacturing (NAICS code 324), chemical manufacturing (NAICS code

[87] CCPS. 2009. Inherently Safer Chemical Processes: A Life Cycle Approach, 2nd ed., American Institute of Chemical Engineers, CCPS New York, Wiley.

[88] See 61 FR 31699, June 20, 1996.

[89] EPA modified the final rule to replace the term ''feasible'' defined in § 68.3 with ''practicability.'' When evaluating the practicability of an IST, the facility owner or operator would determine whether the IST is capable of being successfully accomplished within a reasonable time, accounting for economic, environmental (including consideration of potential transferred risks for new risk reduction measures), legal, social, and technological factors.

325) and paper manufacturing (NAICS codes 322) minimizes the burden of the requirement for many small businesses. Of those approximately 1,557 facilities that are subject to the STAA requirements, approximately 40% of them are owned by small entities, however, about 86% of these small entity-owned facilities have 20 or more full-time equivalent employees.[90] EPA agrees that team members conducting an STAA should be properly trained and knowledgeable on how to conduct the analysis. The facility owner or operator is responsible for ensuring that facility personnel have the proper training to conduct STAAs or hire consultants with the appropriate qualifications. EPA expects that some facilities in NAICS codes 322, 324, and 325 will have staff qualified to conduct the analysis. If the facility owner or operator determines that two different teams should conduct the PHA and STAA, then they may choose to conduct a separate STAA of each entire process, outside of the PHA as long as it is done in same timeframe as the PHA and the results are documented.

As discussed in the RIA, the technical practicability assessment considers the extent of process redesign, its engineering implications, and possible costs. EPA estimates that most facilities except the large facilities in NAICS codes 322, 324, and 325 will seek help from consultants (*i.e.,* engineering firms) to conduct STAA and determine the practicability of IST/ISD considered. However, EPA does not expect facilities to spend resources evaluating hypothetical untested alternatives that they believe are not proven within their industry.

Finally, the final rule provides facility owners or operators the flexibility to use facility personnel with expertise and experience with facility processes and their industry to conduct STAAs and determine the practicability of IST/ISD considered. However, EPA does not believe the RMP rule is the appropriate mechanism to address worker rights or whistleblower protections.

Overlap or conflict with PHA analysis. A few industry trade associations and a facility expressed concern that an IST analysis would detract from the goal and focus of the PHA process to identify hazards to be addressed and to identify opportunities for continuous improvement of operations. For example, one commenter was concerned that in an effort to ensure compliance with new safer alternative technology analysis regulations, PHA teams may be distracted from identifying and addressing the hazards of existing processes by spending too much time assessing potential alternative technologies with which they have no experience. Two commenters elaborated, stating that requiring IST or ISD ''consideration'' based on a laundry-list of ''factors'' would substantially increase the already extensive time that is required to complete a PHA, and favor subjective reviews over objective reviews of actual safety problems and the most direct and timely techniques required to resolve them.

EPA disagrees with the commenters. The RMP PHA requirements are not only to identify hazards but also to incorporate measures to reduce or mitigate those hazards. Under § 68.67(a), the rule requires the owner or operator to identify, evaluate and control the hazards involved in the process. Several commenters acknowledge that some companies already evaluate ''safer alternatives'' during their PHAs when it is efficient to consider fundamental process changes. EPA disagrees that consideration of additional inherently safer measures necessarily precludes addressing hazards and applying other risk reduction measures in the hierarchy of controls. If facility owners or operators are concerned that an IST assessment could preclude other aspects of the PHA, they may choose to conduct the STAA separately from the PHA, as long as it is performed on the same timeframe and documented.

IST already incorporated as part of PHA or otherwise considered. Another industry trade association remarked that STAA requirements are already a component of the PHA and concluded that costs of the new requirement would be redundant, but that these costs are incommensurate with the much lower risks faced by facilities in their industry. One trade association disagrees with requiring STAA as part of the PHA because currently approved PHA methodologies already provide for successful risk mitigation (reducing risks to personnel and the environment to 'acceptable' levels), including the consideration of inherently safer design technologies by the PHA team where appropriate. A commenter noted that some companies already evaluate ''safer alternatives'' during their PHAs when it is efficient to consider fundamental process changes. However, they consider available, proven technologies, not ''potentially'' safer technology that may be noted in literature, but not yet in use anywhere within their industry. Another industry trade association remarked on the importance of process safety information for alternatives and its availability to the PHA team. A process safety organization commented that they believe the existing provisions to conduct a PHA automatically includes the team to consider safer alternatives as appropriate and applicable. An industry trade association said that many of the activities being reported as IST in NJDEP's IST Implementation Summary, were activities that already occur as a matter of course in most facilities.

A facility and multiple industry trade associations remarked that other programs such as the Department of Homeland Security's Chemical Facility Anti-Terrorism Standards (CFATS) already provide incentives for facilities to promote safe practices, and implement safer alternatives and designs. Several commenters urged EPA to avoid burdensome requirements that overlap with the CFATS program at additional cost without added benefit. An industry trade association noted that CFATS allows facilities to move to a lower risk tier or out of the program if risk profiles are reduced and vulnerabilities are minimized, resulting in roughly 3,000 facilities that have changed processes or inventories in ways that have enabled them to be excluded from the program. This commenter notes that DHS's risk performance-based approach does not mandate solutions, recognizes the unique situation of each facility, and embraces a public-private sector effort for implementation of safer measures. The commenter further indicated that mandating the adoption of government-selected ISTs would be unduly burdensome, particularly for smaller chemical facilities, and could hinder their overall efforts at improving security.

While EPA recognizes that some facilities may already consider ISTs as part of a PHA, whether as part of a voluntary program or through other incentives, EPA believes that all facilities in NAICS 322, 324, and 325 industry sectors should consider IST to ensure that they are considering all the options to operate their facility safer. EPA expects that these regulatory requirements will raise industry awareness of IST possibilities and will reduce risk. EPA is not mandating implementation or adoption of any particular IST and will rely on facility expertise to reduce the hazard and mitigate risk without causing undesirable consequences such as reducing product quality or transferring risk to some other point in the supply chain.

[90] Regulatory Impact Analysis, Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7), using data from Exhibit 7–3 and 7–5.

Furthermore, EPA disagrees with commenters that asserted that the STAA requirements will overlap with other regulatory requirements and result in an increased burden with no corresponding benefit. In its 2007 Interim Rule for CFATS,[91] DHS stated that Section 550 of the Homeland Security Appropriations Act of 2007 prohibited the Department from disapproving a site security plan ''based on the presence or absence of a particular security measure,'' including ISTs.[92] DHS noted that, even so, covered chemical facilities are certainly free to consider IST options, and their use may reduce risk and regulatory burdens. Therefore, because DHS does not require IST or the assessment of IST, EPA does not believe there is an ''overlap'' in requirements. Furthermore, DHS requirements address site security measures, and not measures designed to reduce accidental releases.

Potential for risk tradeoff or risk transfer. Some commenters, including an association of government agencies and an industry trade association, encouraged a holistic review of IST to avoid or minimize risk transfers. A few commenters stated that, for example, a facility adopting a safer technology may increase transportation requirements of hazardous materials and increase risks of incidents outside of the facility, including necessitating more exotic emergency response equipment or preparation. One commenter noted that minimization frequently involves the decrease of on-site storage and could result in the potential for additional shutdowns and startups due to insufficient raw materials. The same commenter further indicated that substitution of a purportedly safer alternative may introduce environmental or safety risks that are not realized until much later.

In contrast, an advocacy group urged EPA to consider that the commenters citing risk transfer are often industry funded and, in the opinion of the commenter, overlook risk transfer that is caused by actions of the facilities themselves. A process safety organization stated that EPA should not require an STAA as part of a new prevention program, as part of the existing PHA/hazard review, or as a requirement under CAA section 112(r) because the definition of ''inherently safer alternatives'' has always been very debatable and use of these alternatives may not result in the overall reduction of the total quantitative risk of the facility. The organization expressed concerns that a verbatim statement of consideration and/or implementation of inherent safer options has the potential for unintended outcomes, such as risk transfer, risk accumulation, increased opportunities for terrorism, and other undesirable tradeoffs. This commenter recommended that EPA should not require the IST analysis because few technologies would be inherently safer with respect to all hazards, there may not be a clear implementation path for all situations, and facilities would have to address multiple tradeoffs in the decision making process. The commenter warned that improper implementation of a ''safer'' alternative may have negative consequences. Some commenters note that an absolute safer alternative is highly dependent on the hazard, the process, the technology and the facility. For every process there could be different type of alternative chemical use.

EPA recognizes the risk transfer concerns raised by the commenters. However, EPA believes that the final rule allows the owner or operator to consider the potential for quantitative risk reduction, risk transfers and tradeoffs when determining whether it is practicable to implement ISTs or ISDs considered. EPA agrees that some technologies may not be inherently safer with respect to all hazards, may not be implementable for all situations and may involve multiple tradeoffs in the decision making process. IST is a relative concept dependent on the hazard, the technology, and the facility. Therefore, EPA is requiring facilities to only consider IST as a possibility for addressing hazards rather than requiring ISTs be implemented. The final rule gives the facility owner or operator the flexibility to assess IST as well as passive, active, and procedural measures to reduce risk associated with a process and to determine the practicability of any IST considered based on various factors (including those involving risk transference).

Current PHA requirements and other risk reduction measures already adequate address risks. Several facilities and industry trade associations urged that existing requirements and principles, such as PHA and Layer of Protection Analysis (LOPA), are sufficient for determining if proper safeguards are in place in existing process units. Industry trade associations said that LOPA or similar risk-based analyses are more easily implemented and cost effective than IST, and stated that risk-based analyses also minimize risk shifting. A state agency urged EPA to require a LOPA but to ensure that it is clearly separated from the STAA.

Some facilities and an industry trade association remarked that industry has proven capable of reducing hazards from current operations by using active, passive, or procedural measures. A facility and an industry trade association asked why the proposed rulemaking is not specifically focused on STAAs for new or potential processes when, according to the commenters, nothing indicates that IST evaluations have become more beneficial or less expensive for existing process units since the 1996 RMP rule.

A facility asserted that current regulations that require compliance with RAGAGEP already ensure that appropriate controls are implemented in equipment and processes. One commenter expressed concerns that the STAA evaluation will become a paperwork exercise that will not result in any increase to safety. This commenter suggests that EPA require a review of safer technology or IST only when the PHA results show that a technology or design scenario does not meet the company's appropriate risk tolerance/reduction requirements.

EPA believes that where feasible, reducing or eliminating hazards through change in materials, chemistry, or process variables is preferable to adding layers of safety to a process. While layers of passive, active or procedural controls will reduce the risk, they will do nothing to reduce the nature of the hazard itself. Failure of control devices or human error can result in an accidental release. However, an inherent safer strategy seeks to preferentially remove the hazard at the source, as opposed to accepting the hazard and attempting to mitigate the effects.[93] In addition to eliminating or reducing a hazard, IST can also minimize the impact of a release or terminate the accident sequence before there are major impacts on people, property or the environment.

EPA agrees with other commenters who have indicated that the PHA can and should consider IST as hazard reduction or risk management measures where feasible and appropriate. Opportunities for the application of the

[91] See 72 FR 17718, April 9, 2007, *https://www.gpo.gov/fdsys/pkg/FR-2007-04-09/pdf/E7-6363.pdf.*

[92] Section 550 has since been replaced by the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014, Public Law 113–254. However, the prohibition on DHS disapproving a security plan based on the presence or absence of a particular security measure remains. See 6 U.S.C. 622(c)(1)(B).

[93] CCPS. 2009, Inherently Safer Chemical Processes: A Life Cycle Approach. 2nd ed. American Institute of Chemical Engineers, Center for Chemical Process Safety. pp. 10–11.

inherently safer strategy of simplification can be evaluated for each safety device or procedure during a PHA as well as in review of mechanical integrity program practices and procedures. CCPS provides examples for this.[94] Although we agree that the general principles of PHA combined with LOPA may at times be appropriate to address the risk of an accidental release, EPA believes that facility owners or operators should consider IST first in the hierarchy of risk reduction measures to reduce and/or control the hazards of a process.

Consideration of untested and unproven technologies. One commenter was concerned that any potential IST considered should not have to include untested and unproven technologies. An industry trade association urged that technology takes time to mature and become acceptable and safe for widespread use. Concerns were that facilities might be encouraged to substitute novel and untested controls for existing controls and layers of protection that are in place at existing processes to control and manage risks, detracting from actual safety performance. One commenter was concerned that operators should not be required to update or replace technology on a year-in, year-out basis simply because new technologies are introduced into the marketplace. One commenter stated that any alternative considered should be easy to be applied and should have been properly tested.

EPA agrees that a facility owner or operator may conclude that IST measures that have not been tested or used commercially should not be considered. It may be difficult to evaluate the practicability of hypothetical technologies or those that are still undergoing research and testing.

f. General Opposition to STAA

Benefits and cost of STAA not adequately explained or justified. Commenters warned that analysis of existing facilities and processes is unlikely to provide significant insights or opportunities for safety improvement, but may be very costly. A facility and a number of trade associations asserted that IST analysis would not meaningfully increase safety. Stating that safer technology would have been adopted if it made business sense to do so, a facility remarked that the STAA requirement is unnecessary.

An industry trade association and a facility expressed concern that the process of retrofitting existing facilities would be expensive and could result in facilities shutting down. Several commenters agreed with EPA conclusions made in the 1996 RMP rule regarding an IST analysis mandate where the agency stated, ''EPA does not believe that a requirement that sources conduct searches or analyses of alternative processing technologies for new or existing processes will produce additional benefits beyond those accruing to the rule already.'' The commenters, including a facility and industry trade associations, warned that EPA changed its position on whether or not a mandatory IST analysis leads to any incremental benefits, without any clear rebuttal, analysis, explanation, or substantiation of benefits from the STAA and urged EPA to withdraw the STAA mandate from the proposed rulemaking. An industry trade association, agreeing with EPA's 1996 assessment, remarked that the new conclusion was made without regard for the nature of the reported accidents or any scientific support. Many commenters stated that requiring STAAs would create a burden for industries that would not produce any significant benefits if the existing process has already had risks addressed by a PHA. A few commenters asserted that, for most facilities, an IST analysis would likely produce limited options that would not justify the cost and effort of the exercise itself.

Two industry trade associations contend that there is no data to suggest that requiring an STAA analysis provides any measurable benefit or reduces the frequency or severity of incidents or any empirical studies showing that STAA effectively improves process safety. They believe that the analysis of the New Jersey data for facilities conducting IST analysis since 2008, shows no decrease in reportable accidents and that revising the RMP rule will likely have a negligible effect at great cost to covered facilities. Commenters asked whether or not EPA's analysis of the IST programs implemented by New Jersey and Contra Costa County has yielded any concrete data demonstrating that the programs have successfully reduced hazardous safety risks over voluntary adoption. One commenter urged EPA to withdraw the proposed IST requirement until EPA has conducted such an analysis.

Several trade associations commented that the regulatory burden of requiring costly IST reviews tends to stifle innovation. The commenters asserted that for those companies already looking to improve safety by implementing IST options, a formal IST review would add costs to a process by forcing them to document the activities they are already performing. They further indicated that small operations might not have the manpower or expertise to do this and lack the resources to hire it out cost effectively. The same commenters further stated that for companies that do not implement IST options, the IST review becomes a ''paper exercise'' where they document why it is ''infeasible'' to implement these options. Another commenter argued that if EPA only intends for an analysis to be conducted and not for the technologies to be implemented, then the proposal should be withdrawn on the basis that it provides no benefit to the public.

One trade association commented that there is no value in having a facility perform an IST assessment if one was already performed earlier in the lifecycle of the process or to repeat the same STAA every five years on the same process. The association asserts that nothing new will be learned from doing so.

According to a facility and some industry trade associations, the claim in the proposed rulemaking preamble that voluntary adoption of IST is becoming more prevalent indicates that the incremental benefits of mandatory adoption are decreasing, which the commenters remarked would be in line with the 1996 decision not to require IST analysis.

EPA believes that the STAA should identify potential process changes including IST that, if implemented, would result in owners or operators using less hazardous substances, minimizing the amount of regulated substances present in a process, moderating process conditions, reducing process complexity, or implementing passive, active, or procedural changes to make processes safer. Such changes help prevent accidents by either eliminating the possibility of an accidental release entirely, by making a process more fault-tolerant, such that a minor process upset or equipment malfunction does not result in a serious accidental release, and by reducing the severity of releases that do occur. The STAA provision does not actually require the owner or operator to implement any changes, so facilities will only incur additional costs beyond the analysis when the benefits of the change make adoption of the change reasonable for the facility.

IST is widely recognized as a concept or principle that can be used in process safety management along with other types of hazard reduction measures to eliminate or reduce the frequency and/or impact of accidents. As recognized in

[94] CCPS. 2009, Inherently Safer Chemical Processes: A Life Cycle Approach. 2nd ed. American Institute of Chemical Engineers, Center for Chemical Process Safety. pp. 112–113.

process safety technical literature, the benefit of using practicable IST as the first choice for accident prevention is more likely permanent risk reduction. Some trade associations agree that individual companies often consider inherently safer approaches or safer alternatives as a matter of course. In fact, one of the key elements under ACC's Responsible Care, Process Safety Code [95] requires ACC member companies to consider inherently safer approaches as one of many risk reduction measures when conducting a process safety risk assessment.

Since 1996, EPA has seen that advances in ISTs and safer alternatives are becoming more widely available and are being adopted by some companies. Voluntary implementation of some ISTs has been identified through surveys and studies and potential opportunities have been identified through EPA enforcement cases and CSB incident investigations.[96] The Contra Costa County Health Services (CCHS) and New Jersey Department of Environmental Protection (NJDEP) IST regulations requirements to consider IST have resulted in some facilities adopting IST measures.[97] The concept of IST is more widely understood and accepted within the chemical process industry than it was 20 years ago. Innovations and research in chemical process safety have evolved and continue to evolve. Industries change and update their processes over time for a variety of reasons and when possible, EPA believes that opportunities to improve chemical process safety using all available means—not only passive, active, and procedural measures—should also be considered.

EPA disagrees that increasing voluntary adoption of IST means that incremental benefits of mandatory adoption are decreasing. Benefits derived by those implementing IST do not negate any potential benefits from those who have not. As stated in the 1996 rule, ''EPA encourages sources to continue to examine and adopt viable alternative processing technologies, system safeguards, or process modifications to make new and existing processes and operations inherently safer.'' [98] For those facilities who have not considered adopting any IST or have only done so in limited fashion, EPA believes that there is value in requiring facilities with extremely hazardous substances to evaluate whether they can improve risk management of current hazards through potential implementation of ISTs or risk management measures that are more robust and reliable than ones currently in use at the facility. For those facilities who have already considered IST, EPA believe facilities should re-evaluate whether any improvements in hazard or risk reduction can be made and we believe the five-year re-validation timeframe of the PHA is an appropriate time period for such re-evaluation.

EPA did not perform any further analysis of the NJDEP or Contra Costa County IST data. The main purpose of providing these reports was to demonstrate that regulations involving IST in these two jurisdictions resulted in implementation of IST at some of their facilities and to explain what types of IST were implemented. NJDEP's 2010 IST Implementation Summary report [99] on IST reports submitted by NJ facilities since August 2008 is available in the docket and discusses 143 additional IST measures reported to have been implemented or scheduled to be implemented by 41 of the 85 facilities submitting reports. CCHS and Richmond CA annual performance review and evaluation reports on the Industrial Safety Ordinance include a summary of Inherently Safer Systems (ISS) results from their nine total facilities, as well as the actual ISS data reported by each facility. Three of these reports are in the docket for this rulemaking.[100]

Because the requirements involve prevention of accidents before they occur, it is difficult to provide a quantitative assessment that the requirement would reduce a certain number of accidents. The assertion of increase in the number of NJ accidents reported cannot be explained as a result of implementation or non-implementation of IST because there are other factors involved. For example, the number of NJ facilities reporting over the years varies, which can affect the number of reportable accidents and not all NJ facilities may have implemented IST. In principle, because of the ''inherentness'' of any actual IST changes, there should be a hazard and risk reduction for a particular RMP chemical, because IST eliminates or minimizes the opportunities for a chemical release in a more rigorous fashion than relying on a device or human intervention. EPA recognizes that IST will not eliminate all hazard or risk and that reliance of other risk reduction measures will probably still be needed for other points in a process.

Contra Costa County commented that it has seen improvements at existing facilities with existing processes subject to its ISS requirements.[101] The county indicated that facilities have eliminated unnecessary vessels, shortened piping and replaced chemicals with less toxic chemicals. CCHS has seen that by considering ISS, facilities have looked at the highest level of risk reduction such as using passive means (such as a change in metallurgy) instead of relying on administrative means (such as increased piping inspections).

As some commenters indicated, some facilities have been evaluating IST as a best practice for decades and, in most cases, have already taken steps to implement beneficial technologies where it is practicable and cost-effective to do so. In those situations, where IST was previously evaluated but not implemented, facilities should review the analysis to determine if new information is available that would affect the analysis. The facility should document the STAA and practicability of IST and ISD considered.

Inconsistent STAA implementation. A facility remarked that the lack of clarity and consensus about the methodology, definitions or standards for STAA would contribute to burden and could lead to inconsistent implementation of STAA across companies.

EPA does not expect to see ''one-size-fits-all'' implementation of STAA by sources. The STAA requirements are not prescriptive in nature, but more similar to a performance-based standard (like other provisions of the RMP regulations) that give facilities the flexibility and allow facility owners and operators to exercise reasonable judgement to determine what technology or risk reduction measures work best for their particular chemical use, process or facility. However, in an effort to ensure a consistent understanding of EPA's expectations for conducting an STAA and determining practicability of IST and IST considered, the rule defines several terms related to the STAA, such as practicability, inherently safer technology or design, passives measures, active measures and

[95] ACC. 2016. Responsible Care Process Safety Code *https://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Process-Safety-Code/Responsible-Care-Process-Safety-Code-PDF.pdf.*

[96] For more information, see the preamble of the proposed rulemaking at 81 FR 13663–13665, March 14, 2016.

[97] For more information, see the preamble of the proposed rulemaking at 81 FR 13665–13666, March 14, 2016.

[98] See 61 FR 31700, June 20, 1996.

[99] *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0143.*

[100] *https://www.regulations.gov/document?D=VEPA-HQ-OEM-2015-0725-0147, https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0148,* and *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0149.*

[101] *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0450.*

procedural measures. EPA has also cited various references and technical sources of information that explain the concepts and principles of STAA and provided examples.[102]

Impact to agribusinesses. One commenter stated that the proposed mandate for regulated facilities to consider STAA as a part of the PHA, and to evaluate the feasibility of IST, will fail to generate tangible RMP outcomes in the fertilizer industry or with other ag-industry RMP regulated chemicals, beyond what the current PHA requirements and procedural measures can accomplish in controlling hazards. The commenter further asserted that the administrative and recordkeeping burden associated with this portion of the proposed rulemaking will undoubtedly increase costs on the agribusiness industry at a time when margins across the industry are thin to non-existent. The same commenter indicated that these requirements will cause many small agricultural fertilizer retail facilities to close.

EPA is not requiring agricultural fertilizer retail facilities to perform STAA and thus there should be no burden to this particular industry as a result of the STAA provision. The STAA requirement in the PHA will only apply to Program 3 facilities in chemical manufacturing (NAICS code 324), petroleum and coal products manufacturing (NAICS code 325) and paper manufacturing (NAICS code 322).

Feasibility costs. One trade association stated that the cost of determining feasibility was wholly underestimated by EPA because feasibility study costs can be quite large depending upon the type of project, but still be only a fraction of the cost of what it would take to implement any projects determined to be feasible. The commenter noted that a typical project consists of conceptual level design, feasibility level design, and then engineering and implementation. The association member's experience with hundreds of projects is that the cost of a conceptual level design is about 1% of the total project cost and the cost of a feasibility level design is 1% to 2% of the total project cost.

EPA acknowledges that for some industries, evaluation of chemical substitution and process redesign will involve a greater level of effort and resources to consider the practicability of such changes. EPA has revised the cost estimates in the RIA to reflect the greater effort involved in conducting such practicability studies.

g. Model STAA Provisions After Other Regulatory Programs

Several commenters suggested that the STAA requirement align with similar requirements by CCHS and NJDEP. Some of these comments are addressed under other STAA topic headings, as appropriate. Other specific comments are discussed further in this preamble.

Establish qualifications for IST review team. One commenter recommended expanding on the NJDEP requirement which specifies that an IST review team should be ''a team of qualified experts, convened by the owner or operator, whose members shall have expertise in environmental health and safety, chemistry, design and engineering, process controls and instrumentation, maintenance, production and operations, and chemical process safety.'' This commenter also wanted EPA to require the names, qualification, and experience of team members to be stated in the review report and to explicitly specify that workers and union representatives can fully participate in the STAA. Another commenter noted that the proposed STAA requirement does not require employee participation and stated that employees have deep experience and knowledge of the processes and are best equipped to determine inherently safer technology or design, but cautioned that workers must have adequate education and training to participate in STAAs.

EPA notes that § 68.67 requires the PHA to be performed by a team with expertise in engineering and process operations, and the team shall include at least one employee who has experience and knowledge specific to the process being evaluated. Also, one member of the team must be knowledgeable in the specific process hazard analysis methodology being used. These same qualifications apply to team members involved in conducting the STAA. EPA believes most PHA reports already include the names and qualifications of team members in the report, and we do not believe it is necessary to prescribe a regulatory requirement to address this issue. EPA already requires Program 3 facilities to consult with their employees and their representatives on the conduct and development of process hazard analysis and on the development of other elements of process safety management, and EPA believes it would be inappropriate to incorporate additional provisions related to worker participation in the PHA requirements of § 68.67.

Establishing goals. A Federal agency recommended incorporating a goal setting requirement similar to that of CCC's ISO, expressing concern that a lack of goal setting requirements could allow regulatory requirements to be satisfied even if analyses fail to identify or control major hazards. The commenter explains that there is no RMP requirement to reduce risks to ''as low as reasonably practicable,'' or ''ALARP'', while CCHS ISO requires facilities to select and implement ISS to the greatest extent feasible and as soon as administratively practicable.

EPA disagrees with commenters. EPA did base some components of the STAA requirement on NJDEP and CCHS regulations (see discussion in section in IV.C.3.c Definitions of this preamble). Also see further discussion in section in IV.C.3.k of this preamble regarding documentation of feasibility. NJDEP and CCHS require a separate Inherently Safer Technology review or Inherently Safer Systems Analysis (ISSA), but NJ requires IST updates (covering both new and existing processes) on the same schedule as the PHA. CCHS requires an ISSA for existing and new processes every five years, but the analysis can be done as part of a PHA. CCHS also requires that an ISSA for any major changes (which could be result of accident investigation). EPA is requiring that the five-year PHA revalidation address the findings from all incident investigations required under section 68.81, as well as any other potential failure scenarios.

EPA did not propose to require any implementation of any IST. EPA proposed to require facilities to determine the feasibility of IST options, but the final rule allows flexibility for facility owners or operators to decide whether to implement an IST in order to allow them to balance the appropriateness of the technology for their process, costs, risk transfer and other requirements that would have to be met along with possible integration with the use of existing risk reduction measures in place. In the final rule, EPA also replaced the term ''feasibility'' with ''practicability.''

[102] CCPS. 2009, Inherently Safer Chemical Processes: A Life Cycle Approach. 2nd ed., *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0253;* CCPS. July 2010. Final Report: Definition for Inherently Safer Technology in Production, Transportation, Storage, and Use, *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0274;* Contra Costa Hazardous Materials Program. June 15, 2011. Industrial Safety Ordinance Guidance Document, Attachment C—Inherently Safer Systems Checklist. Contra Costa County Health Services, Martinez, CA, *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0146;* NJDEP. January 15, 2015. Guidance for Toxic Catastrophe Prevention Act (TCPA), Inherently Safer Technology (IST), *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0142.*

Requiring risk reduction to be ''as low as reasonably practicable (ALARP)'' is a standard that can be seen as stricter than the ''to the greatest extent feasible'' requirement set by CCHS and could require implementation of risk reduction measures ''except where they are ruled out because they involve grossly disproportionate sacrifices.'' [103] EPA does not believe that adopting a requirement that facilities reduce risks to ''ALARP'' is advisable for the RMP program because there are no set standards to define what level of risk is reasonably practicable for the variety of chemicals, processes, and hazards involved.

h. Feasibility

Insufficient guidance and clarity for methodology for comparing risks. A facility, a local agency, and industry trade associations, among others, remarked that IST cannot be meaningfully and consistently implemented because there is no consensus in science or among the industry on its definition, how to implement it, or how to measure its effect. Stating that the concept of IST is vague, an industry trade association said that multiple factors are taken into account when making a determination of feasibility, including materials used for equipment.

One commenter stated that the feasibility factors in the proposed STAA provision also provide no guidance on how to measure or balance risks or hazards. This commenter notes that there is no simple way to measure whether one process is safer than another or when a process is ''safe enough'' as discussed in the July 2010 DHS report by CCPS. The commenter indicated that the proposed rulemaking does not address a multitude of critical questions: What does the PHA team measure? Does the team evaluate reduction in particular hazards or in overall risk? Is that reduction measured quantitatively or qualitatively? Who or what is the required beneficiary of that reduction—the employees, the adjacent community, the environment? What level of risk is tolerable? If EPA requires STAA analysis under the final RMP rule, it will necessarily need to become involved in measuring, evaluating, and determining the tolerable level of risk. It is unlikely that EPA has the expertise or bandwidth to take this on.

EPA based its definition of IST upon CCPS' descriptions of inherently safer strategies and its definition of ''practicability'' upon CCHS' definition of ''feasible'' in their Industrial Safety Ordinance. EPA has existing requirements under § 68.67 for facilities to evaluate and control hazards in the process and to establish a system to address the PHA's team findings and recommendations. Management response to hazard evaluation studies and recommended options involve risk management considerations that are developed based on a facility's risk tolerance criteria. EPA has not prescribed how facilities define or manage risk, whether it involves conforming to minimum standards such as codes or tries to reduce risk to as low as reasonably practical or whether it uses risk matrices or assesses qualitative or quantitative risk. EPA expects only that facilities consider IST as one of the types of risk management measures employed. Much of the structure of the RMP rule requires owners and operators to collect information and relies on them to make reasonable judgments in light of that information. The requirement here is no different. EPA only requires the analysis. There is no mandate to implement IST under this rule. For further information, EPA recommends consulting Chapter 9—Hazard Identification and Risk Analysis in the 2007 CCPS Guidelines for Risk Based Process Safety.[104]

Efforts involved for determining feasibility. One commenter asserted that EPA has failed to consider the substantial complexity of the activities it is proposing to require, and the significant burden that will be placed on facilities with multiple or complex RMP regulated processes. The commenter cited issues involved with many chemical manufacturing processes that involve multiple optimizations of complicated reactions and integration of many processes with each other. The commenter cited as an example, the efforts involved by the National Academy of Sciences (NAS) to identify and evaluate the many individual alternative paths to methyl isocyanate (MIC) production for potential safer operations.[105] The commenter stated that each alternative then had implications for the facility, the customer, the surrounding community and numerous other factors that needed to be identified, considered and weighed carefully. The commenter further explained that these factors included the costs of the chemicals, labor and energy requirements, new capital expenditures, quality of the product and revenues expected from its production, environmental impacts anticipated from the process, regulatory constraints, environmental policy and regulations and influence of local community on company decision making. The commenter indicated that many of these characteristics involve a substantial degree of uncertainty. The commenter also stated that the framework for decision-making discussed by NAS is akin to the proposed EPA requirement to perform a feasibility analysis for all ISTs considered. The commenter concluded that under the EPA proposal, complex chemical manufacturing RMP facilities would be required to go through this analysis multiple times for each and every regulated process.

EPA believes a practicability determination for any considered IST or ISD is necessary to ensure the facility owner or operator seriously considers whether IST or ISD modifications could further reduce risks and prevent accidents at the facility. EPA expects that facilities will only evaluate chemical substitutes that have already been shown to be commercially viable and does not expect facility owners or operators to expend a major effort on hypothetical or untested chemical substitutes or uses.

Insufficient time to complete a feasibility analysis. One commenter stated that when evaluating IST, a facility owner may at times be able to reject an alternative based on determining a single basis of infeasibility. The commenter asserted that if there is no known rationale for infeasibility, a facility may need to conduct lengthy and costly engineering studies, which would require a unit revamp on an existing process unit. The commenter further stated that under such circumstances, feasibility or practicality must consider unit congestion and constructability in addition to all of the issues associated with a new process. The commenter indicated that this need to perform detailed engineering study/design, in many cases, is indicative of impracticability. The commenter concluded that the proposed rulemaking allows four years after the rule become final for each PHA to consider IST/ISD alternatives for covered processes and, in the event the EPA decides to include this requirement in the final rule, facility owners should be allowed a second PHA cycle, following the four-

[103] *http://www.hse.gov.uk/risk/theory/alarpglance.htm.*

[104] CCPS. 2007. Guidelines for Risk Based Process Safety. American Institute of Chemical Engineers, CCPS, NY, Wiley. Chapter 9—Hazard Identification and Risk Analysis.

[105] National Research Council of the National Academy of Sciences, The Use and Storage of Methyl Isocyanate (MIC) at Bayer CropScience, 2012. *https://www.nap.edu/catalog/13385/the-use-and-storage-of-methyl-isocyanate-mic-at-bayer-cropscience.*

year applicability, where the determination of feasibility or practicality requires engineering studies and design. Another commenter stated that the feasibility analysis outlined in the proposed regulation is ill-defined and doesn't allow sufficient time for the work to be properly completed.

EPA allows that where a practicability evaluation is complex and resource intensive and may not be completed within the four-year compliance timeframe from the final rule or within the five years between PHA reviews, a facility should document during their PHA review that the IST is under consideration and that the practicability of implementing the technology is unknown and still undergoing evaluation.

Practicability decisions made by facilities or outside parties. An environmental advocacy group argued that, if decisions are left up to facilities themselves, the economic interests of the facilities will outweigh considerations of public health. The advocacy group concluded that an independent body should be tasked with reviewing facilities' IST/ISD evaluations to determine whether or not such technologies are feasible and to prevent facility self-regulation. One local agency asserted that stationary sources rather than a regulatory body should determine the feasibility of ISD and document their decision.

EPA disagrees that practicability decisions should be made by outside parties. These decisions are based on site-specific circumstances that a third-party may not have the experience to evaluate. EPA believes it would not be practical for many reasons including: The delay that may result in finding a third-party to assess practicability; the variety of factors that must be considered in establishing a basis for choosing an outside party (*e.g.* there may not be enough qualified third-parties with the expertise and resources to evaluate the various options and processes for the number of facilities subject to this provision); and the need to protect CBI and sensitive information that could reveal security vulnerabilities.

Feasible definition does not take into account removal of existing safeguards. One commenter stated that the proposed definition for feasible precludes any reasonable basis for replacing existing controls and safeguards that have already been identified and implemented to address the risks. This commenter believes that since all the engineering and administrative controls necessary to address risk have already been identified and implemented in an operating plant, it is not appropriate to require a repeated analysis of alternatives that that are not feasible for an operating plant.

EPA disagrees with the commenter. The definition of ''practicability'' in the final rule is not intended to be used to judge the reasonableness or effectiveness of existing risk reduction measures, but whether new IST measures could be implemented. The STAA requirements allow a combination of risk measures to be used to achieve the desired risk reduction; therefore, they do not necessarily preclude the use of existing controls and safeguards.

Feasibility factors go beyond scope of a PHA. One commenter asserted that requiring consideration of the five factors mentioned in the proposed definition of ''feasibility'' goes beyond the scope of a PHA.

EPA disagrees. While the PHA identifies the hazards, the RMP PHA requirements require the facility to identify the risk management measures applicable to eliminating or reducing the risks from the process hazards. EPA believes that it is appropriate for a facility to consider the five feasibility (now practicability) factors (''economic, environmental, legal, social and technological'') for evaluating the appropriateness of implementing for potential IST measures because some IST can involve significant costs or involve impacts that go beyond the facility.

Feasibility does not take into account full supply chain. An industry trade organization and a facility warned that the proposed definition of ''feasible'' does not sufficiently consider costs and benefits and fails to take into account the full supply chain. Facilities pressured to take these measures, such as reducing inventories of products, would prevent companies from meeting customers' needs. For example, downstream users may not even be able to receive an alternative product.

EPA disagrees that the practicability determination does not allow facilities to take into account costs and benefits and the effect on the full supply chain. The STAA requirements do not require any implementation of any particular IST. EPA expects that facility owners or operators will seriously consider the merits and consequences of ISTs for their facilities and use their expertise and judgement to ensure safety while not severely affecting the economic viability of their businesses. Facilities can consider the effects in their supply chain (downstream and upstream) when evaluating potential IST options.

i. IST Implementation

Several industry trade associations and a facility expressed support for EPA's decision not to require implementation of feasible safer alternatives and noted that the best approach would be to allow operators to decide which measures, methods, or IST components would be feasible at their facilities. An industry trade organization requested that EPA include language stating that ''the scope of the STAA for a regulated process will be based on the expert judgment of owners and operators'' because only the facility is uniquely qualified to determine what types of changes are feasible and practical. The commenter cited an example where reducing the volume of chlorine dioxide on-site at a paper mill may not be practical because a minimum amount is needed to ensure that production of pulp and paper can continue when operation of the chlorine dioxide generator is momentarily disrupted due to maintenance or other issues. The commenter also cited another example in which eliminating the use of chlorine dioxide for bleaching may not provide the necessary characteristics of the finished product.

Many commenters, including multiple mass mail campaigns joined by approximately 24,610 commenters and advocacy groups, urged that upon identifying alternatives in an analysis, facilities should be required to switch to the safest cost-effective chemicals and technologies available. Among other reasons, one commenter cited the need to implement feasible alternatives because the NAS report on the Bayer CropScience accident stated that feasible alternatives should be attempted before moving on to specification of risk management equipment and procedures.[106] This commenter notes that existing safeguards used have not prevented accidents from occurring and that CAA section 7412(r)(7)(B)(i), directs that regulations and guidance under this provision must ''*provide, to the greatest extent practicable,* for the prevention and detection of accidental releases of regulated substances and for response to such releases.'' [Emphasis added] In addition, this commenter states that not requiring implementation of IST also creates a competitive disadvantage for those facilities that do so voluntarily, as compared to other facilities who will avoid taking available preventative safety measures to maximize short-term profits. This commenter wants EPA to

[106] National Research Council, The Use and Storage of Methyl Isocyanate (MIC) at Bayer CropScience, at 4–53 (2012).

require a timeframe for implementation of IST for those facilities who plan to implement IST as this will prevent accidents from happening sooner. A commenter urged that required implementation of feasible alternatives would reduce the risks associated with a catastrophic release, including from terrorist attacks, and would be important for protection of public health.

One commenter wanted IST to be implemented wherever feasible because IST is likely to be more effective and less costly in the long run than other safeguards, noting that the existing rule requires that facilities implement the recommendations from a conventional PHA. This commenter also stated that EPA should model its implementation requirements on California's Contra Costa County Industrial Safety Ordinance, which directs companies to ''select and implement each inherently safer system identified to the greatest extent feasible and as soon as administratively practicable'' or consider California's Department of Industrial Relations current proposed requirements for refineries which directs each facility to ''implement all recommendations'' from inherent safety analyses, unless the facility can demonstrate that a recommendation is factually flawed or infeasible on grounds other than cost alone.

An industry trade association said that in their industry, operations are diverse and are constantly evolving, making it difficult to implement IST. A few industry trade associations warned that substitution is not a legitimate option for their industries, for manufacturing of agricultural products or in fragrance industry, for example. Stating that active ingredients in fragrances are extremely specific and non-fungible, an industry association commented that any substitution of fragrance ingredients should be done at the point of design to minimize the threat to fragrance businesses. The commenter requested that EPA provide a clear statement acknowledging the infeasibility of substitution in the fragrance industry. Some commenters stated that the analysis would be of no benefit for their facility because a Federal permit requires it to use certain processes.

EPA agrees that the facility is in the best position to decide what safeguards or risk reduction measure can be employed to eliminate or reduce process hazards. Facilities must consider safeguards, in the following order of preference: IST, passive, active or procedural measures; however, the rule does not automatically require the facility to implement the measures preferentially in that order. EPA recognizes that for any particular hazard point, any one of the four types of safeguards may not exist or may not be practicable for a variety of reasons. EPA also recognizes that facilities may wish to employ more than one safeguard.

The purpose of the STAA requirement is to ensure that facilities consider the available options and for them to find the best method for the facility to address accidental releases. The hierarchy of control methods in an STAA analysis—IST/ISD, passive, active, administrative—is consistent with the language of CAA section 112(r)(7)(B)(i) in that it systematically provides for the identification of practicable control methods while also recognizing that the regulation must be reasonable. This approach is consistent with the current PHA requirements which provide flexibility for the owner or operator to decide which safeguards are appropriate to prevent accidental releases. We expect STAA analyses to lead to new control approaches at sources where management finds such approaches to be reasonable and practicable.

EPA is not requiring implementation of IST at any facility because we believe that only the facility has the expertise and resources to determine whether implementation of any IST or ISD should be undertaken, taking into account that many factors must be considered when substituting a chemical or modifying a process, including cost, risk transfers, technological hurdles, etc. Facilities that choose to adopt the use of IST or ISD can eliminate or reduce hazards by using different materials and/or process conditions, which would make accidental releases less likely, or the impacts of such releases less severe. The results of the practicability determination must be documented as part of the current PHA requirements in § 68.67(e), which requires the owner or operator to document actions to be taken and resolution of recommendations.

Also EPA does not believe we should establish a required timeframe for any planned implementation of IST. Planning, design, equipment modification and cost to implement IST can vary tremendously depending on the technology and scope of the project and could only be best determined by the facility involved in such implementation.

EPA acknowledges that chemical substitution or whole design processes may be not practicable for some processes for a variety of reasons and that facilities should document these reasons for any particular IST that were considered by the facility for purposes of complying with the STAA requirements.

j. Security and Risk

Terrorism. A commenter cited an increased risk of global and domestic terrorism as a reason to broaden the applicability of STAA requirements to cover transportation and storage of liquid chlorine. Another commenter stated that the existing RMP provisions already require the PHA team to consider safer alternatives, and warned that explicitly stating consideration or implementation of IST can expose facilities to risks, such as increased opportunity for terrorism, risk transfer, and risk accumulation. The commenter remarked that chemicals handled are highly dependent on the processes employed, so it would be difficult or impossible to identify an absolute safer alternative. The commenter concluded that facilities should asses the total risk reduced by implementation and stated that any alternative considered should be easily applied and properly tested.

EPA acknowledges that transportation and storage of liquid chlorine can pose risks, not only from accidental releases, but from intentionally caused releases. However, EPA is limiting the scope of applicability of the STAA requirements in order to balance the regulatory and administrative burdens of assessing IST against the accident rate and possible opportunities to employ IST because of process complexity for various industries. EPA believes that the industries subject to the STAA provisions are also more likely than others to have the expertise and resources to properly assess and implement IST.

In response to the commenter's concern that explicitly stating consideration or implementation of IST can expose facilities to risks, EPA believes that the STAA provisions in the final rule provide enough flexibility for owners and operators to consider a hierarchy of risk management measures to minimize the hazard of a process without prescribing an approach that could compromise facility security or transfer or increase risks. The STAA requirement does not require IST implementation but instead allows the facility owner or operator to determine whether an IST considered would achieve a reduction in risk, specific to the hazard being addressed. More specifically, the STAA requirement allows for a combination of risk management measures to be used to achieve the desired risk reduction. This

flexibility acknowledges that there is not always an absolute safer alternative to a chemical, which is highly dependent on the process or application and the chemical involved. EPA is also requiring the facility to evaluate the practicability of any IST or ISD considered to account for economic, environmental, legal, social, and technological factors. Environmental factors would include consideration of potential transferred risks for new risk reduction measures. This allows facilities to carefully consider whether an IST could create new risks or security concerns, including those involving terrorism.

Security concerns related to STAA documentation. An industry trade association urged that if (or when) IST becomes applicable to a certain process, methods should be available for additional review. For example, the commenter said that documentation of safer technology information should be considered from a homeland security and critical infrastructure perspective.

EPA agrees that documentation that could reveal vulnerabilities at an RMP-regulated facility must be secured. Therefore, although EPA is requiring facility owners and operators to document STAA and practicability determinations, EPA is not requiring this information to be submitted to implementing agencies, LEPCs or local emergency response officials. These entities have the ability to request documentation, at which point representatives of the facility and the requesting agency can discuss the security concern and involve security agencies as appropriate.

k. STAA Documentation

Extent of STAA documentation. Some commenters urged EPA to require sufficient, detailed documentation of feasibility and alternatives considered. One commenter asserted that requiring sufficient documentation of alternatives would facilitate the incorporation of safer design principles into the PHA and would enhance the integrity of the process and encouraged a more extensive documentation of feasibility similar to the program in Contra Costa County, California. An advocacy group suggested that entities should be required to document economic benefits as well and quantify specific economic benefits of adopting safer options, such as reduced liability and insurance costs, public benefits such as savings to municipalities for reduced emergency response, and savings to workers and affected residents for medical care, property damage, etc.

An industry trade association asserted that any requirement for entities to determine or document feasibility would be beyond EPA's authority and would be inappropriate because it does not provide sufficient detail of what would be required in a ''determination'' or information about how the determination was considered. An industry trade association expressed general opposition to a documentation requirement. A state agency requested clarification as to what type of documentation would be required in order to demonstrate compliance.

EPA is not specifying any particular form of documentation for STAA given the potential complexity of analysis, variety of risk reduction measures involved and the factors that may be considered for feasibility and/or implementation. Facilities should retain any reports, analysis, findings and recommendations used to comply with the STAA requirements for the life of the process as is required by § 68.67(g). For IST/ISD measures considered, facilities should document the analysis and methodology used to evaluate or consider IST, its feasibility and the recommendations of the review team. Facilities may follow, for example, guidance for IS Review Documentation found in CCPS's Inherently Safer Chemical Processes, which suggests documenting the summary of the approach used for the IS review (*i.e.,* methodology, checklist, etc), names and qualifications of the review team, IS alternatives considered, as well as those already implemented or included in the design, results of each consideration including those not considered and why, documentation of feasibility and rationale for rejection of IS opportunities. Facilities must provide in their RMP, any inherently safer technology or design measures implemented since the last PHA, if any, and the technology category (substitution, minimization, simplification and/or moderation) (§ 68.175(e)(7)).

CBI. A facility contended that changes in process technology involving IST or ISD could be considered CBI, have a substantial impact on the strategic competitive nature of their operation and necessitates provisions to ensure that CBI claims can be asserted for IST or ISD implementation. An environmental advocacy group stated that facilities should have the ability to withhold CBI based on existing standards when they submit their STAA to EPA.

EPA is not requiring the STAA or its documentation within the PHA to be automatically submitted to EPA nor to anyone else, but such analysis or documentation must be kept as records under the recordkeeping requirements of § 68.200 and be available for inspection or review by EPA. Owners or operators may assert claims of CBI for information requested by EPA following the procedures in §§ 68.151 and 68.152 if the information meets the criteria set forth in 40 CFR 2.301.

l. Availability and/or Submission of STAA Documentation

Many commenters, including multiple mass mail campaigns joined by approximately 22,260 commenters, a Federal agency, and advocacy groups, stated that RMP facilities should be required to submit their STAA information to EPA. An environmental advocacy group suggested that the collection of STAAs is vital for the establishment of a clearinghouse of safer technology and alternatives and that EPA should certify STAAs for accuracy and completeness. One commenter suggested that by requiring the submission of STAAs to EPA, the Agency will enhance the quality of STAA assessments and feasibility analysis. This commenter also believed STAA submission would better inform enforcement under the CAA's General Duty Clause by providing the Agency with world class knowledge of feasible safer alternatives and effects taken under the EPA's 2017–2019 NEI approved on February 18, 2016.

Two local agencies stated that STAA information should be retained on-site at the facility for inspection or be submitted upon request to be reviewed by EPA and implementing agencies. One commenter said that information on IST should be maintained at the stationary source.

In contrast, other commenters, including multiple industry trade associations, remarked that EPA should not require RMP-regulated facilities to submit STAA information to EPA. Some industry trade associations argued that EPA or any other implementing agency will likely lack the required knowledge, resources, or expertise to evaluate an STAA or feasibility determination. An industry trade association asserted that EPA should have no role in analyzing or approving the plans. An industry association argued that any requirement for approval of STAAs by EPA would be too similar to a permitting program and would thus be against Congress' intent as per CAA section 112(r)(7)(F).

Some commenters suggested that the submitted STAA information should be included in the RMP National Database and facilities be allowed to withhold CBI based on current RMP CBI

protections and facility-specific, element-specific, up-front substantiation of security claims. A professional organization encouraged EPA to use the STAA summary information provided in the RMPs to gather helpful data and incorporate lessons learned. One commenter reasoned that collection of STAA data is necessary for EPA and other regulatory agencies to carry out their regulatory responsibilities. Another commenter asserted that incorporating summary STAA information into RMPs will facilitate knowledge of successful practices as well as knowledge of barriers.

Two commenters suggested that EPA collect information from facilities that change program levels within RMP or deregister entirely in order to collect valuable lessons learned for future use about IST preventive measures and reducing on-site quantities. One commenter expressed concern that the current deregistration reason codes are not sufficient to allow EPA to collect basic information about lessons learned from deregistered facilities and suggested adding a code representing ''implemented IST/ISO'' paired with a field to indicate the nature of the change.

Some commenters wanted more detailed information about STAA to be provided in the RMP. Suggested additional information included: Descriptions of the alternatives evaluated; description of each option chosen for implementation and timeline; reasons for not implementing IST such as (1) cost; (2) technical feasibility; (3) conflicts with other regulatory requirements or good practices; (4) other hazards; (5) other (indicate reason) or by listing one of the factors included in the definition of ''feasible:'' time, economic, environmental, legal, social, or technological; and an attestation and checklist demonstrating a comprehensive accounting of potential benefits, savings, and avoided costs associated with each major option.

One commenter recommended that an independent body be in place to carefully review the facilities' IST/ISD evaluations to assist in determining whether or not such technologies are feasible and to prevent facilities from self-regulating.

Some commenters wanted STAA and documentation to be made publicly available, and allowed with reasonable protections, for genuine CBI and trade secrets. An advocacy group recommended allowing public comment and response on facilities' STAAs. A few commenters wanted STAA summaries to be available to at-risk communities and the public both online and offline, including at public meetings required at § 68.210.

Reasons given by commenters for providing public availability of STAA included:

- To hold companies accountable and facilitate significant process safety changes with appropriate public discussion and oversight from other stakeholders;
- To ensure right-to-know and transparency for affected workers and communities;
- To provide comments on the STAA and get implementing agency response;
- To have facilities that have adopted IST receive public credit for their positive steps; and
- To ensure opportunities for at-risk communities to engage with facilities about alternatives and prevention plans.

EPA is not requiring automatic submission of STAA information or documentation to EPA or requiring that it be made available to the public. EPA acknowledges there is much public interest in having STAA and documentation available to them, but STAA will be part of a PHA which can be a lengthy (*e.g.,* the sectors subject to STAA requirements have multiple processes and some PHAs are hundreds of pages) technically complex document that could contain not only CBI, but sensitive security information involving process or equipment vulnerabilities. Some commenters' suggested solution of having facilities sanitize submitted documents and provide upfront justification of CBI claims would entail a significant level of burden upon industry and EPA. It would not be practical or good use of resources to have thousands of documents submitted to EPA, to any other body or with the RMP submission. EPA can inspect documents on-site or request their submission from facilities as needed.

EPA believes that primary utility of STAA information for the public is whether or not facilities are implementing IST and the nature of that change. EPA is requiring that basic information on IST being implemented be provided in the RMP submission in accordance with § 68.175(e)(7). Facilities must provide in their RMP any inherently safer technology or design measures implemented since the last PHA, if any, and the technology category (substitution, minimization, simplification and/or moderation). In the event of a public meeting held after an accident, EPA encourages facilities to provide information about any IST or other safer technology alternatives that the facility is using or could be using and suggests that the public use this forum to inquire about ISTs implemented at the facility.

EPA is not adopting an approval process for STAA analyses, either by an independent board, by the implementing agency, or by any emergency planning entity. We recognize nothing in the statute prohibits the adoption of an approval process. The language of CAA section 112(r)(7)(F) is directed towards the need for an operating permit under Title V of the CAA and therefore has no bearing on whether the underlying substantive rule may establish an approval process. In CAA section 112(r)(7)(B)(iii), the statute specifically requires EPA's rules to establish a system that provides for review and, if necessary revision of RMPs (see 40 CFR 68.220). Nevertheless, the approach we adopt in this final rule, which requires the owner or operator to conduct a STAA review and document its review in general and its reasoning for not adopting practicable IST/ISD, is consistent with the overall approach of the RMP rule to rely on the development and assessment of information to lead owners and operators to adopt reasonable measures to prevent accidents.

m. Clearinghouse

Some commenters, including a Federal agency, a state agency, environmental advocacy groups, and a local agency, supported the establishment of a publicly available online clearinghouse providing information about the feasibility and efficacy of safer substances and processes. A Federal agency commented that such a database would also be a useful resource for insurers, chemical process vendors, emergency responders, academic researchers, and other government agencies, such as OSHA.

One commenter remarked that such a clearinghouse should be dedicated to the topic of safer technology and alternatives and should be managed by either EPA, another Federal agency, or an independent third-party rather than industry-funded academics or institutions. One commenter suggested that a clearinghouse could be developed by EPA or a third-party such as CCPS or Texas A&M's Mary Kay O'Connor Process Safety Center.

A few industry trade associations remarked that the creation of a clearinghouse would be redundant with some resources already publicly available. For example, one trade association asserted that it has effectively created its own clearinghouse through the publication and maintenance of its own publicly available publications, semi-annual

conferences, and regular member exchange forums. Additionally, this organization stated that it hosts a technology symposium every other year, where members can learn about new technologies, both from members sharing their experiences and directly from vendors and consultants. Another trade association suggested that the searchable database of all patents and patent applications available from the US Patent and Trademark Office can be used as a clearing house for safer technology and that information on unpatented technologies is readily available through the internet and other means.

Another industry trade association warned that a government clearinghouse would not reduce chemical accidents because each chemical process is highly complex and unique and it would be difficult to find value in a massive database of technologies. A commenter warned that any clearinghouse would be required to have many ground rules so as to clarify what factors were at play in the IST decision. The commenter expressed concern that the clearinghouse could be harmful or not useful if the information was selective in detail because an IST selected by a stationary source may be narrow in scope for a specific set of risks to be avoided or mitigated. The commenter also stated that it is possible companies would provide information lacking enough detail to be useful. Another commenter cautioned that one type of technology, system or design that works for one facility or process may not work for another facility or process, due to differing processes and other conditions.

EPA is not finalizing a provision to establish a clearinghouse in this rule. EPA will further consider the comments and suggestions on establishing a safer technologies and alternatives information clearinghouse should we pursue an effort to develop and establish such a clearinghouse in the future. Currently, industry and other stakeholders can share chemical safety and security best practices, including those involving safer technologies and alternatives, at the Executive Order 13650 best practices Web site.[107] EPA encourages stakeholders to review information shared through this forum and to submit best practices on safer alternatives or other best practices that serve to improve chemical safety and security.

[107] *https://www.osha.gov/chemicalexecutiveorder/LLIS/index.html.*

D. Stationary Source Location and Emergency Shutdown

EPA discussed the importance of location of stationary sources and their emergency shutdown capabilities in the preamble of the proposed rulemaking. However, EPA did not propose any provisions related to these issues.

1. Discussion of Comments on Stationary Source Location

The location of stationary sources, and the location and configuration of regulated processes and equipment within a source, can significantly affect the severity of an accidental release. The location of the stationary source in relation to public and environmental receptors may exacerbate the impacts of an accidental release, such as blast overpressures or concentrations of toxic gases, or conversely may allow such effects to dissipate prior to reaching receptors. EPA requested comments on whether to consider stationary source location requirements for future rulemakings, including the scope of such requirements, or whether the Agency should publish guidance. EPA received multiple comments on this issue.

Commenters indicated that EPA should use stricter standards for calculating blast radius areas for new and existing facilities to ensure that communities, schools, and hospitals are outside of the blast impact. One commenter stated that EPA should use information availability requirements to better inform and protect local communities from accidents. A Federal agency and state/local agency requested that EPA consider the stationary source location issue in future rulemakings. A professional organization requested that EPA consider a 2014 Fire Protection Research Foundation report in future requirements for stationary source location.

Several commenters argued that facilities should be located where no damage could occur to people and homes, asserting that the proposed rulemaking does not go far enough to ensure public safety. Some of these commenters specifically mentioned the Rancho LPG facility in San Pedro, California, and asked that EPA review the siting of this facility due to the danger it poses to the surrounding community.

A local agency and an advocacy group asked that EPA consider IST or risk reduction methodologies and the importance of buffer zones in siting of new stationary sources. Multiple state and local agencies and an association of government agencies requested new guidance and tools for localities to clarify additional requirements for stationary source location. One commenter stated that EPA should consider reverse 911 calls to public receptors in setting requirements.

However, numerous commenters opposed adding provisions to address stationary source location issues in the proposed rulemaking, citing OSHA's PSM regulations and the lack of authority in the CAA. One commenter stated that EPA should not propose any additional requirements on the location of stationary sources. Multiple comments indicated that states and localities, not EPA, should regulate the siting of facilities.

EPA will consider these comments when determining whether to develop guidance or propose stationary source location requirements in a future action.

2. Discussion of Comments on Emergency Shutdown

The RMP regulation requires owners and operators of stationary sources to develop and implement written operating procedures for the safe and timely emergency shutdown of Program 2 and Program 3 processes, to ensure operator training for these procedures, and for maintaining the mechanical integrity of emergency shutdown systems. However, the regulation does not explicitly require that all covered processes must include emergency shutdown systems.

EPA requested comment on whether emergency shutdown system requirements should be considered for future rulemakings, including the scope of such requirements, or whether the Agency should publish guidance.

Many commenters supported additional regulations and/or guidance on emergency shutdown systems regulations and/or guidance. Local agencies stated that EPA should issue regulations or guidance requiring that all processes be built such that they can be placed in a safe state during an emergency. Another local agency recommended that EPA publish guidance on emergency shutdown systems to assist regulated entities in evaluating various alternatives, but argued that including emergency shutdown systems in a future rulemaking would be infeasible for existing locations. One commenter stated that EPA should consider reverse 911 calls to public receptors in setting requirements. A state/local agency expressed support for emergency shutdown systems requirements in a future rulemaking, to include operating procedures and annual testing.

However, several commenters argued that EPA should not propose any additional requirements—regulations or guidance—on emergency shutdown systems. These commenters asserted that existing regulation and facility practices address emergency shutdown issues. One commenter supported EPA's decision to forgo an emergency shutdown system requirement, arguing that exclusion is consistent with RMP's performance-based nature, but opposed EPA's suggestion to issue a guidance document. Another commenter opposed a ''one-size-fits-all'' rule or guidance for emergency shutdown systems and argued that EPA should propose specific regulatory text in a future rulemaking should it decide to regulate emergency shutdown.

EPA will consider these comments when determining whether to develop guidance or propose emergency shutdown system requirements in a future action.

V. Emergency Response Preparedness Requirements

A. Emergency Response Program Coordination With Local Responders

1. Summary of Proposed Rulemaking

EPA proposed to require owners or operators of ''responding'' and ''non-responding'' stationary sources to coordinate response needs with local emergency planning and response organizations to ensure that resources and capabilities are in place to respond to an accidental release of a regulated substance. Responding stationary sources also would be required to comply with the emergency response program provisions of § 68.95 when the outcome of coordination activities demonstrated that local public emergency response capabilities were not adequate to appropriately respond to an accidental release at the stationary source, or when the LEPC or equivalent requested in writing that the owner or operator comply with the requirements of § 68.95. ''Non-responding'' stationary sources need not have complied with § 68.95 provided that the coordination activities indicated that adequate local public emergency response capabilities are available to appropriately respond to accidental releases at the source, appropriate mechanisms are in place to notify emergency responders when there is a need for a response, and the LEPC or equivalent has not requested in writing that the owner or operator comply with the requirements of § 68.95.

The proposed coordination provisions would have required coordination to occur at least annually, and more frequently if necessary to address changes at the source, in the source's emergency action plan, in local authorities' response resources and capabilities, or in the local community emergency response plan. The owner or operator would also have been required to document coordination activities, including the names of individuals involved and their contact information, dates of coordination activities, and the nature of coordination activities. The proposed coordination provisions of § 68.93 also would have required sources with regulated toxic substances to coordinate response actions with the LEPC or equivalent, and sources with only regulated flammable substances to coordinate with the local fire department. This language is similar to the language in § 68.90(b)(1) and (2) of the original rule, which requires that sources with toxic substances held above threshold quantities be included in the community emergency response plan developed under EPCRA, and sources with only regulated flammable substances held above threshold quantities coordinate response actions with the local fire department.

The proposed rulemaking retained all emergency response program provisions from § 68.95 of the original rule, and made two additions. The first was to modify § 68.95(a)(1)(i) to require that release notification procedures included procedures to notify Federal and state emergency response agencies, in addition to the existing rule's requirement to notify the public and local emergency response agencies. The second addition was to modify § 68.95(a)(4) to require the owner or operator to review and update the emergency response program annually, or more frequently if necessary, to incorporate recommendations and lessons learned from emergency response exercises, incident investigations, or other available information. The proposed rulemaking also would have replaced the phrase ''local emergency planning committee'' with the acronym ''LEPC.''

2. Summary of Final Rule

In this rule, EPA has retained the proposed term ''Responding stationary source'' as a heading for § 68.90(a) and ''Non-responding stationary source'' as a heading for § 68.90(b), as an indication of whether or not a facility is required to comply with the emergency response program provisions of § 68.95. Section 68.90(a) is otherwise unchanged from the existing rule, as are § 68.90(b)(1), (2), and (3). EPA is also adopting as proposed paragraphs § 68.90(b)(4) and (5), which require the owner or operator of a non-responding stationary source to perform the annual coordination activities required under § 68.93, and the emergency notification exercises required under § 68.96(a), respectively.

The final rule adopts as proposed § 68.93, but with some changes, which are discussed in the following sections. Section 68.93 requires the owner or operator to coordinate response needs with local emergency planning and response organizations to determine how the source is addressed in the community emergency response plan and to ensure that local response organizations are aware of the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility to respond to an accidental release of a regulated substance.

Section 68.93(a) requires coordination to occur at least annually, and more frequently if necessary, to address changes at the source, in the source's emergency response and/or emergency action plans, and/or in the local community emergency response plan.

Section 68.93(b) requires coordination to include providing to the local emergency planning and response organizations, the facility's emergency response plan if one exists, emergency action plan, updated emergency contact information, and any other information that local emergency response planning and response organizations identify as relevant to local emergency planning. For responding stationary sources, § 68.93(b) also requires coordination to include consulting with local emergency response officials to establish appropriate schedules and plans for field and tabletop exercises required under § 68.96(b). Lastly, § 68.93(b) require the owner or operator to request an opportunity to meet with the LEPC (or equivalent) and/or local fire department as appropriate to review and discuss these materials.

Section 68.93(c) adopts as proposed the coordination documentation provisions without revision. Under § 68.93(c), the owner or operator is required to document coordination with local authorities, including the names of individuals involved in coordination and their contact information, dates of coordination activities, and the nature of coordination activities.

EPA is finalizing several modifications to § 68.95. EPA has adopted the proposed addition to § 68.95(a)(1)(i), which requires that release notification procedures include procedures to notify Federal and state emergency response agencies, in addition to public and local emergency

response agencies. The final rule also adopts as proposed revisions to § 68.95(a)(4), with some modifications. The final rule requires the owner or operator to review and update the emergency response plan as appropriate based on changes at the source or new information obtained from coordination activities, emergency response exercises, incident investigations, or other available information, and ensure that employees are informed of the changes.

3. Discussion of Comments and Basis for Final Rule Provisions

Many commenters, including industry trade associations, advocacy groups, professional organizations, facilities, Federal and state agencies, and others supported EPA's efforts to increase emergency response program coordination between facilities and local responders. Other commenters including industry trade associations and regulated facilities stated the proposal would potentially duplicate other Federal or state requirements or voluntary efforts, or suggested that EPA should increase enforcement efforts rather than impose additional requirements in certain areas.

Although ATF ruled that the fire at West Fertilizer in West, Texas was intentionally set,[108] the incident highlighted the need for better coordination between facility staff and local emergency responders. The approach EPA adopts in the final rule retains the proposed rulemaking's promotion of coordination between facilities and responders while recognizing the concerns of many of the commenters about LEPCs and owners and operators making determinations about the abilities and roles of owners and operators as well as LEPCs. We preserve local flexibility under our approach. Public comments on each proposed provision to the emergency response coordination and emergency response program provisions of Subpart E are discussed further in this preamble, along with EPA's responses and decisions for the final rule.

a. Designation of ''Responding'' and ''Non-Responding'' Stationary Sources

Some commenters objected to EPA's proposal to designate all sources as either responding or non-responding sources. These commenters pointed out these discrete categories do not accurately represent the realities of emergency response, which can include many different degrees of involvement by facilities and local communities in planning, preparing for and responding to accidental release events. One commenter stated that all facilities, regardless of whether they are responding or non-responding facilities, should have a partnership with the LEPC or local emergency responders. Another commenter stated that even facilities with full on-site emergency response capability would likely rely on local public responders to order and manage shelter-in-place actions or evacuations. Another commenter stated that all facilities are responsible for and must be prepared to deal with the regulated substances they handle and there should be no such thing as a ''non-responding'' stationary source, but this does not mean every facility needs a technician-level hazmat response team. This commenter stated that every facility must be able to immediately notify emergency response agencies when a release having the potential to impact the public occurs, take actions to protect the lives of employees and the public, minimize or contain the release, and coordinate with local response agencies who respond to the release.

EPA agrees there is a wide spectrum of planning, preparedness, and response arrangements available to facilities and local communities, and the two categories of ''responding'' and ''non-responding'' facilities do not fully capture this continuum. EPA also acknowledges there is some overlap between the obligations of non-responding and responding facilities. For example, both non-responding and responding facilities must have mechanisms or procedures in place to notify emergency responders about accidental releases, and both types of sources must coordinate emergency response activities with local responders (and under the final rule, these coordination activities must occur annually and be documented, as further described further in this preamble). Because the outcome of coordination activities may result in different types of response arrangements involving regulated facilities and communities, EPA understands that a facility's designation as ''responding'' or ''non-responding'' does not, by itself, explain all facets of emergency preparedness and response for the facility.

These designations are still useful, however, because ''responding'' facilities must meet certain requirements that ''non-responding'' facilities are not required to meet. Responding facilities must comply with all of the provisions of § 68.95, which include developing an emergency response plan, developing procedures for the use, inspection, and testing of emergency response equipment, conducting training for employees in relevant procedures, and updating the emergency response plan to reflect changes at the source. Any facility that plans to use its employees to take response actions beyond those specified in its emergency action plan under 29 CFR 1910.38 as a result of an accidental release at the source—which could include, for example, donning emergency air breathing apparatus in order to enter an area where a toxic gas leak has occurred with the intention of stopping or controlling the release—would be expected to have obtained appropriate equipment and training, and to address these activities in its emergency response program, even if the facility is also relying on local responders to supplement its own response, or to manage offsite response actions such as evacuations and sheltering-in-place. Therefore, in the final rule, EPA has retained the proposed terms ''Responding stationary source'' as a heading for § 68.90(a) and ''Non-responding stationary source'' as a heading for § 68.90(b), as an indication of whether or not a facility is required to comply with the emergency response program provisions of § 68.95.

b. Evaluating Resources and Capabilities of Local Responders

The proposed rulemaking would have made the owner or operator's decision to develop an emergency response program contingent on the outcome of local coordination activities. Under the NPRM, in order to be a non-responding facility, the owner or operator would have been required not only to coordinate with local responders and have appropriate notification mechanisms in place, but also to confirm that adequate local public emergency response capabilities are available to appropriately respond to any accidental release of the regulated substances at the stationary source.

EPA received numerous comments objecting to this provision. Many commenters, including industry trade associations, government agencies, an association of government agencies, facilities, and other commenters, expressed concern over ambiguity in the terms ''adequate'' response capabilities and ''appropriate'' response. One commenter noted that unless they are notified by the LEPC or fire department, facilities will not know when a change in community response capabilities or resources occurs. Another commenter pointed out there is no accepted standard for community emergency

[108] See ATF Announces $50,000 Reward in West, Texas Fatality Fire, *https://www.atf.gov/news/pr/atf-announces-50000-reward-west-texas-fatality-fire*.

response capability applicable nationwide, and that response resources and capabilities can only be evaluated in the context of the overall community's response plan.

EPA has not adopted this provision in the final rule. While EPA believes it is important for regulated facilities and local responders to share information on response resources and capabilities, the Agency acknowledges the capabilities and resources of local response organizations are subject to numerous influences, including other potential demands within the community for local response resources, local government organization and budgets, Federal, state, and local regulations, and others. Few if any of these factors are within the purview of the owners and operators of individual regulated facilities, and therefore in many cases, owners and operators will not be in a position to judge the adequacy of local response capabilities and resources.

c. Developing an Emergency Response Program Upon Receiving a Written Request From the LEPC

The NPRM would also have required the owner or operator to develop an emergency response program in accordance with § 68.95 upon receiving a written request to do so from the LEPC or local response authorities. Numerous commenters objected to this provision. These commenters indicated that the provision would allow or incentivize LEPCs to absolve themselves of their emergency response obligations under EPCRA, even if this may not be in the best interest of the overall emergency response. Several commenters stated that allowing local authorities to ''opt out'' of their responsibilities would undermine the mission of those authorities, and that relying on facilities to fulfill emergency response obligations if an LEPC ''opts out'' may not be within these facilities' authority or capability. Several commenters also expressed concern that EPA's proposal did not include criteria LEPCs must meet before requesting a facility become a responding facility. One commenter representing an association of state government response commissions stated that this provision would cause the vast majority of LEPCs to request facilities become responding facilities.

EPA disagrees the proposed provision would have absolved local responders of their responsibilities under EPCRA or allowed them to disregard their other response obligations. The proposed provisions would have had no effect on local authorities' community emergency planning responsibilities under EPCRA. Also, even in situations where regulated sources maintain full emergency response capabilities, local responders would still be responsible for managing the aspects of the response external to the source, such as community evacuations and sheltering-in-place. Nevertheless, EPA has decided not to finalize this provision because of the objections raised by commenters, and because it would have allowed local governments to place emergency response program obligations on the owners or operators of regulated facilities without requisite knowledge of the facility's operations, business practices, financial condition, and other relevant factors. Also, commenters pointed out that many facilities—particularly small businesses—would as a practical matter simply be unable to manage all of their own response needs, which could include maintaining a full hazardous materials response team, as well as firefighting capabilities. In the preamble to the original rule, EPA acknowledged that small businesses would often be unable to manage these duties.

d. Emergency Response Coordination Activities

Many commenters, including industry trade associations, advocacy groups, facilities, government agencies, professional organizations, and others supported EPA's proposed requirements for improved emergency response coordination between facilities and local responders. Several commenters recommended EPA clarify what is meant by ''coordination.'' Some commenters opposed EPA's proposed coordination requirements on the basis that these activities were already required under other regulations, or were being carried out voluntarily. Other commenters expressed concerns about an historical lack of participation by LEPCs in emergency response coordination activities, or that the proposed coordination provisions would place increased burdens on local responders.

In the final rule, EPA has adopted as proposed the emergency response coordination provisions of § 68.93, with some changes. One significant change relates to the modified applicability provisions discussed previously. In addition to removing the two provisions from § 68.90 of the final rule that would have made the owner or operator's decision to develop an emergency response program contingent on the outcome of local coordination activities, and required the owner or operator to develop an emergency response program upon receiving a written request to do so from the LEPC or local response authorities, EPA has also removed the proposed language in § 68.93 that placed the focus of coordination on ensuring response resources and capabilities are in place. This language has been replaced with language that places the focus of coordination on sharing information related to emergency planning.

EPA has also clarified what coordination activities are required. In the final rule, under § 68.93 the owner or operator is required to provide local authorities with information about the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility to respond to an accidental release of a regulated substance. Section 68.93(a) requires coordination to occur at least annually, and under § 68.93(b), the owner or operator is also required to provide the facility's emergency response plan if one exists, the emergency action plan required under 29 CFR 1910.38, updated emergency contact information, and any other information local emergency planning and response organizations identify as relevant to local emergency planning. EPA notes that under 29 CFR 1910.38(b), OSHA requires emergency action plans to be kept in writing, unless an employer has 10 or fewer employees, in which case they may communicate the plan orally to employees. Under the final rule, if the owner or operator has a written emergency action plan, that written plan should be provided to local authorities, but if the plan is an oral plan, the owner or operator may also communicate the plan orally to local authorities.

In requiring ''any other information that local emergency planning and response organizations identify as relevant to local emergency planning,'' EPA is encouraging local emergency officials to consider what other facility information may aid them in preparing for emergencies at the source beyond those specific elements identified in § 68.93 and § 68.93(b), and request such information from the owner or operator when conducting annual coordination activities. Such information could include accident histories, portions of incident investigation reports relevant to emergency response, incident after-action reports, records of notification exercises, field and tabletop exercise evaluation reports, etc. The owner or operator is required to provide any information requested by local emergency planning and response organizations, to the extent the information is relevant to local emergency planning.

EPA disagrees with commenters who suggested not adopting the proposed emergency response coordination requirements on the basis that they are already required under other regulations, or are being carried out voluntarily. While it is true that in some cases, other Federal or state regulations contain emergency response coordination provisions similar to those in the final rule, many regulated sources are not subject to other regulations with requirements comparable to those in the final rule. Also, in locations without functional LEPCs, other local response authorities may be carrying out local emergency planning functions, and these organizations may be unable to rely on authorities granted to LEPCs under EPCRA to obtain needed information. Where regulated sources are already subject to other Federal or state emergency response coordination requirements comparable to those in the final rule, compliance with those regulations may be used to demonstrate compliance with the final rule, to the extent the activities meet the specific requirements of the rule. Similarly, while EPA agrees that some facilities may already voluntarily carry out the coordination activities required under the final rule, not all regulated facilities do so. Facilities that already carry out these activities voluntarily may also use them to demonstrate compliance with the final rule to the extent the activities meet the specific requirements of the rule.

EPA understands some communities do not have functional LEPCs, but has accounted for this possibility by requiring coordination to be with ''local emergency planning and response organizations.'' This term is intended to encompass all manner of local public emergency planning and response organizations. In many cases this will be the LEPC, but in other cases it may be a local emergency management agency, a local fire department, or another local response organization (or, if appropriate, multiple organizations). These non-LEPC planning entities can use this provision to obtain necessary planning information even when they lack the authority granted LEPCs under EPCRA 303(d)(3). Regardless of whether or not their community has an active LEPC, EPA expects owners and operators of regulated sources to make good faith efforts to carry out the coordination activities required in the final rule. If local emergency planning and response organizations decline to participate in coordination activities, or the owner or operator cannot identify any appropriate local emergency planning and response organization with which to coordinate, the owner or operator should document their coordination efforts, and continue to attempt to perform coordination activities at least annually.

EPA is also aware that increasing regulated facilities' emergency response coordination obligations will often place increased demands on local emergency planning and response organizations through increased coordination requests made by the owners or operators of regulated sources located in their communities. This is an unavoidable consequence of increasing the owner or operator's emergency response coordination obligations. However, the final rule's emergency response coordination requirements are intended to be a straightforward information exchange for both regulated sources and local response organizations, and therefore should not be highly burdensome for either party. Also, the regulatory requirements for coordination have been placed on the owner or operator, rather than local emergency planning and response organizations. Therefore, local response organizations are not obligated to participate in the coordination activities specified in the final rule. In our estimate of the burden of the rule, we have conservatively projected an estimate of the cost of coordination on local responders. EPA expects in most cases, local responders will participate in these coordination activities because it is in their best interest to have up-to-date information about the risks posed by regulated stationary sources in their community and sources' emergency response plans.

e. Frequency of Emergency Response Ccoordination Activities

Many commenters, including state or local agencies and industry trade associations, expressed support for EPA's proposal to require annual emergency response coordination activities between owners and operators and local emergency response officials. Commenters noted such ongoing coordination could help clarify roles and responsibilities and refresh contacts. Some commenters expressed concerns that annual coordination may be difficult or impractical if a source is remote or if local authorities refuse to participate. One commenter suggested that coordination activities should occur on a regular basis at an appropriate frequency determined by the facility and when there is a significant change to the source's emergency plan.

EPA has decided to finalize as proposed the requirement at § 68.93(a) for coordination to occur at least annually and more frequently if necessary. EPA agrees with the majority of commenters that believe that regular ongoing coordination is useful to address changes at the source and in the local community emergency plan. EPA believes most sources are located close enough to local responders to make annual coordination activities practical. Where necessary, owners and operators and local authorities may conduct coordination activities remotely (*e.g.,* using conference calls, webinars, email, etc.). EPA does not agree the frequency of coordination should be left completely up to the source. Sources and local response organizations may choose to coordinate more frequently than annually, but the Agency believes annual emergency coordination between regulated sources and local responders is necessary to the development and maintenance of effective response plans,[109] and unlikely to impose an undue burden on any source.

f. Annual Coordination Meetings

In the proposed rulemaking, EPA did not specifically propose to require that the owner or operator ''meet with'' local authorities to conduct annual coordination. However, in the preamble to the proposal, EPA did indicate that as part of the coordination, the owner or operator and the local response authorities should ''work together'' to determine who will respond if an incident occurs, and what would be an appropriate response. Additionally, in the information availability section of the preamble to the proposed rulemaking, EPA requested comment on whether the Agency should require owners and operators to meet with LEPCs and emergency responders. Several commenters recommended EPA clarify that coordination activities should include regular meetings between the owner or operator and local authorities. These commenters noted that such regular meetings would provide opportunities for both parties to exchange, update, and discuss information relating to emergency response planning. One commenter noted that annual meetings would allow the owner or operator to communicate potentially security-sensitive information needed for emergency preparedness and response. A few commenters noted that while they were in favor of coordination meetings, the owner or operator should not be held to a requirement for such meetings in situations where local authorities are

[109] See preamble discussion in proposed rulemaking, 81 FR 13671, March 14, 2016.

unable or unwilling to participate. Another commenter stated that coordination meetings should occur, but the frequency of such meetings should be left up to the owner or operator and local authorities to decide.

In § 68.93(b) of the final rule, as part of the required annual coordination activities, EPA is requiring the owner or operator to request an opportunity to meet with the local emergency planning committee (or equivalent) and/or local fire department. The purpose of the annual coordination meeting is to allow the owner or operator to update and discuss the information being provided to local authorities, and to allow local authorities to provide the owner or operator with updated information on how the source is addressed in the community emergency response plan. The annual coordination meeting will also provide an opportunity for local authorities to request any other information that may be relevant to local emergency planning, and for the owner or operator to provide this information. In the final rule, EPA has worded the meeting requirement to only require the owner or operator to request such a meeting, so that the owner or operator would not be required to hold a meeting if local authorities are unable or unwilling to participate. The forum for coordination meetings is left up to the reasonable judgement of the owner or operator and local response authorities. They may choose to hold a meeting specifically for this purpose, or combine the coordination meeting with another appropriate meeting, such as a regularly scheduled LEPC meeting, if both parties agree to the arrangement. Where necessary, owners and operators and local authorities may hold meetings remotely (*e.g.,* via conference call or webinar).

g. Coordination of Exercise Frequencies and Plans

In § 68.96(b) of the final rule the owner or operator of a responding stationary source is required, as part of their emergency response coordination activities, to consult with local emergency response officials to establish appropriate frequencies and plans for tabletop and field exercises. This provision was added because numerous commenters, including industry associations, facilities, government agencies, and others, objected to the potentially high burden associated with conducting field exercises every five years and tabletop exercises every year. An association of government agencies noted that requiring field exercises every five years and tabletop exercises every year would place substantial burdens on LEPCs and response agencies, particularly as these organizations are often composed of volunteers. This commenter recommended that the frequency and scope of field and tabletop exercises be determined as part of the coordination process. EPA adopted a modified form of this provision (which is discussed further in the following preamble section on Emergency Response Exercises) in the final rule, and therefore added language to § 68.93 (b) to also require that for responding stationary sources, coordination must include consulting with local emergency response officials to establish appropriate schedules and plans for field and tabletop exercises.

EPA understands there may be cases where local emergency response agencies are unable or unwilling to coordinate with a regulated stationary source on exercise frequencies and plans, or to participate in exercises. In such cases, the owner or operator may establish appropriate exercise frequencies and plans on their own, provided they meet the minimum requirements set forth in § 68.96. Also, the owner or operator should revisit their exercise schedules and plans at the next annual coordination opportunity with local response officials, so that these officials are given an opportunity for input on exercise schedules and plans, even if they remain unable to participate in the exercises.

h. Documentation of Coordination Activities

Many commenters, including state and local agencies and industry trade associations, expressed support for EPA's proposal to require documentation of coordination activities. Several commenters requested EPA clarify how facilities should document coordination activities when local responders are not available or responsive to a facility's attempts to coordinate. Some commenters suggested that EPA require facilities make a reasonable attempt to make arrangements to coordinate with local responders and document any failure to complete such arrangements. One commenter suggested facilities should be required to seek a written or electronic acknowledgement from local responders of coordination efforts, or, if unavailable, document any efforts made to coordinate. A few commenters expressed opposition to the requirement for documentation of coordination. One indicated that such documentation could ''serve as a basis for mutual accusations or second-guessing between first responders and the RMP-regulated facility in the aftermath of an emergency.'' Another indicated that fire departments in California have found CalARP requirements to document emergency coordination to be a large burden. A third commenter stated that if facilities are included in the community response plan, this should be all the documentation needed to demonstrate coordination.

EPA has decided to finalize the requirement at § 68.93(c) for coordination to be documented, as proposed (the final rule reverses the order that the coordination and documentation provisions appear in the regulatory text). The final rule does not specifically require the owner or operator to seek acknowledgement from local responders of coordination efforts. The owner or operator may seek such acknowledgement if desired, but local authorities are not required to provide it. EPA believes the required documentation elements, which include the names of individuals involved in coordination activities and their contact information, the dates of coordination activities, and the nature of coordination activities, should clearly demonstrate whether local responders were involved in coordination, without requiring any other specific acknowledgement from local responders. EPA agrees with commenters that suggested the owner or operator should document any unsuccessful attempts to coordinate with local response organizations. The final rule does not specifically require the owner or operator to document unsuccessful coordination attempts, but EPA believes it will be in the owner or operator's best interest to do so, and allow the owner or operator to demonstrate their good faith efforts to conduct coordination activities in the event an implementing agency requests this information.

EPA does not agree with commenters' objections to documentation of coordination activities. If response to an emergency goes badly, documentation of prior coordination is more likely to clarify deficiencies than obscure or exacerbate them. The objection that documentation could cause a large burden on fire departments is not applicable to this provision, as the requirement for documentation in this rule is placed on the owner or operator rather than local responders, and in any case, the Agency does not view the documentation requirement as highly burdensome. Most of the documents the final rule requires the owner or operator to provide to local authorities are either already required to exist (*i.e.,* emergency response plan and emergency action plan), or should require minimal effort

to produce (*i.e.,* updated emergency contact information, names and contact information of individuals involved in coordination activities, dates of coordination activities, and the nature of coordination activities). EPA views these documentation requirements as straightforward and minimally burdensome.

During coordination meetings, EPA encourages owners and operators to provide local emergency response officials with additional documentation relating to emergency planning if those officials request it. The annual coordination provisions require the owner or operator to ensure local response organizations are aware of the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility to respond to an accidental release of a regulated substance. The final rule also requires the owner or operator to provide any other information local emergency planning and response organizations identify as relevant to local emergency planning. In most cases, the Agency believes the most efficient way for the owner or operator to provide such information is to not only discuss it during annual coordination meetings, but also to provide appropriate documentation to local authorities.

Lastly, EPA does not agree that a facility's inclusion in the community response plan is sufficient documentation to demonstrate annual coordination. EPA notes that community emergency response plans are not prepared or maintained by stationary sources, and that EPCRA does not require community emergency plans to be updated annually. Without regular emergency response coordination activities involving local authorities, the owner or operator could remain unaware of important changes in the community emergency plan, and local responders could remain unaware of changes at the source that could potentially affect the response to an accidental release.

EPA believes there is a wide range of potential outcomes from emergency response coordination activities, but the primary purpose of such coordination should be the regular sharing of information between the owner or operator and local response authorities. Both the owner or operator and local responders should benefit from this exchange by becoming more aware of each organization's response capabilities, resources, and procedures. Based on these increased coordination activities, both regulated sources and local response organizations will be better able to adapt their response plans and procedures to updated information. This information exchange could also prompt some facilities to enhance their existing response capabilities, and even to develop a full emergency response program where none previously existed. Conversely, such increased coordination could result in local authorities, in consultation with an owner or operator, deciding that local public responders are better positioned to respond to releases of regulated substances at the source than the facility itself. Additionally, coordination could lead to development of mutual aid agreements with neighboring facilities, arrangements with response contractors, or other means to improve community and/or facility response plans, procedures, and resources. Such measures could enhance both the community's and facility's ability to effectively respond to emergencies without necessarily requiring a facility to maintain its own hazardous materials response team and/or fire brigade, unless the owner or operator, after coordinating with local authorities, decides this is the most effective approach.

i. Changes to Emergency Response Program Provisions

The proposed rulemaking contained two substantive changes to the emergency response program provisions of § 68.95. The first change would have modified the emergency response plan provision in § 68.95(a)(1)(i) that requires the plan to include procedures for informing the public and local emergency response agencies about accidental releases, to also require these procedures to inform appropriate Federal and state emergency response agencies about accidental releases. EPA received no comments on this provision, and therefore is finalizing it as proposed.

The second change would have modified § 68.95(a)(4). Under the existing rule, this provision requires the emergency response program to include procedures to review and update the emergency response plan to reflect changes at the stationary source and ensure employees are informed of changes. The proposed change would have required the owner or operator to review and update the emergency response plan annually, or more frequently if necessary, to incorporate recommendations and lessons learned from emergency response exercises, incident investigations, or other available information.

Some commenters stated that requiring annual updates to the facility emergency response plan is unnecessary, and that EPA should allow updates to be performed less frequently, such as every three or five years, unless changes occur. Others stated that the proposed requirement was vague and should be clarified. A few commenters, including an industry trade association and a private citizen, commented that EPA's proposed requirement to require annual updates to emergency response plans incorrectly assumes the owner or operator will know when changes in community emergency response resources and capabilities occur. One facility requested EPA clarify in the final rule that facilities would not be deemed noncompliant if changes in local authorities' response plans or capabilities occur without notification to the facility. A private citizen suggested EPA add a requirement for local response authorities to provide a copy of the local community emergency response plan to the facility.

The final rule has adopted a modified version of the proposed emergency response plan update provision. Under the final rule, the owner or operator must review and update the emergency response plan as appropriate based on changes at the source or new information obtained from coordination activities, emergency response exercises, incident investigations, or other available information, and ensure that employees are informed of the changes. EPA agreed with commenters who stated that requiring annual emergency response plan updates is unnecessary. EPA is not finalizing a requirement to update the emergency response plan annually, because while coordination activities will occur annually, they may not always generate information that necessitates changes to the facility's emergency response plan. Other events that could trigger updates to the emergency response plan, such as incident investigations and field and tabletop exercises, may also occur less frequently than annually, and may or may not produce information that could affect the emergency response plan. Therefore, EPA has decided to finalize a more flexible update provision. Under the final rule, the owner or operator is required to update the emergency response plan, but only when changes at the source, or new information obtained from coordination activities, exercises, incident investigations, or other information sources make it appropriate to change the plan.

EPA disagrees with commenters who stated the owner or operator will be unaware of changes in community

emergency response resources that could affect the source's emergency response plan. EPA believes the annual coordination provision should ensure the owner or operator is kept up to date on relevant changes in the community emergency response plan. EPA agrees with commenters that the owner or operator should not be held responsible for updating the facility emergency response plan to reflect changes in the local community emergency response plan if local response officials do not provide the necessary information. However, the Agency is not requiring local authorities to provide a complete copy of the local community emergency plan to the owner or operator. Local authorities may provide it if they choose, and in some cases the community emergency response plan may be publicly available information. However, the local community emergency response plan may also contain a significant amount of information that is not relevant to the owner or operator, so local response authorities may prefer to provide only the information from the community emergency response plan that relates to the stationary source.

In the final rule, the Agency has also included a requirement to ensure employees are informed of any changes to the emergency response plan. This requirement was already in § 68.95(a)(4) of the existing rule, but had inadvertently been omitted from the proposed rulemaking language that revised this section. One commenter noted this issue, and stated that workers should continue to be involved in reviewing the emergency response plan. EPA agrees, and therefore has restored this provision in the final rule.

Lastly, EPA is finalizing the proposal to replace the term ''local emergency planning committee'' with the acronym ''LEPC.'' EPA received no comments on this issue.

B. Facility Exercises

1. Summary of Proposed Rulemaking

In § 68.96 of the NPRM, EPA proposed to require three types of emergency response exercises under Subpart E of the RMP rule—notification, field, and tabletop exercises. Under § 68.96(a), EPA proposed to require all stationary sources with any Program 2 or Program 3 process to conduct annual notification exercises that would include contacting the Federal, Tribal, state, and local public emergency response authorities and other external responders that would respond to accidental releases at the source. EPA also proposed that these exercises be documented and written records maintained for a period of five years.

Under § 68.96(b), EPA proposed that responding stationary sources develop and implement an exercise program that includes field and tabletop exercises. Under § 68.96(b)(1), field exercises would have been required at least once every five years, and within one year of any accidental release meeting the accident history reporting requirements of § 68.42. Under § 68.96(b)(2), tabletop exercises would have been required annually, except during the calendar year when a field exercise was conducted. Also under these provisions, when planning field and tabletop exercises, EPA proposed to require the owner or operator to coordinate with local public emergency responders and invite them to participate in exercises.

Lastly, under § 68.96(b)(3), EPA proposed to require the owner or operator to prepare an evaluation report for both field and tabletop exercises, within 90 days of the exercise. The report would require a description of the exercise scenario, names and organizations of each participant, an evaluation of the exercise results including lessons learned, recommendations for improvement or revisions to the emergency response exercise program and emergency response program, and a schedule to promptly address and resolve recommendations. In the preamble to the proposed rulemaking, EPA indicated the report would also include an evaluation of the adequacy of coordination with local emergency response authorities, and other external responders, as appropriate.

2. Summary of Final Rule

EPA is finalizing the notification exercise provisions of § 68.96(a) as proposed but with modifications. Under § 68.96(b), the final rule requires responding stationary sources to develop and implement an exercise program that includes both field and tabletop exercises; however, EPA is modifying the exercise frequency to allow an owner or operator to establish a schedule in coordination with local officials, with minimum timeframes prescribed in the rule. Exercises must involve facility emergency response personnel and, as appropriate, emergency response contractors. When planning emergency response field and tabletop exercises, the owner or operator must coordinate with local public emergency response officials and invite them to participate in the exercise.

a. Field Exercises

Section 68.96(b)(1) requires the owner or operator to conduct field exercises involving a simulated accidental release of a regulated substance. Under § 68.96(b)(1)(i), as part of the coordination with local emergency response officials required by § 68.93, the owner or operator is required to consult with these local officials to establish an appropriate frequency for field exercises. However, in all cases, the owner or operator must conduct a field exercise at least once every ten years.

Section 68.96(b)(1)(ii) identifies the scope of the field exercises including tests of: Notification procedures; procedures and measures for emergency response actions (including evacuations and medical treatment); and communications systems. Field exercises must also involve: Mobilizing of facility emergency response personnel, including contractors, as appropriate; coordinating with local emergency responders; deploying emergency response equipment; and any other action identified in the emergency response program, as appropriate.

b. Tabletop Exercises

Section 68.96(b)(2) requires the owner or operator to conduct tabletop exercises involving the simulated accidental release of a regulated substance. Under § 68.96(b)(2)(i), as part of the coordination with local emergency response officials required by § 68.93, the owner or operator is required to consult with these officials to establish an appropriate frequency for tabletop exercises. However, in all cases, the owner or operator must conduct a tabletop exercise at least once every three years.

Section 68.96(b)(2)(ii) requires tabletop exercises to include discussions of: Procedures to notify the public and the appropriate Federal, state, and local emergency response agencies; procedures and measures for emergency response including evacuations and medical treatment; identification of facility emergency response personnel and/or contractors and their responsibilities; coordination with local emergency responders; procedures for equipment deployment; and any other action identified in the emergency response plan, as appropriate.

c. Documentation and Alternatives

EPA is finalizing the documentation provisions of § 68.96(b)(3) as proposed. The owner or operator must prepare an

exercise evaluation report within 90 days of each field and tabletop exercise.

The final rule also adds § 68.96(c) to describe alternative means of meeting RMP exercise requirements. Under § 68.96(c)(1), the owner or operator may satisfy the requirement to conduct notification, field and/or tabletop exercises through exercises conducted to meet other Federal, state or local exercise requirements, provided such exercises meet the RMP exercise requirements of § 68.96(a) and/or (b), as appropriate.

Under § 68.96(c)(2), the owner or operator may satisfy the requirement to conduct notification, field and/or tabletop exercises by responding to an accidental release, provided the response includes the actions indicated in § 68.96(a) and/or (b), as appropriate. When response to an accidental release is used to meet field and/or tabletop exercise requirements, the final rule requires the owner or operator to prepare an after-action report comparable to the exercise evaluation report required in § 68.96(b)(3), within 90 days of the incident.

3. Discussion of Comments and Basis for Final Rule Provisions

Many commenters, including industry trade associations, facilities, government agencies, environmental advocates, private citizens, and others supported EPA's proposal to incorporate emergency response exercise requirements into the RMP rule. Most commenters supported EPA's proposal to require notification exercises. Many commenters also supported incorporating requirements for field and tabletop exercises into the RMP rule, but some of these commenters also recommended various changes to the proposed provisions. Other commenters, including industry trade associations, facilities, and others, recommended eliminating field and/or tabletop exercises. The approach adopted in this rule increases the flexibility for local responders and stationary source owners and operators to tailor their exercises to their communities and to their resources. Public comments on each proposed requirement within the emergency response exercise provisions of Subpart E are discussed further in this preamble, along with EPA's decisions for the final rule.

a. Notification Exercises

Almost all commenters that addressed EPA's proposed notification exercise requirements supported those requirements as proposed. Many of these commenters stated notification systems must be tested regularly to ensure they function successfully in the event of an emergency. A few commenters recommended changes to the notification exercise requirement. One commenter suggested notification exercises should occur every five years unless changes occur (*e.g.,* management, operation, or physical changes), in which case they should occur within 60 days of the change. Another commenter supported a requirement to confirm emergency contact information but opposed a requirement to send an actual ''test'' notification, stating this would be an unnecessary burden on facilities and responding organizations. A different commenter requested EPA exempt RCRA-permitted facilities from annual notification exercise requirements, where the RMP-regulated process is also covered by a RCRA permit, stating the proposed requirements are duplicative of RCRA requirements.

EPA disagrees notification exercises should occur every five years unless changes occur, because the Agency believes five years is too long of a gap to confirm whether emergency notification information is correct and emergency notification systems function properly. For example, EPA notes that emergency contact information provided in RMPs frequently changes, particularly when facilities go several years between RMP updates. For this reason, in 2004 the Agency modified the RMP submission requirements to require emergency contact information provided in RMPs to be corrected within one month of any change in that information. EPA also disagrees management, operational, and physical changes at the facility necessarily represent appropriate triggers for verification of emergency response contact information. In some cases, such changes may affect emergency notification, but notification systems and procedures may also be affected by other changes, such as changes in the community emergency response plan. While EPA believes it would be beneficial for the owner or operator to update their emergency contact information and confirm the functionality of notification systems whenever relevant changes occur, in some cases changes that affect emergency contact information and notification systems may be infrequent, and result in facility personnel and local responders becoming unfamiliar with stationary source emergency notification procedures. EPA believes a requirement for annual notification exercises will ensure that emergency contact information and notification systems remain relatively current, and also provide regular training for facility personnel and local responders.

EPA also disagrees that requiring an actual test of the facility's notification system is unnecessary. Requiring annual testing of notification systems should prevent situations where emergency notification systems are only found to be ineffective when they are most needed. Short of actually using the emergency notification system during an accidental release, performing a test of the facility's emergency notification system is the most practical way to evaluate whether or not the system is functional.

EPA expects the notification exercise will involve testing of on-site notification equipment and procedures, including contacting each entity listed on the facility's notification list to verify the contact information and identify that the facility is conducting a notification exercise. Therefore, EPA does not believe testing notification mechanisms is unduly burdensome. EPA also disagrees with exempting RCRA-permitted facilities from the notification exercise requirement. However, in the final rule, EPA has added § 68.96(c) to clarify that exercises conducted to meet other Federal, state, or local exercise requirements will also satisfy the requirements of this rule, provided such exercises meet all of the applicable requirements of the RMP exercise provision.

Due to the significant support for and minimal opposition to the proposed notification exercise requirements of § 68.96(a), EPA is finalizing those requirements without modification. Therefore, under the final rule, all regulated sources with any Program 2 or Program 3 process must conduct an exercise of the source's emergency response notification mechanisms at least once each calendar year. During listening sessions conducted under Executive Order 13650, members of the public expressed significant concerns about ineffective emergency notification systems and procedures during accidental release events at regulated sources, and about receiving little or no information on procedures for evacuation and sheltering-in-place. In most cases, community notification, evacuation, and sheltering are managed by local authorities after receiving an emergency notification from the regulated source. EPA encourages owners and operators to work with local authorities to perform joint comprehensive testing of facility and community notification systems where possible, and to provide updated information to local communities on

evacuation and sheltering procedures. In some cases, regulated facilities provide direct notification to nearby residents and other members of the community when an accident has occurred. These may include audible and/or visual alarms and sirens, reverse 911 calling systems, or other direct notification systems. Where such systems are in place, annual notification exercises should include tests of those systems during the exercise. In either case, EPA recommends regulated sources and communities work together after conducting notification exercises to evaluate the effectiveness of notification, evacuation, and sheltering systems and procedures, and make improvements to those systems and procedures as appropriate, based on lessons learned during exercises.

b. Field and Tabletop Exercises

EPA received numerous comments on the proposed field and tabletop exercise provisions. Most commenters, including industry trade associations, facilities, government agencies, environmental advocates, and others provided general support for including field and tabletop exercise requirements in part 68, although many also recommended changes to the required frequency of field and tabletop exercises, expressed concerns regarding any requirement for local public responders to be involved in exercises, or recommended other changes to the proposed requirements. Several other commenters entirely opposed adding field and tabletop exercise requirements to the rule. In general, these commenters stated that field and tabletop exercises were unduly burdensome on both facilities and local responders, and exercises are unnecessary because annual coordination activities would be sufficient to prepare facility employees and local responders to respond to accidental releases.

EPA disagrees with comments that recommend completely eliminating requirements for field and/or tabletop exercises in the final rule. The Agency views exercises as an important component of an emergency response program for responding stationary sources, because it allows these sources to implement their emergency response plans, test their actual response procedures and capabilities, identify potential shortfalls, and take corrective action. EPA also continues to believe both field and tabletop exercises will provide essential training for facility personnel and local responders in responding to accidental releases, and will ultimately mitigate the effects of such releases at RMP facilities. Therefore, in the final rule, EPA is requiring all responding stationary sources to perform field and tabletop exercises. However, in the final rule EPA has also modified some provisions of § 68.96 in order to address public comments. These changes are discussed in more detail in the following sections.

c. Frequency of Exercises

The greatest number of comments on the proposed field and tabletop exercise provisions related to the required frequency for exercises. While several commenters supported EPA's proposed requirements for annual tabletop exercises and field exercises every five years, some commenters recommended requiring more frequent field exercises, while others recommended requiring field and/or tabletop exercises less frequently, and still others argued that EPA should retain the requirement for field and tabletop exercises but allow owners and operators to have flexibility in the scheduling of exercises.

Support for more frequent field exercises. Commenters who argued for more frequent field exercises included non-governmental organizations, government agencies, and others. These commenters stated that EPA's proposed five-year frequency for field exercises was insufficient. One commenter argued a five-year timeframe for field exercises does not conform to CAA section 112(r)(7)(B)(i), which states ''the Administrator shall promulgate reasonable regulations and appropriate guidance to provide, to the greatest extent practicable, for the prevention and detection of accidental releases of regulated substances and for response to such releases by the owners or operators of the sources of such releases.'' This commenter also stated that more frequent exercises are necessary so that response personnel would gain more experience. Several other commenters who recommended more frequent exercises noted that sources subject to the New Jersey Toxic Catastrophe Prevention Act (TCPA) regulations are required to conduct annual field exercises. Other commenters argued more frequent field exercises are needed due to the potential for personnel turnover that results in the loss of institutional knowledge and collaborative relationships between covered facility owners/operators and community emergency responders.

EPA disagrees that CAA section 112(r)(7) requires EPA to establish a requirement for more frequent exercises. The statute itself in CAA section 112(r)(7)(B)(i) does not contain a requirement for emergency response exercises, therefore, nothing in the statute mandates a frequency for such exercises if the EPA decides some exercises may be reasonable. The requirement to conduct emergency response exercises derives from EPA's authority to set ''reasonable regulations'' that include ''procedures and measures for emergency response after an accidental release of a regulated substance in order to protect human health and the environment.'' CAA section 112(r)(7)(B)(ii) further requires owners and operators to prepare and implement a risk management plan that includes, among other things, ''a response program providing for specific actions to be taken in response to an accidental release of a regulated substance so as to protect human health and the environment, including procedures for informing the public and local agencies responsible for responding to accidental releases, emergency health care, and employee training measures.'' This statutory language provides the Administrator with discretion to decide what components of an emergency response program are reasonable to include in regulations.

EPA believes exercising emergency response plans is a reasonable requirement in order to ensure that emergency response programs will work well in the event of an accidental release. However, EPA is cognizant of the resources (*e.g.,* staffing, cost, expertise) that exercises demand both from stationary sources and from local responders. To ensure the reasonableness of the exercise requirement, EPA has provided flexibility for stationary sources and local emergency responders to set schedules for such exercises. Given the differences among communities and stationary sources impacted by the national Risk Management Program rule, the reasonable minimum frequency for exercises will vary by locale from that which is appropriate under the NJ TCPA requirements.

EPA disagrees with commenters who recommended requiring field exercises more frequently than every five years. EPA notes that its own regulatory impact analysis for the NPRM projected the emergency response exercise provisions to be the costliest provision of the NPRM, and the Agency is concerned that a requirement for even more frequent field exercises could be prohibitively expensive for some facilities and local responders.

Regarding commenters' concerns about the potential that less frequent exercises may result in response personnel gaining less experience, and for personnel turnover to result in the

loss of institutional knowledge and relationships between facility operators and community emergency responders, EPA shares such concerns, but must balance those concerns with the potentially higher burdens that more frequent exercises could place on facility response personnel and community responders. Also, EPA believes the annual emergency response coordination requirements of § 68.93 will foster strong ongoing relationships between facility personnel and local responders, and prevent the loss of institutional knowledge. Furthermore, the timeframes EPA is establishing in the final rule are minimum expectations and we encourage owners and operators to establish appropriate schedules for exercises, in consultation with local officials, considering factors such as hazards, organizations (including facility personnel training needs and personnel turnover), budgets, resource demands, regulations, or other factors.

Arguments for less frequent exercises. Commenters who argued for less frequent field and/or tabletop exercises included industry associations, government agencies, facilities, local responders, private citizens, and others. These commenters stated that requiring field exercises every five years and tabletop exercises every year would be overly burdensome on facilities and local responders. Some of these commenters submitted data to EPA to substantiate their burden estimates. One commenter recommended reducing the required exercise frequency because holding exercises as frequently as proposed by EPA would discourage regular participation by facility personnel and local responders. Several commenters recommended the frequency of field and tabletop exercises be left to the discretion of the source and/or local responders, so that the exercise schedule could be tailored to the individual circumstances of sources and local communities. These commenters also stated that exercises—and particularly field exercises—can be very costly for both sources and local responders. They also indicated that setting a single exercise frequency for all sources does not account for the differing situations faced by different sources and communities. In some cases, these commenters argued, requiring too-frequent exercises could potentially divert resources away from other important safety activities. One commenter representing an association of state emergency planning officials supported an exercise requirement, but recommended the frequency for both field and tabletop exercises be determined by collaboration between the source and local responders during the emergency response coordination process.

EPA found these comments compelling. EPA's own projections in the Regulatory Impact Analysis for the proposed rulemaking indicated that exercises would be the costliest provision of the proposed rulemaking, and in order to limit these costs, one alternative considered in the NPRM was to require only tabletop exercises. Additionally, the Agency is sympathetic to the concerns raised by emergency response officials and others that participation in exercises by local responders can be burdensome, particularly in smaller communities with volunteer responders and fewer response resources, as well as in communities where multiple RMP facilities are present—which would place proportionally greater demands on responders who desire to participate in the RMP facility exercises held within their jurisdiction. EPA is also mindful of the concerns raised by small business owners and their representatives both during SBAR panel process and in comments submitted to EPA, who pointed out that exercises could potentially place a relatively larger burden on small businesses.

For these reasons, in the final rule EPA has modified the provision for frequency of both field and tabletop exercises to allow sources and local responders to work together to establish an exercise frequency appropriate to their situation. However, as EPA continues to believe that both field and tabletop exercises are an important component of an emergency response program, the Agency does not believe any responding source should be allowed to reach an agreement that practically exempts the source from the exercise program requirements. This could happen if a source reached agreement with local responders to hold exercises extremely infrequently. Therefore, the Agency is also establishing a minimum required exercise frequency of ten years for field exercises, and three years for tabletop exercises. The Agency believes even the smallest sources will be able to hold field exercises at least once each decade, and in many cases EPA expects sources will hold field exercises more frequently. The Agency set the frequency for tabletop exercises to be more frequent than field exercises because tabletop exercises require less time and fewer resources to plan and conduct than field exercises, and therefore EPA believes sources will be able to perform tabletop exercises at least every three years.

Under the final rule, owners and operators are required to coordinate with local responders to establish an exercise frequency that works for both organizations. In establishing the exercise frequency, owners or operators and local responders may account for whatever factors they deem appropriate. Owners or operators and local authorities may also adjust exercise frequencies as needed to account for changes in hazards, organizations, budgets, resource demands, regulations, or other factors, provided that field exercises occur at least every ten years, and tabletop exercises occur at least every three years. The agency notes that some RMP facilities may be subject to a more frequent schedule for exercises under other (*e.g.,* state or local) regulations. In such cases, the owner or operator should comply with the more stringent exercise frequency requirement. By doing so, they will ensure that they also meet the required exercise frequency for the RMP exercise requirements.

d. Local Responder Participation in Exercises and Exercise Planning

EPA proposed to require owners and operators to coordinate with local public emergency response officials when planning emergency response field and tabletop exercises, and invite them to participate in exercises. While most public comments on this issue supported the idea that local response officials should be involved in exercise planning and execution, many comments submitted by industry associations, facilities, government agencies, and others expressed concerns that local responders could easily become overburdened by any requirement to participate in planning or conducting exercises. These commenters pointed out that in many communities, local response organizations may be staffed with volunteers, or may have multiple RMP facilities within their jurisdiction, such that local response organizations could be significantly impacted by a requirement to participate in exercises. These commenters agreed that local responders should be invited to participate in exercises, but recommended that EPA not require local authorities to participate in planning or conducting exercises, and not hold facilities accountable if local response organizations decline to participate. Comments submitted by industry associations and facilities also recommended EPA address the possibility that exercises may

sometimes need to be postponed if local response organizations are unable to participate due to actual emergencies or lack of resources. These commenters recommended that EPA allow extensions of the required timeframe for conducting the next exercise, or allow the owner or operator to meet the exercise requirement by conducting the exercise as soon as possible without participation by local responders, if necessary.

In addition to coordinating with local response authorities to establish an exercise frequency, the final rule also requires the owner or operator to coordinate with local public emergency response officials when planning field and tabletop exercises, and to invite local responders to participate in exercises. EPA agrees with the many commenters who stated that any requirement for local responders to participate in planning or conducting exercises could in some cases overburden local response organizations or make it difficult for regulated facilities to timely meet the exercise requirements. EPA is aware of, and various public comments have noted, the fact that in the past some sources have been unable to locate local response organizations who are able or willing to perform such coordination activities. Therefore, while the final rule requires the owner or operator to coordinate with local public responders to establish field and tabletop exercise frequencies and plan exercises, and invite local emergency responders to participate in exercises, the final rule does not require local responders to participate in any of these activities.

In most cases, the LEPC, fire department, or equivalent local emergency response authority would be the appropriate party for the owner or operator to conduct exercise planning and coordination. EPA believes these local response authorities will usually be willing to perform emergency response coordination activities, including exercise coordination activities, with regulated sources. In many cases, EPA expects that exercise planning can be included as part of the annual coordination meetings required under § 68.93. In other cases, the owner or operator and local responders may choose to hold separate exercise planning meetings. EPA also understands that in some cases local responders may elect to limit their participation in exercise coordination activities because of limitations on their available time and resources. However, if the owner or operator is unable to identify a local emergency response organization with which to coordinate field and tabletop exercise schedules and plans and participate in exercises, or the appropriate local response organizations are unable or unwilling to participate in these activities, then the owner or operator may unilaterally establish appropriate exercise frequencies and plans, and if necessary hold exercises without the participation of local responders. In these cases, the owner or operator must still ensure that field exercises occur at least every ten years, and tabletop exercises occur at least every three years. Additionally, the owner or operator should continue to make ongoing efforts to locate appropriate local public response officials for purposes of emergency response and exercise coordination and participation.

As EPA believes the final rule provides the owner or operator with ample flexibility to establish and modify exercise schedules, EPA sees no reason to provide for additional extensions of time for conducting exercises in the event that local responders cannot participate, or if for some other reason the exercise must be rescheduled. EPA recommends that owners and operators and local response organizations take such contingencies into account when establishing exercise schedules, so there is still time to complete the field or tabletop exercise within the allotted timeframe (*i.e.,* at least every ten years for field exercises and at least every three years for tabletop exercises) in the event the exercise must be postponed.

e. Exercise Scope

Some commenters recommended EPA clarify the required scope of exercises. One commenter indicated that if EPA does require exercises, the Agency should allow some variation in the scope of exercises based on the needs and resources of the community.

In the preamble to the proposed rulemaking, EPA explained that field exercises involve the actual performance of emergency response functions during a simulated accidental release event. Field exercises involve mobilization of firefighters and/or hazardous materials response teams, activation of an incident command structure, deployment of response equipment, evacuation or sheltering of facility personnel as appropriate, and notification and mobilization of law enforcement, emergency medical, and other response personnel as determined by the scenario and the source's emergency response plan. Field exercises include tests of:

- Procedures for informing the public and the appropriate Federal, state, and local emergency response agencies about an accidental release;
- Procedures and measures for emergency response after an accidental release of a regulated substance including evacuations and medical treatment;
- Communications systems;
- Mobilization of facility emergency response personnel, including contractors as appropriate;
- Coordination with local emergency responders;
- Equipment deployment, and
- Other actions identified in the source's emergency response plan, as appropriate.

Tabletop exercises are discussion-based exercises without the actual deployment of response equipment. During tabletop exercises, responders typically assemble in a meeting location and simulate procedural and communications steps for response to a simulated accidental release, as determined by the scenario and the source's emergency response plan. Tabletop exercises include tests of:

- Procedures for informing the public and the appropriate Federal, state, and local emergency response agencies about an accidental release;
- Procedures and measures for emergency response after an accidental release of a regulated substance including evacuations and medical treatment;
- Identification of facility emergency response personnel and/or contractors and their responsibilities;
- Coordination with local emergency responders;
- Procedures for deploying emergency response equipment, and
- Other actions identified in the source's emergency response plan, as appropriate.

EPA believes these elements allow ample flexibility for the owner and operator, in consultation with local emergency response officials, to choose appropriate exercise scenarios. Involving local response officials in selecting exercise frequencies and in planning exercises should ensure that RMP facility exercises are consonant with the needs and resources of regulated facilities and local communities. By involving local public responders in the exercise scenario itself, responders may also be able to test or simulate important offsite emergency response actions that are usually managed by local public emergency response officials, such as community notification, public evacuations, and sheltering in place, and EPA encourages sources and local response officials to design exercise

scenarios where these functions are also tested. Responding stationary sources that rely on response contractors to perform emergency response functions during accidental releases should also ensure that response contractors participate in field and tabletop exercises.

In preparing the exercise evaluation report required under § 68.96(b)(3), the owner or operator should evaluate all aspects of the exercise, including, to the extent possible, any offsite aspects of the exercise such as community notification, evacuation, and sheltering in place. In many cases, this will require the owner or operator to involve local response officials in the exercise evaluation.

f. Post-Accident Exercises

In the NPRM, in addition to requiring periodic field and tabletop exercises, EPA proposed to require the owner or operator to hold a field exercise within one year of any accidental release required to be reported under § 68.42. Many commenters objected to this requirement. These commenters stated that this provision could potentially overtax facility and local responders, who would be required to deploy once for the incident, and again for the exercise following the incident.

EPA agrees with these comments, and therefore has decided not to finalize the requirement to conduct a field exercise within one year of an accidental release.

g. Alternatives for Meeting RMP Exercise Requirements

Several commenters indicated EPA should allow sources to meet the periodic field exercise requirements through the actual deployment of emergency response resources and personnel during accidental release events. Other commenters indicated that many regulated facilities are already subject to exercise requirements under other Federal, state, or local regulations, or through an industry code of practice, and these exercises should suffice to meet the exercise requirements of the proposed rulemaking. Comments from state regulatory agencies indicated that one agency already requires more frequent field exercises under state law, and another state government agency is considering imposing more frequent exercise requirements.

EPA generally agrees with these comments. The Agency does not want to establish exercise requirements that conflict with other Federal, state, or local laws. Therefore, in the final rule, EPA has added § 68.96(c) to describe alternative means of meeting exercise requirements. This section allows the owner or operator to meet requirements for notification, field, and/or tabletop exercises either through exercises conducted to meet other Federal, state, or local exercise requirements (or under a facility's industry code of practice or another voluntary program) or by responding to an actual accidental release event, provided the exercise or response includes the actions required for exercises under § 68.96(a) and (b), as appropriate.

h. Joint Exercises

Several commenters, including industry associations and regulated facilities, indicated that some companies have formed mutual aid associations among several neighboring or nearby facilities so that participating facilities can share response personnel and resources in order to aid one another in responding to accidental release events at any member's facility. These commenters recommended that in such situations, or situations where there are clusters of regulated facilities located close together, EPA should not require each facility to conduct a field exercise, but rather allow these facilities to meet their periodic field exercise obligation by conducting a single joint exercise, where all participating facilities perform simulated response actions to an exercise scenario staged at one member-facility's site. These commenters indicated that this approach would reduce the exercise demands on small and medium-sized facilities, as well as local responders.

EPA agrees with these comments, and encourages owners and operators of neighboring RMP facilities to consider planning and conducting joint exercises. However, sources that participate in joint exercises must ensure that their participation meets all of the provisions of § 68.96(a) and/or (b), as appropriate. As commenters have noted, RMP facilities participating in mutual aid agreements with other nearby facilities already coordinate response actions and resources with those facilities, and EPA believes conducting joint exercises among these facilities will more accurately simulate their behavior in the event of an actual release event, and further enhance the ability of these facilities and surrounding communities to effectively respond to accidental releases. Even where such mutual aid agreements are not currently in place, EPA believes the owners and operators of neighboring regulated facilities should consider whether joint facility exercises may have benefits for participating facilities, local responders, and surrounding communities. Such benefits could include improved identification and sharing of response resources, enhanced training for facility personnel and local responders, improvements in facility procedures and practices resulting from information sharing, and others. EPA also agrees that joint exercises may be particularly beneficial for small businesses. While the Agency believes that even small sources can design and conduct field and tabletop exercises that are appropriate to the size, hazards, and capabilities of the source, joint exercises involving multiple neighboring small sources would allow these sources to pool resources together in order to carry out more extensive exercise scenarios that could better simulate serious accidental release events. In areas where multiple RMP facilities are located close together, joint exercises could also reduce the overall burden of exercises on local response organizations, who might otherwise be asked to participate in multiple separate exercises.

i. Exercise Documentation

While most commenters who addressed the issue of exercise documentation acknowledged the need for exercise evaluation reports to be prepared, some commenters expressed concerns about specific aspects of the proposed exercise documentation requirements. Some commenters objected to the proposed rulemaking's requirement to prepare the evaluation report within 90 days, stating that evaluation reports for large exercises could take longer than 90 days to prepare, and that EPA should allow extensions of the required timeframe where appropriate. Still other commenters objected to the possibility that exercise evaluation reports that indicate deficiencies outside the control of an owner or operator could potentially be used by EPA in an enforcement action against the owner or operator. Other commenters stated EPA should not require exercise reports to include the names and associations of exercise participants, because this information could be difficult to obtain and would risk the privacy of exercise participants without any benefit.

EPA is finalizing the exercise documentation requirements of § 68.96(b)(3) as proposed. EPA is also requiring in § 68.96(c)(2), documentation of a response to an accidental release in order for the response to be used to satisfy the RMP field exercise requirements. The owner or operator must prepare an after-action report comparable to (and in lieu of) the exercise evaluation report required in § 68.96(b)(3), within 90 days of the incident, when the owner or operator

uses the response to an accidental release to meet their field or tabletop exercise requirement. This provision is necessary because documenting the response to an accidental release may differ from documenting the results of an exercise. For example, instead of documenting the ''exercise scenario,'' the owner or operator would document the nature of the accidental release prompting the response. Also, there may be additional aspects of the response to an accidental release that should be documented, such as any injuries, first aid and/or medical treatment that occurred. To the extent possible, the owner or operator should ensure that additional items such as these are documented in the after-action report, as well as information equivalent or comparable to that documented in an exercise evaluation report.

EPA disagrees with commenters who contend that 90 days is insufficient time to develop an exercise evaluation report (or after-action report), or that extensions of time should be granted for development of evaluation reports in certain circumstances. Unlike incident investigations, where report completion may require extensive and time-consuming evidence collection and forensic analysis, the basic elements required to be documented in an exercise evaluation report should be known relatively quickly after the conclusion of the exercise.

Regarding commenters concerns about the use of exercise evaluation reports in enforcement actions—an exercise report is like any other record required to be developed under 40 CFR part 68. Whether or not an exercise evaluation report would be used in an EPA enforcement action would depend on the specific facts and circumstances of the case.

EPA disagrees that exercise evaluation reports should not contain the names and associations of exercise participants. Under the final rule, the frequency of both field and tabletop exercises is mainly left to the reasonable judgement of the owner or operator and local response officials. In some cases, exercises may occur infrequently, and EPA believes that maintaining a written record including, among other things, the identification and affiliation of exercise participants will be useful in planning future exercises.

VI. Information Availability Requirements

EPA proposed requirements for making information available to LEPCs or emergency response officials, and the public in order to ensure that communities have the necessary chemical hazard information to protect the health and safety of first responders and residents. The following sections provide an overview of the proposed and final rule provisions, public comments received, and EPA's responses.

A. Disclosure Requirements to LEPCs or Emergency Response Officials

1. Summary of Proposed Rulemaking

EPA proposed that owners and operators of all RMP-regulated facilities provide certain information to LEPCs or local emergency response officials upon request. EPA stated that the facility should make this information available in a manner that is understandable and avoids technical jargon, convey it without revealing CBI or trade secret information, and adequately explain any findings, results, or analysis being provided.

EPA proposed that the owner or operator be required to develop the following chemical hazard information for all regulated processes and provide it, upon request, to the LEPC or local emergency response officials:

- *Information on regulated substances.* Information related to the names and quantities of regulated substances held in a process;
- *Accident history information.* The facility's five-year accident history information required to be reported under § 68.42;
- *Compliance audit reports.* Summaries of compliance audit reports developed in accordance with §§ 68.58, 68.59, 68.79, or 68.80, as applicable;
- *Incident investigation reports.* Summaries of incident investigation reports developed in accordance with § 68.60(d) or § 68.81(d), as applicable;
- *Inherently Safer Technologies (IST).* For each process in NAICS codes 322, 324, and 325, a summary of the IST or ISD identified that the owner or operator has implemented or plans to implement;
- *Exercises.* Information on emergency response exercises required under § 68.96 including, at a minimum, schedules for upcoming exercises, reports for completed exercises, and other related information.

2. Discussion of Comments and Basis for Final Rule Provisions

Overall, commenters agreed that providing communities, local planners, and local first responders with appropriate chemical hazard-related information is critical to ensuring the health and safety of the first responders and local communities. Commenters that supported the proposed requirements provided general support and offered no suggested changes other than to expand the IST requirement to apply to all facilities; require facilities to submit IST analyses to the LEPC; and make IST analyses available to the public.

However, most commenters, including professionals (*e.g.,* consultants or technical/process safety experts), state agencies, facilities, and industry trade associations, did not support the requirement for facilities to submit specific chemical hazard-related information to LEPCs and local emergency response agencies, as the appropriate mechanism to ensure that local responders and planners have the information they need to mitigate chemical risks. Commenters provided several reasons for their objections including:

- A lack of data supporting the Agency's concern that LEPCs are not receiving the information they need to develop local emergency response plans;
- Unnecessary redundancy with existing requirements, such as data reported under EPCRA;
- Data proposed is too broad and does not provide useful information pertinent to emergency response planning;
- The data may overwhelm LEPCs with technical information and the concern that most LEPCs lack the expertise needed to use this information to develop local emergency response plans; and
- Security concerns regarding how the information is maintained and handled by the LEPC or emergency response officials.

Of those commenters that did not support the proposed requirements, several stated that EPA provided no data supporting the Agency's concern that some LEPCs were not receiving the information they needed to develop local emergency response plans. These commenters pointed to EPA's 2008 National Survey of Local Emergency Planning Committees (LEPCs),[110] which did not reveal any concerns about RMP facilities withholding information from LEPCs. According to these commenters, LEPCs indicated in the survey that they were able to obtain RMP data from EPA, the state, or RMP facilities and noted their greatest obstacle was lack of funding. In addition, commenters pointed out that the Executive Order 13650 Working Group report, Actions to Improve Chemical Facility Safety and

[110] 2008 Nationwide Survey of Local Emergency Planning Committees (LEPCs). *https://www.epa.gov/epcra/nationwide-survey-local-emergency-planning-committees.*

Security—A Shared Commitment, May 2014 [111] contains no findings about facilities ignoring LEPC requests for information or that lack of information provided to the LEPCs was an issue, but rather the report stated that LEPCs had concerns about managing all of the information provided under various laws and regulations, understanding how each chemical is regulated, and how to properly respond to an emergency involving specific chemicals. In addition, these commenters stated that while some CSB investigations [112] [113] [114] highlighted a lack of emergency preparedness and recommended strengthening local infrastructures supporting LEPCs, they did not find that facilities refused to cooperate with the community or withheld chemical information from LEPCs.

Multiple commenters, including professionals, state and local government agencies, facilities, and industry trade associations, also stated that the information elements that EPA proposed to require facilities to share with LEPCs are already available to them through the EPCRA or reported in RMPs, which are also already available to the LEPCs. Several commenters noted that communication between LEPCs and facilities is satisfactory via the EPCRA process and stated that LEPCs were able to obtain RMP data from EPA. One commenter requested the EPA refocus its efforts into collecting required data from ''outlier facilities who are not providing required chemical hazard information'' rather than impose a duplicative requirement for the creation and distribution of data.

Many commenters also asserted that the scope of information required by the proposed provision was too broad. These commenters argued that incident investigation summaries, compliance audit summaries, and IST or ISD implementation summaries would not provide useful information for emergency planning and that the proposed information requirements were unnecessarily detailed. Several of these commenters also suggested that the type and format of the information should be determined by individual LEPCs. Furthermore, commenters expressed concern that the information in these summaries would be too technical and LEPC staff may not have the expertise to understand the information being submitted or extrapolate information that may be useful.

Multiple commenters raised concerns regarding the security of sensitive chemical and facility information that would be shared with LEPCs under the proposed requirements. These commenters indicated that LEPCs would be unable to keep the information secure because they lack procedures and resources to properly vet those who would have access to the information, and that the information would be considered ''public information'' once it is provided to the LEPC. These commenters indicated that there are multiple ways for the public to access sensitive information from LEPCs through information requests from the public. Commenters also suggested that these requirements to disclose information to LEPCs interfere with the Department of Homeland Security's (DHS) Chemical Facility Anti-Terrorism Standards (CFATS). Commenters further suggested that since much of this information might reveal security vulnerabilities at facilities, providing this information to LEPCs increases the risk of terrorism or criminal use of the information which could cause harm to first responders and the community.

EPA also received comments regarding how the information should be provided to LEPCs and the timeframe for providing that information. Many commenters suggested the information should be provided through existing systems in a format which is useful to LEPCs or local emergency responders for developing their local emergency plans. Several states and a state association suggested LEPCs and emergency response officials should determine what information is useful and necessary to developing preparedness and response plans. An industry trade association suggested that information should not be in an electronic format but should be communicated to LEPCs, local emergency officers, neighbor groups, and Community Advisory Panels at regular intervals. Two state agencies commented that RMP information should be incorporated into existing management systems and that providing information in a stand-alone single document was of little value to emergency planners. A few commenters suggested that the format of the information should be determined by the individual LEPC. Finally, several commenters proposed that the information be relayed during the annual coordination meeting between LEPCs and facility personnel.

In response to these comments, EPA maintains that it is very important to ensure that LEPCs or local emergency response officials have the chemical information necessary for developing local emergency response plans, however, EPA believes it is unnecessary to specify in the RMP rule the types or format of information that LEPCs or emergency response officials may request. EPCRA section 303(d)(3) already provides the necessary authority to allow LEPCs to request information needed to develop the local emergency response plan. Additionally, EPCRA requires facilities to provide Safety Data Sheets (SDSs) and inventory information to LEPCs to assist emergency planners and responders. Under EPCRA section 312(f), fire departments have the authority to inspect these facilities to better understand the risk associated with these chemicals and how to deal with those risks in the local emergency response plan.

As pointed out by the commenters, the proposed requirements could be perceived as limiting the flexibility of LEPCs and emergency response officials to collect the information they need to develop a local emergency response plan that addresses their community's specific chemical risks. Furthermore, the proposed requirements would have owners or operators preparing information summaries on an annual basis, regardless of whether the LEPC requests the information, and EPA agrees that this is overly burdensome for facility owners and operators. This could also result in reports being sent to the LEPCs or emergency response officials without the necessary context to help officials to understand the information contained within the reports and utilize it for planning purposes.

Without acknowledging any inconsistency with CFATS or other regulatory structure, EPA recognizes both the security concerns that commenters expressed and the challenges associated with securing arguably sensitive information.

[111] Executive Order 13650 Actions to Improve Chemical Facility Safety and Security—A Shared Commitment, May 2014. *https://www.osha.gov/chemicalexecutiveorder/final_chemical_eo_status_report.pdf.*

[112] CSB. January 2016. Final Investigation Report, West Fertilizer Company Fire and Explosion, West, TX, April 17, 2013. Report 2013–02–I–TX, pgs. 201–203, 242. *http://csb.gov/west-fertilizer-explosion-and-fire-/.*

[113] CSB. January 2011. Investigation Report: Pesticide Chemical Runaway Reaction Pressure Vessel Explosion, Bayer CropScience, LP, Institute, West Virginia, August 28, 2008. Report No. 2008–08–I–WV, *http://www.csb.gov/assets/1/19/Bayer_Report_final.pdf.*

[114] CSB. July 10, 2007. CSB News Release: CSB Chairman Merritt Describes the Lessons from Five Years of Board Investigations to Senate Committee, Urges Additional Resources and Clearer Authorities for Federal Safety Efforts. *http://www.csb.gov/csb-chairman-merritt-describes-the-lessons-from-five-years-of-board-investigations-to-senate-committee-urges-additional-resources-and-clearer-authorities-for-federal-safety-efforts/.*

Therefore, EPA has decided not to finalize § 68.205 of the proposed rulemaking, and is instead adding language to the emergency response coordination provisions of § 68.93, which requires the owner or operator to provide ''any other information that local emergency planning and response organizations identify as relevant to local emergency planning.'' (For more information see section V.A. of this preamble.) Under this structure, assertions of Chemical-terrorism Vulnerability Information (CVI) status for certain information can be addressed on a case-by-case basis by the stationary source, the LEPC, DHS, and other appropriate entities.

EPA agrees with commenters that this approach will allow LEPCs and other local emergency officials to obtain the information they require to meet their emergency response planning needs. It will also allow local emergency planners and response officials to ask questions of facility personnel about the risks associated with the chemical hazards at the facility and about appropriate mitigation and response techniques to use in the event of a chemical release. It further allows the facility owner or operator and the LEPC to identify information that may need to be maintained securely and discuss strategies to secure the information or to provide only information that is pertinent to emergency response planning without revealing security vulnerabilities.

The LEPC or local emergency response officials may request information such as accident histories, portions of compliance audit reports relevant to emergency response planning, incident investigation reports, records of notification exercises, field and tabletop exercise evaluation reports, or other information relevant to community emergency planning. For example, this may include requesting information on changes made to the facility that affect risk such as incorporating safer alternatives. Furthermore, EPA directs commenters who indicated that the IST analyses should apply to all facilities and be submitted to the public to refer to sections IV. C. and VI. B. in this preamble.

B. Information Availability to the Public

1. Summary of Proposed Rulemaking

Under § 68.210(a), EPA proposed to add a reference to 40 CFR part 1400, which addresses the restrictions on disclosing ''offsite consequence analysis'' (OCA) information under the CSISSFRRA.

Under § 68.210(b), EPA proposed to require the owner or operator of a stationary source to distribute certain chemical hazard information for all regulated processes to the public in an easily accessible manner, such as on a company Web site. EPA proposed to require the owner or operator to distribute, as applicable:

- Names of regulated substances held in a process;
- SDSs for all regulated substances at the facility;
- The facility's five-year accident history required under § 68.42;
- Emergency responses program information concerning the source's compliance with § 68.10(f)(3) or the emergency response provisions of subpart E, including:
  - Whether the source is a responding stationary source or a non-responding stationary source;
  - Name and phone number of local emergency response organizations with which the source last coordinated emergency response efforts, pursuant to § 68.180; and
  - For sources subject to § 68.95, procedures for informing the public and local emergency response agencies about accidental releases.
- Information on emergency response exercises required under § 68.96, including schedules for upcoming exercises, reports for completed exercises as described in § 68.96(b)(3), and any other related information; and
- LEPC contact information, including LEPC name, phone number, and Web site address as available.

EPA proposed to add § 68.210(c), to require that the owner or operator update and submit information required under § 68.210(b) every calendar year, including all applicable information that was revised since the last update.

EPA also proposed to redesignate the current § 68.210(b), which addresses the non-disclosure of classified information by the Department of Defense or other Federal agencies or their contractors, as § 68.210(e). In new § 68.210(f), EPA proposed to require that an owner or operator asserting CBI provide a sanitized version of the information required under this section to the public. Assertion of claims of CBI and substantiation of CBI claims was proposed to be in the same manner as currently required in §§ 68.151 and 68.152 for information contained in the RMP required under subpart G.

2. Summary of Final Rule

EPA is finalizing § 68.210(b) with changes to address public comments. Under the final rule, § 68.210(b) requires the owner or operator to make certain chemical hazard information for all regulated processes at a stationary source available to the public upon request. The information that shall be provided is the same as proposed, except EPA is revising the exercise information element. Under § 68.210(b)(5) of the final rule, upon receiving a request for the information from a member of the public, the owner or operator is required to provide a list of scheduled exercises required under § 68.96, rather than summary information for those exercises, as proposed.

Section 68.210(c) is now titled ''Notification of availability of information,'' and it changes the manner by which the facility informs the public about what chemical hazard information is available upon request and how the public may obtain such information. The owner or operator shall provide the public with an ongoing notification of the following: (1) The required information elements in § 68.210(b)(1) through (6) that is available to the public upon request, (2) instructions for requesting the information elements and (3) where to access any other available information on community emergency preparedness.

Section 68.210(d) requires that the owner or operator provide the requested information listed under § 68.210(b) to the public within 45 days of receiving a request.

Finally, EPA is finalizing several sections as proposed, including:

- § 68.210(a), RMP availability;
- § 68.210(f), which addresses the non-disclosure of classified information by the Department of Defense or other Federal agencies or their contractors (this was formerly proposed as § 68.210(e)); and
- § 68.210(g), which relates to CBI, redesignated from § 68.210(f).

3. Discussion of Comments and Basis for Final Rule Provisions

a. Legal Issues

An industry trade association and a facility stated that legislation subsequent to the CAA narrowed EPA's authority to mandate public disclosure of RMP information. Relevant legislation described by the commenters includes (1) the 1999 CSISSFRRA, (2) the Critical Infrastructure Information Act (CIIA), (3) the Chemical Facilities Anti-Terrorism Standards Act of 2007, and (4) the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014.

Another industry trade association commented that requiring private companies to publish qualitative or

quantitative environmental information inappropriately seeks to delegate EPA's own duties to communicate with and deal with public requests to the regulated entity.

A few industry trade associations argued that the proposed information disclosure requirements are compelled speech that may violate the first amendment. An industry trade association commented that EPA's proposal to require disclosure of RMP information and chemical hazard information raises constitutional issues, as it amounts to compelled commercial speech. The commenter described compelled commercial speech as subject to an intermediate-level of scrutiny, and asserted that, unless EPA can affirmatively prove that (1) its asserted interest is substantial, (2) the speech regulation directly and materially advances that interest, and (3) the regulation is narrowly tailored to that interest, then the compelled commercial speech will likely be found to be unconstitutional.

The information disclosures required by the final rule are fully consistent with the statutes and regulatory programs identified by the commenters as enacted after the 1990 CAA Amendments. CSISSFRRA specified that portions of RMPs containing OCA information, any electronic data base created from those portions, and any statewide or national ranking derived from such information is subject to restrictions on disclosure (CAA sections 112(r)(7)(H)(i)(III) and 112(r)(7)(H)(v)). Regulations promulgated jointly by EPA and the Department of Justice further define OCA information in 40 CFR 1400.2(j). The final rule does not require disclosure of release scenarios or rankings based on such scenarios, nor does it make available any information based on such scenarios. The CIIA restricts information ''not customarily in the public domain.'' CFATS creates a category of information, CVI, which further restricts certain information generated to implement CFATS (see 6 CFR 27.400). In promulgating CFATS, DHS announced its intent to preserve Federal release disclosure, emergency planning, and accident prevention statutes, including EPCRA and CAA section 112(r) (72 FR 17714, April 9, 2007). In this final rule, EPA has not promulgated the new mandatory disclosure of STAA and incident investigation information that we had proposed, thereby eliminating the tension between these after-enacted programs and modernization of the risk management program. The information required to be disclosed by this rule largely draws on information otherwise in the public domain and simplifies the public's access to it.

This final rule requires an owner or operator of a stationary source to alert the public, via any one of a wide variety of methods, of how to access information about the source that is publicly available. Other statutes and regulatory programs, or other provisions of the risk management program, require the stationary source to assemble the information that the rule would make available upon request (*e.g.,* accident history, SDSs, and aspects of the emergency response program). The burden of making this information directly available from the source is minimal. The public's ability to participate in emergency planning and readiness is materially advanced by being better informed about accident history, types of chemicals present, and how to interact with the stationary source. EPA has been selective in identifying what information a source must make available; for example, we have not required the facility to provide an RMP to the public. Having the source provide the information set out in § 68.210 directly to the public promotes accident prevention by facilitating public participation at the local level.

b. RMP Availability (§ 68.210(a))

EPA did not receive any comments on this issue.

c. Chemical Hazard Information (§ 68.210(b))

Comments on making information available to the public. EPA received multiple comments that supported the proposed provisions. These comments generally indicated that the revisions would strengthen the community's ''right to know.'' A mass mail campaign joined by approximately 450 commenters provided general support for the disclosure of information to the public. EPA also received comments stating that the RMP and accompanying chemical hazard information would be valuable to communities in order to understand the risks involved.

Many commenters opposed the proposed information provisions. Multiple commenters, including state agencies, facilities, and industry trade associations, argued that the proposed provisions for public disclosure of information have the potential to create a security risk, with several commenters expressing opposition to the proposed provisions because they appear to conflict with CFATS or other existing information security requirements. Two diverse groups of commenters remarked that OCA data should remain accessible to the public only through Federal reading rooms, but an advocacy group remarked that keeping information solely in reading rooms would limit access by the public. Some commenters stated that the information requirement was already available through EPCRA or Freedom of Information Act (FOIA) requests, while others stated that EPA had not given enough reasoning for how the increase in information disclosure to the public would result in a safer community in proportion to the burdens imposed on facilities.

EPA continues to believe that providing chemical hazard information to the general public will allow people that live or work near a regulated facility to improve their awareness of risks to the community and to be prepared to protect themselves in the event of an accidental release. EPA believes that this information should be more easily accessible to the public than the existing approaches to access information under EPCRA or through FOIA requests. However, EPA acknowledges the security concerns raised by commenters and is committed to ensuring a balance between making information available to the public and safeguarding that information. Therefore, EPA is finalizing an approach that requires facility owners and operators to notify the public that certain information is available upon request. This allows community members [115] an opportunity to request chemical hazard information from a facility, so they can take measures to protect themselves in the event of an accidental release, while allowing facility owners and operators to identify who is requesting the information. EPA worked closely with Federal partners, including DHS, to develop information availability requirements that strike a balance between security concerns and the need for sharing chemical hazard information with the public. EPA believes that this approach is consistent with existing requirements to secure sensitive information under CSISSFRRA and CFATS. Furthermore, EPA is committed to safeguarding OCA information in accordance with requirements specified in CSISSFRRA, which allows for any member of the public to access paper copies of OCA information for a limited number of facilities. This OCA information remains accessible to the public only in Federal Reading Rooms.

EPA believes that the current approach to notify the public that information is available upon request

[115] Community members can include a wide variety of stakeholders that work or live near an RMP-regulated facility.

strikes an appropriate balance between various concerns, including information availability, community right-to-know, minimizing facility burden, and minimizing information security risks.

Scope of information to be shared. Commenters provided suggestions on the scope of information to be disclosed. An advocacy group commented that information on chemical hazards, safer alternatives (such as information on ISTs), incidents, inspections, and training should all be made publically available. Some commenters remarked that the public should be given information on the schedules and types of emergency response drills performed; how to adequately protect oneself during a release; where to evacuate; how the decision to evacuate will be made and communicated; and how the all-clear signal will be given. However, several commenters objected to making exercise reports available to the public. These commenters stated that providing the public with information about potential weaknesses in a facility or community field response could reveal security vulnerabilities. A few other commenters stated that only information that could improve community awareness of risks should be made available to the public, such as names of regulated substances held in a process above threshold quantities, names and phone numbers of local emergency response organizations, and LEPC contact information.

Some commenters recommended making available to the public the same information elements proposed for disclosure to LEPCs (*i.e.* STAA/IST, incident investigation reports and third-party compliance audits), while several other commenters opposed these suggestions. For example, a mass mail campaign suggested that facilities disclose STAA directly to the public. However, one trade association opposed publicly disclosing STAA, citing that the information would be highly technical and potentially confusing to the general public and may involve the disclosure of confidential, proprietary or other sensitive information. The association further argued that facilities would be put in a position where they must publicly defend IST evaluations and decisions.

Some commenters stated that incident investigation reports should be included in the scope of information delivered to the general public, while others said that providing such reports would be burdensome and confusing to the public. Other commenters argued specifically against making root cause analyses available to the public indicating that this greatly increases the likelihood that facilities will have to respond to lawsuits. One commenter expressed concern that disclosing root cause analyses would discourage facilities from performing meaningful analyses.

A state agency commented that third-party compliance audit reports should be made publicly available to assure the public that appropriate investigation has been done and appropriate steps are being taken to avoid future incidents. A group of commenters argued that emergency contact information should not be shared publicly online because it will encourage unwanted telemarketing and email spam and solicitations.

EPA agrees with commenters that who suggested that only information that could improve community awareness of risks should be made available to the public. EPA disagrees with commenters that suggest making additional information available to the public, such as STAA reports, incident investigation reports (with root cause analyses), and third-party audit reports. As some commenters indicated, much of the information in these reports can be technically complicated and potentially confusing for the general public. Furthermore, this information is not always relevant to community emergency preparedness and could potentially reveal CBI or security vulnerabilities. Therefore, the Agency is finalizing the following chemical hazard information elements to be made available to the public, upon request:

- Names of regulated substances held in a process;
- SDS for all regulated substances located at the facility;
- Five-year accident history information required to be reported under § 68.42;
- The following summary information concerning the source's compliance with § 68.10(f)(3) or the emergency response provisions of subpart E:
  - Whether the source is a responding stationary source or a non-responding stationary source;
  - Name and phone number of local emergency response organizations with which the owner or operator last coordinated emergency response efforts, pursuant to § 68.180; and
  - For responding stationary sources (*i.e.,* those subject to § 68.95), procedures for informing the public and local emergency response agencies about accidental releases;
- A list of scheduled exercises required under § 68.96; and
- LEPC contact information, including the LEPC name, phone number, and Web address as available.

EPA expects that making the information available upon request will minimize security vulnerabilities as well as unwanted telemarketing and email spam and solicitations.

EPA agrees with commenters that members of the public do not necessarily need access to exercise evaluation reports. Therefore, to address concerns that summary information of facility exercise may be confusing to the public and could reveal security vulnerabilities, EPA is revising § 68.210(b)(5) to remove the requirement to provide summary information about exercises and only require a list of scheduled exercises required under § 68.96. EPA believes that one benefit of sharing exercise schedules is to avoid unnecessary public alarm when exercises are conducted. However, EPA expects that facility owners and operators will use good security practices when revealing details about upcoming exercises.

d. Notification of Availability of Information (§ 68.210(c))

EPA proposed requiring the owner or operator to make chemical hazard information publicly available and update the information every calendar year. Many commenters supported the use of a streamlined, one-stop Web format for disseminating information to the public. Several commenters opposed posting information for the public on facility Web sites due to security concerns. Some commenters argued that EPA should utilize existing online public information resources (such as the Agency's Web site or available RMP*Info or Enforcement and Compliance History Online (ECHO) [116] databases) to share information, while a few commenters concluded that appropriate state level agencies should be responsible for making information available to the public.

Many other commenters remarked on the variety of options to disseminate information suggested by EPA, including local libraries, government buildings, or the Internet, and stated that this fragmented approach would not improve public access to information. One commenter cited that EPA should ensure availability of information to those without Internet or electronic media access, and another commenter suggested that hard copies should be made available for those without access to online resources, in addition to information published on an EPA Web site. Another commenter remarked that information should be made available only after an email

[116] *https://echo.epa.gov/?redirect=echo.*

request is made directly to the facility. An advocacy group commented that information on accidental releases should be reported, immediately, to the public through the Internet, radio, telephone, and television.

Commenters also provided suggestions on the format of the information. Some of these commenters suggested that a one to two-page summary of information would be sufficient for the public.

EPA is committed to ensuring that chemical hazard information is available to the public in an easily accessible manner; however, the Agency acknowledges commenters' security concerns associated with providing information to the public and the additional burden that may fall on owners or operators that do not have Web sites or other means to publicly and routinely post such information. In response to these concerns, EPA is requiring that owners and operators notify the public that certain information is available along with instructions on how to request the information. The facility owner or operator must ensure that the notification is ongoing through a publicly accessible means, such as a Web site or social media platform.

The facility owner or operator can notify the public that information is available in a variety of ways. For example, the owner or operator could make the notification of information availability by using free or low cost Internet platforms, file sharing services, and social media tools that are designed to be able to share information with the public. As another option, the facility could post hard copy notices at publicly accessible locations, such as at a public library, or a local government office. If the facility has the means to handle public visitors, it could choose to have notices available at the facility's public visitor location. The facility could also provide notices that information is available to the public by email. EPA encourages the facility owner or operator coordinate information distribution with the LEPC or local emergency response officials to determine the best way to reach public stakeholders in their communities. Facility owners and operators may also want to consider outreach efforts that would allow the public to provide input on the best way to make this notification available. The owner or operator shall document whatever method and the location of the notification in the RMP pursuant to § 68.160(b)(21).

EPA believes that providing this notification to the general public would allow people that live or work near a regulated facility to gather the information they need to improve their awareness of risks to the community and to prepare to protect themselves in the event of an accidental release. The notice shall specify what information is available and provide instructions for how to obtain the information. The facility owner or operator shall also identify where to access information on community preparedness, if available, including shelter-in-place and evacuation procedures. The facility should work with the LEPC and local emergency responders to distribute and convey relevant information on appropriate shelter-in-place and evacuation procedures.

e. Timeframe To Provide Information Following a Request (§ 68.210(d))

One commenter expressed concern that requiring public information to be updated annually would be an unnecessary burden on facilities. In contrast, another state agency reasoned that the public should not have to request information, it should be readily available. An advocacy group requested that a version of the chemical hazard information provided by the facility be made on an annual basis.

While EPA agrees that requiring facilities to annually update their information could be unnecessarily time-consuming, EPA encourages facilities to update their chemical hazard information as needed to ensure that accurate information can be made available to the requester within the required timeframe. Therefore, § 68.210(d) requires that the facility owner or operator provide the information under § 68.210(b) to the requester within 45 days of receiving a request. EPA selected 45 days because that timeframe is consistent with the requirement for public provision of facility chemical inventory information (*i.e.,* ''Tier II information'') under § 312(e)(3)(D) of EPCRA, which states, ''a State emergency response commission or local emergency planning committee shall respond to a request for Tier II information under this paragraph no later than 45 days after the date of receipt of the request.''

f. Classified Information (§ 68.210(f))

EPA received no comments on this issue.

g. CBI (§ 68.210(g))

Several commenters stated that the public information disclosure requirement would place CBI at risk, and therefore EPA should eliminate this requirement. Other commenters requested that EPA clarify that CBI would still be protected from public dissemination. Many commenters requested that EPA require that certain information in STAA reports either may not be claimed as CBI or should require up-front substantiation of confidentiality claims. Some commenters suggested that CBI claims for STAA information include a certification by the owner or operator or a senior official. Other commenters recommended that EPA prohibit STAA reports from being claimed as CBI. Two commenters stated that it may not be practical or possible to provide the public with a useful STAA document after removing appropriate CBI.

EPA is finalizing § 68.210(f) relating to CBI as proposed, but renumbered the paragraph as § 68.210(g). EPA acknowledges and shares industry's concerns pertaining to protection of CBI information. By incorporating a CBI provision in the information availability section of the rule EPA is emphasizing the facility owner or operator's right to protect CBI. EPA has also limited the types of information to be disclosed to eliminate matters likely to contain CBI (*e.g.,* names of regulated substances; SDSs) as well as to include information elements for which CBI cannot be claimed (*e.g.* five-year accident history information and emergency response program information). Section 68.151 clearly identifies what information cannot be claimed as CBI and § 68.152 identifies the procedure for how to protect CBI. EPA believes that the RMP rule adequately addresses CBI concerns. Furthermore, EPA is not requiring STAA reports to be submitted to LEPCs or the public in the final rule and therefore, no CBI concerns exist for these reports.

An owner or operator of a stationary source asserting that a chemical name is CBI shall provide a generic category or class name as a substitute. If an owner or operator has already claimed CBI for a portion of the RMP, then that claim still applies for the disclosure elements the information availability provisions of the rule. The owner or operator should provide a sanitized version as described in the RMP*eSubmit User's Manual. This policy is consistent with existing guidance and practices.[117]

[117] For more information on CBI, see Chapter 9 of the General Guidance on Risk Management Programs for Chemical Accident Prevention (40 CFR part 68), March 2009. *https://www.epa.gov/sites/production/files/2013-11/documents/chap-09-final.pdf.*

C. Public Meetings

1. Summary of Proposed Rulemaking

EPA proposed to require all facilities to hold public meetings within 30 days after any RMP reportable accident to share information concerning the accident with the public including: When the accident occurred; the nature of the accident; chemicals involved and quantities released; on-site and offsite impacts; notifications made to emergency responders; weather conditions (if known); initiating event and contributing factors (if known); and operational changes (if any) that have resulted from the investigation of the release. EPA also proposed that at this public meeting, facilities would provide other relevant chemical hazard information such as the names and SDSs for regulated substances at the facility; accident history information for the facility; information on the emergency response and exercise programs; and LEPC contact information.

2. Summary of Final Rule

In the final rule, EPA is requiring all facilities to hold a public meeting after an RMP-reportable accident, but is extending the timeframe for the public meeting to 90 days in response to comments. The public meeting provision proposed as § 68.210(d) is redesignated as § 68.210(e) in the final rule. The owner or operator shall document in the RMP whether a public meeting has been held following an RMP reportable accident, pursuant to § 68.160(b)(22).

3. Discussion of Comments and Basis for Final Rule Provisions

EPA received a wide range of comments on the proposed public meeting requirements—comments generally in support of or against the requirement for public meetings; concerns about sufficient attendance or availability of information at public meetings; comments on the appropriate timeframe for the meetings; and comments on alternative options.

a. Attendance at Public Meetings

Many commenters opposed requirements for public meetings. Some commenters opposed based on their experience that public meetings held under CSISSFRRA were not well attended. One commenter said the public would not attend a meeting after a minor incident, but a public meeting for an event with major offsite impacts should include a report summarizing the incident. Some commenters questioned the benefit of such a meeting if a facility is in compliance with regulatory requirements.

Other commenters offered ideas for improving or gauging public interest. For example, one commenter suggested that EPA establish minimum requirements for sources to notify the public of upcoming meetings but did not offer suggestions for what those requirements should be. Another commenter suggested that polls could be used to prescreen members of the public who would like to attend or participate in the public meeting, in order to establish effective participation.

EPA recognizes concerns about attendance at public meetings. When the CSISSFRRA was enacted in 1999, it required owners or operators of all facilities regulated under the RMP rule to hold a public meeting within 180 days of enactment.[118] The purpose of the public meeting was to discuss the OCA information that was restricted under other portions of CSISSFRRA. Relatively few of these meetings were hosted by facilities that had recently suffered an RMP-reportable accident. The Agency expects that after a reportable accident occurs, attendance at public meetings will be higher than was the case at many public meetings held under CSISSFRRA because of interest generated by the accident itself (*e.g.,* an emergency response or media reports). This public meeting requirement applies only following an RMP reportable accident, so this provision has a much lower burden than the CSISSFRRA public meeting requirement because of the relatively few number of RMP reportable accidents that occur annually. CSB highlighted in their comments that public meetings held shortly after accidents occur have the greatest level of participation.

EPA supports commenters' suggestions to find practical strategies to increase attendance and encourages public participation at public meetings; however, we are not incorporating these suggestions as mandatory requirements in the final rule. Facilities have the flexibility to encourage attendance at meetings by means that are appropriate and effective in their communities. This could include methods suggested by commenters, such as polling nearby residents to gauge interest.

b. Applicability Criteria and Timeframe

Comments on applicability criteria. One commenter requested clarification on the meaning of ''reportable accident'' that would trigger a public meeting. Another commenter remarked that multiple meetings may be necessary in certain circumstances, for instance if the investigation report has not been finalized. Commenters also suggested that public meetings should be required of all program level facilities while others indicated that a ''one-size-fits-all'' approach was not appropriate. Several commenters requested that public meetings be required only when an incident generated offsite impacts. Finally, another commenter suggested EPA require periodic public meetings regardless of accident history.

The term ''reportable accident'' refers to accidents required to be reported in the five-year accident history required under § 68.42 of the existing rule, which include accidental releases from covered processes that resulted in deaths, injuries, or significant property damage on site, or known offsite deaths, injuries, evacuations, sheltering in place, property damage, or environmental damage. EPA agrees that in some cases, multiple public meetings may help to fully describe the circumstances of an accident. While EPA is requiring the owner or operator to hold only one public meeting after an RMP-reportable accident, the Agency encourages owners and operators to hold additional meetings if appropriate. The final rule requires public meetings for regulated sources, regardless of program level, if the facility has an RMP-reportable accident. The Agency does not view the public meeting requirement as a ''one-size fits all'' requirement. Sources have flexibility to structure public meetings as appropriate to their circumstances and the needs of the surrounding community. EPA recommends that facility owners and operators engage in community outreach to determine how best to structure the public meetings. Involving the public in advance of the meeting will help to ensure public participation in meetings. EPA considered requiring public meetings only after accidents with offsite impacts but decided to apply the requirement to all RMP-reportable accidents because even though some RMP-reportable accidents have only on-site impacts, those accidents are often serious enough to raise safety concerns within the surrounding community.

Finally, EPA is not requiring periodic public meetings, regardless of accident history, in the final rule. EPA believes that public interest in a meeting is highest after an accident, and notes that many commenters indicated that public

[118] Chemical Safety Information, Site Security and Fuels Regulatory Relief Act, Public Law 106–40, August 5, 1999. See *http://www.gpo.gov/fdsys/pkg/STATUTE-113/pdf/STATUTE-113-Pg207.pdf.*

meetings required by CSISSFRA were not well attended.

Comments on timeframe. Several commenters expressed support for the proposed 30-day timeframe. Other commenters said that a 30-day timeframe would be too long, as the greatest need for a public meeting occurs within 2 weeks after an accident. However, many commenters stated the 30-day timeframe for a public meeting is too short, as a facility is unlikely to complete an incident investigation in that timeframe. Commenters warned that incomplete information would not be appropriate to share with the public and could breed distrust between the public and facilities over the lack of complete data. Some commenters cited the burden placed on facilities to schedule and prepare for a meeting, especially during an incident investigation and other post-incident actions. Commenters recommended alternative timeframes for public meetings after an accident including: 60 days, 90 days, 120 days, six months, nine months, and 12 months or after the investigation is completed. One commenter suggested that EPA provide an opportunity to extend the public meeting timeframe with reasonable justification. Another commenter suggested that EPA allow the LEPC to consult on or determine when to hold the public meeting after an RMP reportable accident.

EPA acknowledges concerns raised by commenters about diverting facility resources from post-accident investigations, and the potential for a facility to lack complete information about an accident if the investigation hasn't yielded sufficient information to share with the public within 30 days. Therefore, EPA has revised the timeframe in the final rule for the public meeting to be held no later than 90 days after an RMP reportable accident. EPA expects that sources will either have completed the incident investigation required under § 68.60 or § 68.81 prior to holding the public meeting, or will have developed sufficient information relevant to community members' concerns to allow a productive meeting. Even if the accident investigation is not complete, a 90-day timeframe should allow the owner or operator to share appropriate information about the accident with the local community. The facility could discuss the progress of the investigation so far and next steps planned.

Some comments expressed the view that attendance at a public meeting is higher when the meeting takes place very soon after an accident occurs. The 90-day timeframe in the final rule is a maximum timeframe, and EPA encourages facilities to take into consideration when public interest may be highest when scheduling the public meeting. EPA recognizes that in some cases, such as for complex, protracted investigations, the facility may need to hold the public meeting prior to completing the incident investigation. In such cases, the owner or operator should consider holding a second public meeting after completing the incident investigation, or sharing information about results of the investigation through another means, such as a Web site, social media, with the LEPC or local emergency response officials, or distributing information directly to people who attended the public meeting and expressed interest in the additional information.

EPA does not believe that it is necessary to add a provision that would allow an extension of the 90-day timeframe with reasonable justification. Such a provision would add complexity to the requirement. Furthermore, EPA believes that by extending the timeframe to 90 days this allows sufficient time for the facility to gather information to share with the public after an accident.

EPA is not finalizing any requirements for LEPCs or local emergency response officials with respect to post-accident public meetings. EPA received many comments that opposed increasing LEPC responsibilities in the final rule, citing resource limitations and significant existing responsibilities. While a facility should communicate closely with LEPCs or local emergency response officials after an RMP reportable accident, and may combine public meetings with LEPC meetings or other events as long as those events/meetings are available for public participation, the facility bears the responsibility for the public meeting. The final rule places no additional burden on LEPCs or local emergency response officials with respect to requirements for post-accident public meeting.

c. Scope of Information Provided at Public Meetings

Public commenters provided various recommendations regarding how much and what type of information should be provided at public meetings. One commenter asserted public meetings are useless since the local media relay information about incidents, such as when and where the incident occurred and emergency response information. Another commenter said public meetings after an accident would be redundant, as the information required to be shared would already be made available to the public for all reportable accident investigations. A few commenters said that completed STAAs should be covered in public meetings. One commenter stated that information about the nature of chemical risks within a community and emergency response protocols during an accidental release or another dangerous event would be the best information to share during a public meeting. Another commenter requested clarification about what information is required to be shared at a public meeting.

EPA disagrees with commenters who stated that public meetings are useless or redundant to other sources of information. EPA believes that public meetings, particularly when held after an accident, will often provide easier access for community members to appropriate facility chemical hazard information, which can significantly improve the community's emergency preparedness and understanding of how the facility is addressing potential risks. Public meetings also provide an opportunity for the public to ask questions or share their concerns with appropriate facility staff and local government officials in attendance.

Public meetings must address information about the incident as well as other relevant chemical hazard information such as that described in § 68.210(b) (*i.e.,* names of regulated substances held in a process; SDSs; accident history information; emergency response program information; a list of scheduled exercises and LEPC contact information). The facility representative should describe the risks that are associated with the facility, and what the facility is doing to protect the public from those risks. In addition, the facility personnel should relay information that would assist the public to prepare for accidental releases. It would be extremely useful to have LEPC and local emergency response officials participate in the meeting to discuss the community emergency response plan and explain how the facility is incorporated into that plan. This would provide an opportunity for the facility representative and local officials to discuss the process for public emergency notification procedures, for sheltering in place or evacuating, and where to obtain further updates on the status of an emergency incident. The discussion should also address how the public can access community emergency response plans and identify what the community may expect to see during a field exercise.

In the final rule, EPA maintains the requirement for information in § 68.42 to be addressed at the public meeting.

The facility will have the flexibility to structure the public meeting to focus on areas most relevant to a particular accident, considering the interests of the community. EPA is not requiring that completed STAAs be included, in part because this information is not pertinent to community emergency response planning and also in part because the opportunity for the public to engage in a completed STAA analysis, which may contain CBI or trade secret information, may compromise confidentiality and create security vulnerabilities at the facility.

d. Alternatives to Facility-Hosted Public Meetings

One commenter argued that a facility hosting a public meeting would be redundant when LEPCs already hold public meetings. EPA also received comments that EPA regions or LEPCs should host and facilitate a public meeting instead of the facility, or that facilities should be required to meet with LEPCs or local emergency responders instead of the public. Others requested that LEPCs be able to decline to facilitate a public meeting required by this rule because of their already substantial responsibilities, or that public meetings should be held only at the request of LEPCs or local emergency response agencies regardless of whether a regulated substance was involved, or that they should be held only at the request of the public. Commenters also indicated that small businesses should be allowed to post information that is required to be disclosed, in lieu of a public meeting.

EPA disagrees with the commenters. LEPCs hold meetings with the public to discuss issues related to community planning. The public meetings required by § 68.210(e) in the final rule are intended to be a venue for facility personnel to address questions and concerns raised by the public following an RMP reportable accident at a facility. While communication between the facility and the LEPC is essential, it cannot replace communication between knowledgeable facility staff and the public. LEPCs are encouraged to participate in public meetings, and may collaborate with the owner or operator to host the meeting in conjunction with an LEPC meeting if appropriate. However, LEPCs are not required to co-host or participate in public meetings.

Finally, EPA believes that small businesses should also host public meetings following an RMP reportable accident to allow community members an opportunity to talk with facility personnel. EPA encourages small businesses to find ways to reduce costs of public meetings such as by hosting the meetings at inexpensive venues, such as local schools, community centers, or churches.

VII. Risk Management Plan Streamlining, Clarifications, and RMP Rule Technical Corrections

A stationary source subject to the RMP rule is required to submit an RMP in a method and format specified by the EPA, pursuant to § 68.150(a). The CAA and 40 CFR subpart G require that the RMP indicate compliance with the regulations at 40 CFR part 68 and also include information regarding the hazard assessment, prevention program, and emergency response program. The RMP also includes stationary source registration information, such as name, location and contact information. The EPA may review RMPs for a variety of reasons, including information gathering, inspection preparation, errors in submissions, and changes requiring a correction or re-submission of the RMP. The CAA requires that RMPs be made available to states, local entities responsible for planning or responding to accidental releases at the source, the CSB, and the public. As a result, the information provided in an RMP is intended to be easily understood, thus encouraging the public, local entities, and governmental agencies to interact with stationary sources on issues related to accident prevention and preparedness.

EPA is deferring proposed revisions to delete or revise data elements in the current rule; however, EPA is adding several RMP data elements in subpart G based on the revised rule requirements discussed in this document. This includes data elements to address compliance with:

- Third-party audit requirements,
- IST analysis requirements in the PHA;
- Emergency response preparedness requirements including information on local coordination and emergency response exercises; and
- Information sharing provisions.

By adding these data elements to the RMP requirements in subpart G, EPA will be able to evaluate a stationary source's compliance with these rule requirements. EPA is also finalizing technical corrections as proposed.

A. Revisions to § 68.160 (Registration)

EPA is adding the following RMP data elements that relate to the information sharing provisions discussed in this document:

- § 68.160(b)(21) requires the method of the communication and location of the notification that chemical hazard-related information is available to the public, as set forth in § 68.210(c); and
- § 68.160(b)(22) requires the date of most recent public meeting, as set forth in § 68.210(e).

EPA revised § 68.160(b)(21) to clarify that when identifying how a notification is made, the owner or operator should describe both the method of the communication and the location. For example, if the owner or operator is modifying a Web site to identify that information is available upon request, then EPA expects that the owner or operator will identify in the RMP that the notification is being made through a Web site and then provide the Web address of the notification. Alternatively, if the notification is made via a printed notice, then the owner or operator should identify that a printed notice is available and explain how to obtain the printed materials. EPA received no comments on these provisions.

B. Revisions to § 68.170 (Prevention Program/Program 2)

EPA is revising:

- § 68.170(i) by adding a requirement that the owner or operator identify whether the most recent compliance audit was a third-party audit, pursuant to §§ 68.58 and 68.59; and
- § 68.170(j) by clarifying that the date of the most recent incident investigation be the completion date of the investigation. This would be the date on the final incident investigation report.

EPA received no comments on these provisions.

C. Revisions to § 68.175 (Prevention Program/Program 3)

EPA is revising:

- § 68.175(e) by amending the introductory sentence in paragraph (e) to apply to information on the PHA or PHA update and revalidation information. EPA is moving the date of completion of the most recent PHA or update and the requirement to identify the technique used to subparagraph (e)(1). EPA is deleting the requirement to identify the expected date of completion of any changes resulting from the PHA. Additional PHA information moves to subparagraph (e)(2) through (6) and a new requirement to address inherently safer technology or design measures implemented (if any) and the technology category is in subparagraph (e)(7). This is similar to the proposed revisions but reorganized to simplify the proposed subparagraph (e)(2) and move to a new subparagraph (e)(7);

• § 68.175(k) by adding a requirement that the owner or operator identify whether the most recent compliance audit was a third-party audit, pursuant to §§ 68.79 and 68.80; and

• § 68.175(l) by clarifying that the date of the most recent incident investigation be the completion date of the investigation. This would be the date on the final incident investigation report.

EPA received no comments on these provisions.

D. Revisions to § 68.180 (Emergency Response Program)

Subpart G § 68.180 contains the emergency response program data elements that must be included in the RMP. EPA proposed revisions to add emergency response exercises and revise local coordination provisions of the rule in order to improve coordination with local response authorities and bolster emergency response capabilities and preparedness for accidental releases.

1. Summary of Proposed Rulemaking

• In § 68.180(a) EPA proposed to delete the phrase ''the following information.'' The text in subparagraphs (a)(1) through (3) were reorganized and/or replaced and EPA proposed to delete subparagraphs (a)(4) through (6).

○ In subparagraph (a)(1), EPA proposed to require the RMP to identify the name, organizational affiliation, phone number, and email address of local emergency planning and response organizations with which the stationary source last coordinated emergency response efforts, pursuant to § 68.10(f)(3) or § 68.93.

○ Subparagraph (a)(2) included proposed requirements to identify whether coordination with the local emergency response organizations is occurring at least annually, pursuant to § 68.93(a).

○ Finally, in subparagraph (a)(3) EPA proposed to require the RMP to identify a list of Federal or state emergency plan requirements to which the stationary source is subject.

• In § 68.180(b), EPA proposed to replace the current text with a requirement to identify whether the facility is a responding or non-responding stationary source, pursuant to § 68.90. EPA proposed subparagraph (b)(1) to apply to non-responding stationary sources and subparagraph (b)(2) to apply to responding stationary sources.

○ *Non-responding stationary sources.* In subparagraphs (b)(1)(i) through (iii) the owner or operator would be required to identify whether the owner or operator has confirmed that local responders are capable of responding to accidental releases at the source, whether appropriate notification mechanisms are in place, and whether a notification exercise occurs at least annually.

○ *Responding stationary sources.* In subparagraphs (b)(2)(i) through (v) the owner or operator would be required to identify whether the LEPC or local response entity requested that the stationary source be a responding facility; whether the stationary source complies with requirements in § 68.95; whether a notification exercises occurs at least annually, as required in § 68.96(a); whether a field exercise is conducted every five years and after any RMP reportable accident, pursuant to § 68.96(b)(1)(i); and whether a tabletop exercise occurs at least annually, except during the calendar year when a field exercise is conducted, as required in § 68.96(b)(2)(i).

EPA proposed to delete § 68.180(c), which required the owner or operator to list other Federal or state emergency plan requirements to which the stationary source is subject.

2. Summary of Final Rule

EPA is completely revising and reorganizing subpart G § 68.180 into the following three parts: Requirements for all stationary sources under paragraph (a), requirements for non-responding stationary sources under paragraph (b)(1), and requirements for responding stationary sources under paragraph (b)(2). EPA believes that reorganizing subpart G § 68.180 will clarify the reporting requirements, reduce errors in submitted RMPs, and improve compliance with the RMP requirements. The revisions to subpart G § 68.180 will also improve EPA's ability to evaluate a facility's compliance with the Emergency Response Program requirements.

EPA is amending and finalizing the proposed revisions to require specific information rather than attestations of compliance. EPA is not finalizing the proposed provisions that pertain to LEPCs requesting a stationary source to comply with emergency response program requirements of § 68.95 so EPA is eliminating those requirements under § 68.180.

EPA is finalizing § 68.180(a) as proposed except that subparagraph (a)(2) requires the RMP to identify the date of the most recent coordination with the local emergency response organizations, pursuant to § 68.93(a) (rather than attesting that coordination occurs annually).

EPA is finalizing § 68.180(b) introductory paragraph as proposed. In the final rule subparagraph (b)(1) applies to non-responding stationary sources and subparagraph (b)(2) applies to responding stationary sources. EPA is amending and finalizing the subparagraph as follows:

• *Non-responding stationary sources.* In subparagraphs (b)(1)(i) through (iii) the owner or operator is required to identify whether the stationary source is included in the community emergency response plan developed under EPCRA (for stationary sources with any regulated toxic substance); the date of the most recent coordination with the local fire department (for stationary sources with only regulated flammable substances); what notification mechanisms are in place; and the date of the most recent notification exercise.

• *Responding stationary sources.* In subparagraphs (b)(2)(i) through (iv) the owner or operator is required to identify the date of the most recent review and update of the emergency response plan required in § 68.95(a)(4); the date of the most recent notification, as required in § 68.96(a); the date of the most recent field exercise, pursuant to § 68.96(b)(1)(i); and the date of the most recent tabletop exercise, as required in § 68.96(b)(2)(i).

3. Discussion of Comments and Basis for Final Rule Provisions

EPA received one comment indicating that the revision to § 68.180 is unclear and that the 'data elements' of the proposal do not distinguish between responding and non-responding stationary sources.

EPA believes that the data elements do distinguish between responding and non-responding stationary sources. A stationary source will be required to identify whether they are ''responding'' or ''non-responding'' and responding stationary sources and will answer questions accordingly. EPA will revise its online RMP submission system, RMP*eSubmit, to include the additional data elements, and expects that the submission system will provide clarity for stationary source owners and operators on how to submit responses.

E. Technical Corrections

1. Revisions to § 68.10 (Applicability)

EPA is correcting a typographical error in § 68.10(b)(2). Section 68.10(b)(2) uses the term public receptor and indicates that public receptor is defined in § 68.30; however, the term public receptor is defined in § 68.3, not § 68.30. The revised rule language corrects this typographical error. EPA received no

comments and is finalizing this provision as proposed.

2. Revisions to § 68.48 (Safety Information)

EPA proposed to remove the word ''material'' from the term Material Safety Data Sheet in § 68.48(a)(1) to conform with OSHA's revised terminology for SDS.

Discussion of comments on safety information provisions. A commenter recommended that EPA's revision to § 68.48 should not require facilities to ensure that safety data sheets meet OSHA's hazard communication standard requirements. This commenter argued that operators are given their safety data sheets by vendors and do not have control over their content.

EPA disagrees with the commenter. The current rule requires the owner or operator to maintain Material Safety Data Sheets (MSDS) that meets the OSHA hazard communication standard requirements of 29 CFR 1910.1200(g). In 2012, OSHA made changes to its Hazard Communication Standard at 29 CFR 1910.1200 in order to align with the U.N. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Revision 3 (77 FR 17574, March 26, 2012). One change was in nomenclature from ''Material Safety Data Sheets'' to ''Safety Data Sheets.'' Consequently, OSHA revised the name of the MSDS to Safety Data Sheets (SDS) in the PSM standard at 1910.119(d)(1)(vii) (78 FR 9311, February 8, 2013). Chemical producers and users had to comply with SDS requirements by June 1, 2015.[119] EPA's technical correction is solely to be consistent with the revised OSHA requirements and EPA is finalizing this amendment as proposed.

3. Revisions to §§ 68.54 and 68.71 (Training)

The RMP rule requires initial and refresher training for employees operating a Program 2 or Program 3 covered process. Since the inception of the rule, however, there has been confusion on the types of employees that are considered workers operating a covered process. Although ''employee'' is not defined in § 68.3, EPA has traditionally interpreted an employee to be any worker that is involved in operating a process, including supervisors. This is consistent with the OSHA definition of ''employee'' set forth at 29 CFR 1910.2(d). EPA proposed amendments to clarify that employees ''involved in'' operating a process are subject to the training requirements of the rule. EPA further proposed a provision to clarify that the term employee includes supervisors responsible for directing process operations. EPA is finalizing these amendments as proposed.

Discussion of comments on training provisions. Several commenters suggested that the proposed revisions to § 68.54 are unclear. These commenters indicated that EPA should provide greater clarification regarding the length of time employers should train their employees, which employees need training, and the distinction between employees ''operating'' a process and employees ''involved in operating'' a process.

EPA directs readers to review the Guidance for Facilities on Risk Management Programs for Chemical Accident Prevention (40 CFR part 68) (or General Risk Management Program Guidance), which clarifies expectations for training requirements.[120] The guidance does not specify a specific amount or type of training and allows the owner or operator to develop a training approach that is facility-specific and tailored to the needs of the facility's employees. The revised language to require training for employees ''involved in'' operating a process is intended to include employees that operate a process, as well as supervisors of those employees, and other employees that may occasionally be involved in process operations, such as process engineers and maintenance technicians. For employees other than operators and supervisors, EPA expects that initial and refresher training will be appropriate to the employee's responsibilities in operating the process.

If a supervisor is involved in decision-making for process operations, such as making changes to operating parameters, developing or approving operating procedures, or conducting emergency operations, then EPA expects that the supervisor receives initial and refresher training appropriate to the supervisor's responsibilities. In such cases, the training of a supervisor might not need to be as extensive as that of an operator, but EPA expects that the supervisor training will include process operations for which the supervisor might have decision-making authority.

4. Revisions to § 68.65 (PSI)

EPA is revising § 68.65(a) in order to remove irrelevant text regarding the timeframe for initial development of PSI and to more clearly demonstrate that PSI must be kept up-to-date. EPA is revising § 68.65(a) to remove the phrase ''In accordance with the schedule set forth in § 68.67'' and is adding the phrase: ''and shall keep PSI up-to-date.'' EPA expects that revising § 68.65(a) in this manner will help Program 3 facilities to better comply with PSI requirements and further clarifies the requirement that PSI must be completed prior to conducting a PHA.

Finally, in order to be consistent with OSHA and the GHS, EPA is replacing ''Material Safety Data Sheet'' with ''Safety Data Sheet'' in the note to § 68.65(b). EPA received no comments and is finalizing these revisions as proposed.

5. Revisions to § 68.130—List of Substances

EPA is revising Tables 1 and 4 in § 68.130 as follows:

Table 1 to § 68.130—List of Regulated Toxic Substances and TQs for Accidental Release Prevention. EPA is correcting a typographical error in the Chemical Abstracts Service (CAS) number (no.) for allyl alcohol in Table 1 in § 68.130. The incorrect CAS no. of 107–18–61 for allyl alcohol is corrected to 107–18–6.

Table 4 to § 68.130—List of Regulated Flammable Substances and TQs for Accidental Release Prevention. EPA is correcting a typographical error to the CAS no. for 1, 3-Butadiene, to read 106–99–0, instead of 196–99–0, revising to right justify the first CAS nos. column and deleting the second CAS nos. column because it is redundant. EPA received no comments on these provisions and is finalizing the revisions as proposed.

6. Revisions to § 68.200 (Recordkeeping)

EPA is revising § 68.200 to clarify that records must be maintained at the stationary source. EPA received no comments on this provision and is finalizing the revision as proposed.

VIII. Compliance Dates

The initial Risk Management Program rule applied 3 years after promulgation of the rule on June 20, 1996, which is consistent with the last sentence of CAA section 112(r)(7)(B)(i). The statute does not directly address when amendments should become applicable. The provisions of this action modify terms of the existing rule, and, in some cases, clarify existing requirements.

[119] OSHA Fact Sheet—Hazard Communication Standard Final Rule. *https://www.osha.gov/dsg/hazcom/HCSFactsheet.html.*

[120] General Guidance for Facilities on Risk Management Programs for Chemical Accident Prevention (40 CFR part 68), March 2009. *https://www.epa.gov/rmp/guidance-facilities-risk-management-programs-rmp.*

A. Summary of Proposed Rulemaking

EPA proposed modifications to § 68.10 to establish compliance dates for an owner operator to comply with the revised rule provisions as follows:

- Require compliance with emergency response coordination activities within one year of an effective date of a final rule;
- Provide up to three years for the owner or operator of a non-responding stationary source to develop an emergency response program in accordance with § 68.95 following an LEPC or equivalent's written request to do so;
- Comply with new provisions (*i.e.,* third-party compliance audits, root cause analyses as part of incident investigations, STAA, emergency response exercises, and information availability provisions), unless otherwise stated, four years after the effective date of the final rule; and
- Provide regulated sources one additional year (*i.e.,* five years after the effective date of the final rule) to correct or resubmit RMPs to reflect new and revised data elements.

B. Summary of Final Rule

EPA is finalizing the compliance dates as proposed, except that EPA is deleting language requiring the owner or operator of a non-responding stationary source to develop an emergency response program following an LEPC's written request to do so. Instead, the final provides three years for the owner or operator of a non-responding stationary source to develop an emergency response program in accordance with § 68.95 when the owner or operator determines that they meet the applicability criteria for responding stationary sources in § 68.90.

C. Discussion of Comments

Some commenters provided support for one or more of the compliance dates; however, many commenters were concerned that the timeframes were too long or in some cases too short.

1. General Comments

One commenter argued that the compliance dates should be set at one to two years after the effective date of the rule because the rule provisions are procedural and do not involve capital expenditures. A facility requested that EPA clarify that annual compliance dates and required reoccurring tasks have flexible yearly due dates to allow facilities to perform thorough evaluations without the pressure of tight yearly deadlines.

EPA agrees with commenters that annual compliance dates and required reoccurring tasks should have flexible yearly due dates. This will allow the facility owner or operator and local emergency response officials to schedule coordination activities or exercises based on availability of personnel and minimize unnecessary pressure to comply with a rigid timeframe.

However, EPA disagrees that the compliance dates for all provisions should be shortened to one or two years. EPA believes that additional time is necessary for facility owners and operators to understand the revised rule; train facility personnel on the revised provisions, learn new investigation techniques, as appropriate; research safer technologies; arrange for emergency response resources and response training; incorporate change into their risk management programs; and establish a strategy to notify the public that certain information is available upon request. Furthermore, EPA intends to publish guidance for certain provisions, such as STAA, root cause analysis, and emergency response exercises. Once these materials are complete, owners and operators will need time to familiarize themselves with the new materials and incorporate them into their risk management programs.

2. Third-Party Compliance Audits

One commenter expressed concern that the lack of qualified auditors would result in compliance delays and the three-year timeframe could result in an excessive burden on facilities if there is a limited availability of qualified auditors. The commenter further cited the inability to plan for a third-party audit based on the applicability criteria as a reason for the owner or operator to be unable to comply within the timeframe.

Other commenters urged for shorter timeframes with one commenter pointing out that this provision is triggered by an accident and should therefore be under an accelerated compliance date. Two commenters suggested a three-year compliance date, with the one commenter arguing that there already enough people to perform third-party audits.

EPA disagrees with commenters and is finalizing a four-year compliance date for third-party audits. This means that for any RMP reportable accident occurring later than four years after the effective date of the rule, the owner or operator of a source must conduct a third-party audit. The four-year compliance timeframe will allow potential auditors enough time to establish internal protocols and identify personnel that meet the competency and independence criteria necessary to serve as a third-party auditor. These auditors will also need time to advertise their availability to conduct third-party audits so facility owners and operators can identify potential auditors before there is a need to conduct a third-party compliance audit.

3. Incident Investigations and Root Cause Analysis

Many commenters argued that the proposed four-year compliance date is too long. Commenters offered alternative timeframes such as 12 months, 18 months, and three years. A local agency suggested a one-year compliance date, arguing that many complex facilities are already conducting root cause analyses. One commenter argued that provisions that are triggered by an accident should be required in an accelerated timeframe. Other commenters argued that the compliance date should be required as soon as possible.

EPA disagrees with the commenters and is finalizing a four-year compliance date for incident investigations involving root cause analyses. For any incident that occurs four years after the effective date of the final rule and results in (*e.g.* an RMP reportable accident) or could reasonably have resulted in a catastrophic release, the owner or operator must investigate the incident and conduct a root cause analysis. This will allow facility owners and operators sufficient time to establish training and program development activities. EPA encourages facility owner or operators that are already conducting root cause analyses to continue to do so for any incident that resulted in (*e.g.* an RMP reportable accident) or could reasonably have resulted in a catastrophic release during the compliance timeframe.

4. STAA

A local agency supported the four-year compliance timeframe but numerous commenters argued that the proposed timeframe is too long. Many commenters, including mass mail campaigns joined by approximately 14,000 commenters and multiple advocacy groups, requested that EPA expedite compliance with STAA requirements. A mass mail campaign joined by approximately 300 commenters stated that the proposed compliance period is unlawful and arbitrarily long. The commenter argued that EPA has no lawful legal basis to extend the STAA compliance date

beyond three years. Another commenter suggested that EPA should consider following the NJ model to implement IST requirements and require an initial review report within 120 days of the rule's effective date.

However, other commenters thought the proposed timeframe was too short. One commenter cited the complexity of the IST/ISD analysis as a reason to extend the compliance date into a second PHA cycle to allow more time for engineering studies and design. Another commenter supported the U.S. Small Business Administration (SBA) recommendation to defer the STAA requirement for three years for small facilities so that EPA can gather information on their experience and assess how often safer alternatives were identified and at what cost.

EPA disagrees with commenters and is establishing a four-year compliance date for STAA. EPA believes that in many cases sources will prefer to perform a full PHA update when implementing the STAA requirements. Sources subject to this provision are among the largest and most complex sources regulated under 40 CFR part 68, and therefore PHAs and PHA updates at these sources typically require a significant level of effort. Since PHA updates are normally done at five year intervals, EPA believes it would be appropriate to allow most sources to adopt these provisions in their normal PHA update cycle if they so choose. Sources that performed their most recent PHA update immediately prior to this rule's effective date will have up to four years to perform their next PHA update and adopt the STAA provisions. Most sources could schedule their PHA updates to incorporate the new STAA provisions on their normal PHA update schedule. EPA also intends to publish guidance on STAA and once complete, facility owners and operators will need time to familiarize themselves with the new materials and incorporate them into their risk management programs.

EPA disagrees with the recommendation to defer the STAA requirement for three years for small facilities in order to allow EPA to gather information. STAA for a source is a site-specific determination and would be difficult to compare among facilities. EPA believes it would be impractical to gather/analyze information on STAA implementation to determine the utility of the provision for small facilities.

5. Emergency Response Coordination

EPA received comments supporting the proposed one-year compliance date for emergency response coordination activities. One commenter requested clarification on how to calculate the annual coordination activities, recommending that it be based on a calendar year.

EPA agrees with commenters and is finalizing a one-year compliance date for emergency response coordination activities. EPA believes that a flexible schedule is appropriate for scheduling annual coordination and agrees with the recommendation to base the coordination on a calendar year timeframe.

6. Emergency Response Program

One commenter suggested that EPA should allow a minimum timeframe of 12 months for a non-responding facility to transition to a responding facility. The commenter further suggested incorporating an extension request to local agencies in the event of compliance delays that fall outside the owner/operator's control (such as budget constraints or inability to procure response resources). Another commenter expressed support for the timeframe to develop an emergency response program; however, expressed concerns with the ongoing costs associated with that requirement.

EPA is finalizing a three-year compliance date for a facility owner or operator to develop an emergency response program once he or she determines a need for a program. EPA is not incorporating an extension request to address compliance delays that may fall outside the owner or operator's control. EPA notes that the two provisions from § 68.90 of the proposed rule that would have made the owner or operator's decision to develop an emergency response program contingent on the outcome of local coordination activities, and required the owner or operator to develop an emergency response program upon receiving a written request to do so from the LEPC or local response authorities, were not included in the final rule. EPA believes that by making these changes, the regulatory provisions that would potentially have caused many sources to convert from being non-responding sources to responding sources have been removed from the final rule. However, as the emergency coordination provisions of the final rule require regulated sources to coordinate annually with local responders and to document coordination activities, EPA acknowledges that it is possible that these more frequent coordination activities may still prompt some sources to implement an emergency response program (*i.e.,* for a non-responding source to become a responding source). In such cases, EPA believes a three-year timeframe is appropriate to establish a program that meets the requirements of § 68.95.

7. Facility Exercises

One commenter objected to the proposed four-year compliance date for emergency response exercises arguing that exercises should be required within one year of when coordination activities must begin.

EPA disagrees with the commenter and is finalizing a four-year compliance date for conducting emergency response exercises. This means that the owner or operator has four years after the effective date of this rule to conduct a notification exercise, consult with local emergency response officials to establish a schedule for conducting tabletop and field exercises, and complete at least one tabletop or field exercise. EPA believes that this timeframe will allow owners and operators to develop an exercise program that is appropriate for their facility, train personnel, and coordinate with local emergency response officials. EPA also expects to develop guidance on emergency response exercises and facility owners and operators will require time to familiarize themselves with the guidance.

8. Information Availability

A professional organization stated that the proposed timeline for information sharing should be shortened to three years for information that is shared with the public. The commenter recommended that information sharing with facility workers should begin immediately after the implementation of the rule. Another commenter asserted that the proposed rulemaking provisions and compliance dates are inappropriate for the sharing of information, arguing that provisions triggered by an accident should be required in an accelerated timeframe.

EPA disagrees with commenters and is finalizing a four-year compliance date for information availability provisions. This means that four years after the effective date of the rule, the facility owner or operator must have notifications in place to inform the public that information specified in § 68.210(b) is available upon request. For any RMP reportable accident occurring later than four years after the effective date of the rule, the owner or operator of a source must hold a public meeting within 90 days of the accident. EPA believes that this timeframe is sufficient to allow facility staff an opportunity to determine the best method for providing notifications to the public and to assemble and format

information to prepare to respond to information requests.

9. Update and Resubmit RMP

EPA received no comments on the proposed five-year compliance date for owners or operators to update RMPs to reflect the new and revised data elements in subpart G of the rule. EPA is finalizing a five-year compliance date for this provision, as proposed. This timeframe will allow owners and operators an opportunity to begin to comply with revised rule provisions prior to certifying compliance in the RMP. Additionally, the Agency will revise its online RMP submission system, RMP*eSubmit, to include the additional data elements, and sources will not be able to update RMPs with new or revised data elements until the submission system is ready. Also, once it is ready, allowing an additional year for sources to update RMPs will prevent potential problems with thousands of sources submitting updated RMPs on the same day.

D. Compliance Date Examples

The following examples demonstrate the compliance dates for the final rule as described in Table 6: Final Rule Provisions and Corresponding Compliance Dates.

TABLE 6—FINAL RULE PROVISIONS AND CORRESPONDING COMPLIANCE DATES

Rule provision	Compliance date	Initiated after an RMP reportable accident?
Third-party audit	March 15, 2021	Yes.
Root cause analysis	March 15, 2021	Yes (also required after near misses).
STAA	March 15, 2021	No.
Emergency response coordination activities	March 14, 2018	No.
Owner/operator determines that the facility is subject to the emergency response program requirements of § 68.95.	Within three years of the determination	No.
Emergency response exercises	March 15, 2021	No.
Information sharing	March 15, 2021	Partially-public meeting within 90 days.
Update RMP	March 14, 2022	No (but previously existing correction requirements of § 68.195 still apply).

Example 1: Provisions That Apply to a Non-Responding Stationary Source

Source A (see Table 7) is a non-responding stationary source with a regulated process subject to Program 2 requirements. Source A's owner submitted the latest RMP update to EPA on January 20, 2015 and completed its latest compliance audit on August 11, 2017. The source is not in NAICS 322, 324, or 325, and therefore is not subject to the STAA provisions. The source has not had any RMP reportable accidents since the effective date of the final rule.

TABLE 7—EXAMPLE 1, SOURCE A

Source A—Program 2, non-responding stationary source		
Date of last RMP update	Last compliance audit	Last accident
January 20, 2015	August 11, 2017	N/A.

In this example, the following provisions apply:

- Annual emergency response coordination activities in accordance with § 68.93;
- Notification exercises (§ 68.96(a)); and
- Information availability provisions (§ 68.210).

The owner or operator must coordinate response needs with local emergency planning and response organizations as described in § 68.93 (*i.e.,* to determine how the source is addressed in the community emergency response plan and to ensure that local response organizations are aware of the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility). Coordination activities must occur annually and be documented.

Source A is a non-responding facility, and the owner or operator is required to conduct annual notification exercises. The owner or operator is also required to provide ongoing public notification that certain information is available to the public upon request.

Finally, beginning five years after the rule effective date, the owner or operator must update the RMP to include all revised data elements specified in subpart G. In this case, the owner or operator would update their RMP no later than January 20, 2020 (the source's next scheduled five-year update), and again by March 14, 2022 (the required resubmission date for the final rule).

Table 8: Summary of provisions that apply to a non-responding stationary source summarizes the provisions that apply to Source A.

TABLE 8—SUMMARY OF PROVISIONS THAT APPLY TO A NON-RESPONDING STATIONARY SOURCE

Applicable provisions	Additional information	When to complete *
Emergency response coordination activities.	Occurs annually	Complete coordination activities before March 14, 2018 and document coordination.
Notification exercise	Occurs annually	Complete first notification exercise by March 15, 2021.
Information availability provisions		
Information to the public	Ongoing. Includes notification that specifies the information that is available and provides instructions on how to obtain, and links to community preparedness information.	Complete first calendar year notification by March 15, 2021.
Update RMP	Owner's next five-year resubmission date occurs prior to effective date for provision, so owner must update RMP twice.	Update RMP on regular schedule (by January 20, 2020) and again to include new information by March 14, 2022.

If the Source A's owner or operator determines that the facility is subject to the emergency response program requirements (*i.e.,* the facility has toxic substances and is not included in the community emergency response plan or the facility has flammable substances and has not coordinated response actions with the local fire department), then he or she would have three years from the determination date to develop and implement an emergency response plan, obtain equipment, and train personnel in relevant procedures.

Once the owner has developed an emergency response program, the source is a responding facility and must also comply with tabletop and field exercise requirements for responding facilities.

Example 2A: Provisions That Apply to a Responding Stationary Source

Source B (see Table 9) is a responding stationary source with a process subject to Program 3 requirements. Its latest RMP update was submitted June 30, 2020. Its latest compliance audit was performed on April 6, 2020. The source is not in NAICS 322, 324, or 325, and therefore is not subject to the STAA provisions, and the source has not had any RMP reportable accidents since the effective date of a final rule.

TABLE 9—EXAMPLE 2A, SOURCE B

Source B—Program 3, responding stationary source		
Date of last RMP update	Last compliance audit	Last accident
June 30, 2020	April 6, 2020	N/A.

In this example, the following provisions apply:

- Annual emergency response coordination activities in accordance with § 68.93;
- Emergency response exercises (§ 68.96); and
- Information availability provisions (§ 68.210).

The owner or operator must coordinate response needs with local emergency planning and response organizations as described in § 68.93. Coordination activities must occur annually and be documented.

Additionally, since Source B is a responding facility, the owner or operator is required to conduct annual notification exercises and tabletop and field exercises. The frequency of the tabletop and field exercises will be determined in consultation with local emergency response officials, but at a minimum, shall be every three years for tabletop exercises and every ten years for field exercises. EPA expects that within four years of the effective date of the final rule, that the owner or operator will consult with local emergency response officials to establish a schedule for conducting at least one tabletop and/or field exercise.

The owner or operator is also required to provide ongoing public notification that certain information is available the public upon request.

Finally, by five years after the rule effective date, the owner or operator must update the RMP to include all revised data elements specified in subpart G. Table 10: Summary of provisions that apply to Source B summarizes the provisions that apply in this example.

TABLE 10—SUMMARY OF PROVISIONS THAT APPLY TO SOURCE B

Applicable provisions	Additional information	When to complete *
Emergency response coordination activities.	Occurs annually	Complete coordination activities before March 14, 2018.
Emergency response exercises (§ 68.96)		
Notification exercise	Occurs annually	Complete first notification exercise by March 15, 2021.
Field and tabletop exercises	Tabletop exercise every three years, field exercise once every ten years.	Complete first tabletop or field exercise by March 15, 2021.
Information availability provisions		
Information to the public	Ongoing. Includes notification that specifies the information that is available, provides instructions on how to obtain, and links to community preparedness information.	Complete first calendar year notification by March 15, 2021.
Update RMP	.....	Update RMP to include new information by March 15, 2021.

Example 2B: Additional Provisions That Apply to a Responding Stationary Following an RMP Reportable Accident.

See Table 11.

TABLE 11—EXAMPLE 2B, SOURCE B

Source B—Program 3, responding stationary source		
Date of last RMP update	Last compliance audit	Last accident
June 30, 2020	April 6, 2020	July 5, 2021.

In this example, Source B has an accidental release on July 5, 2021 that meets the reporting requirements of § 68.42. As a result of the accident, Source B's owner is required to comply with the following additional provisions:

- Third-party audit provisions of § 68.80;
- Incident investigation and root cause analysis requirements of § 68.81; and
- Public meeting within 90 days of an RMP reportable accident, pursuant to § 68.210(e).

Chronologically, the first provision that applies is the requirement to host a public meeting. Section 68.210(e) requires the owner or operator to hold a public meeting within 90 days after the accident to inform the public about the accident, including information required under § 68.42, and other relevant information.

An incident investigation must be initiated promptly, but no later than 48 hours following the incident. The incident investigation provisions require the owner or operator to complete an incident investigation that includes a root cause analysis and other elements specified in § 68.81(d), and an incident investigation report, within 12 months of the incident, unless the implementing agency approves an extension of time.

The third-party audit provisions require the owner or operator to hire a third-party auditor to perform a third-

party compliance audit and complete an audit report within 12 months of the accident (unless the implementing agency approves an extension). The owner or operator must also complete an audit findings response report within 90 days of receiving the audit report from the third-party auditor. The owner or operator must also provide the audit findings response report, as well as a schedule to address deficiencies identified in the audit findings response report and documentation of actions taken to address deficiencies, to the owner or operator's audit committee of the Board of Directors, or other comparable committee or individual, if applicable.

By five years after the rule effective date, the owner or operator must update the RMP to include all revised data elements specified in subpart G and § 68.42. Finally, if the owner or operator's response to the incident utilizes the facility's emergency response plan, tested the objectives of an exercise as described in § 68.96(b)(1)(ii), and documents response actions as described in § 68.96(b)(3), then the owner or operator may use the response to satisfy the field exercise requirements of the final rule.

Table 12 summarizes the additional provisions that apply to Source B following an RMP reportable accident (in addition to complying with new requirements triggered by an RMP reportable accident, the owner or operator must annually coordinate response needs with local emergency planning and response organizations, document coordination activities, and comply with the other information disclosure provisions as previously described).

TABLE 12—SUMMARY OF ADDITIONAL PROVISIONS THAT APPLY TO SOURCE B FOLLOWING AN RMP REPORTABLE ACCIDENT

Applicable provisions following an RMP reportable accident:	Compliance date	Additional information	When to complete *
Public meeting	March 15, 2021	The accident occurred after the compliance date for this provision, therefore, schedule a meeting within 90 days after the RMP reportable accident.	Hold public meeting by October 3, 2021.
Incident investigations	March 15, 2021	The accident occurred after the compliance date for this provision, therefore, initiate within 48 hours, complete investigation and root cause analysis within 12 months.	Complete report by July 5, 2022.
Third-party audit	March 15, 2021	The accident occurred after the compliance date for this provision, therefore, complete within 12 months of the RMP reportable accident.	Complete third-party audit by July 5, 2022 Complete findings response report within 90 days of completing audit.
Field exercise	March 15, 2021	May use the response to satisfy the field exercise requirements of the rule when all objectives of the exercise are tested and the response is documented.	Document the response within 90 days of the incident (*i.e.,* by October 3, 2021), if using response to satisfy field exercise requirements.
Accident history information in RMP.		Correct RMP within 6 months of accident (existing requirement).	Correct RMP by January 5, 2022.

Example 3: Compliance Date Example for Sources Subject to STAA Requirements

Source C (see Table 13) is a petroleum refinery in NAICS 32411. Its latest RMP update was submitted on March 31, 2018. Its latest PHA revalidation was completed on March 7, 2017.

TABLE 13—EXAMPLE 3, SOURCE C

Source C—Program 3, NAICS 32411	
Date of last RMP update	Last PHA revalidation
March 31, 2018	March 7, 2017.

Because the source is in NAICS 32411, it is subject to the STAA provisions of § 68.67(c)(8). Therefore, March 15, 2021, the owner or operator must complete a PHA revalidation that addresses safer technology and alternative risk management measures, and determine the practicability of the ISTs and ISDs considered.

By March 14, 2018 the owner or operator of Source C must comply with the emergency response coordination provisions, and by March 15, 2021, the owner or operator must also comply with other applicable rule provisions including: Third-party audits; incident investigations; emergency response exercises; and information availability (including public meetings).

By March 14, 2022, the owner or operator of Source C must update the RMP to include all revised data elements specified in subpart G. Table 14: Compliance date example for sources subject to STAA requirements, summarizes the STAA provisions that apply to Source C.

TABLE 14—COMPLIANCE DATE EXAMPLE FOR SOURCES SUBJECT TO STAA REQUIREMENTS

Applicable provisions	Additional information	When to complete *
STAA	Occurs every five years as part of PHA revalidation	By March 15, 2021.
Update RMP		By March 14, 2022.

IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. The EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. This RIA is available in the docket and is summarized here (Docket ID Number EPA–HQ–OEM–2015–0725).

1. Why EPA Is Considering This Action

In response to catastrophic chemical facility incidents in the United States, President Obama issued Executive Order 13650, ''Improving Chemical Facility Safety and Security,'' on August 1, 2013. The Executive Order establishes the Chemical Facility Safety and Security Working Group (Working Group), co-chaired by the Secretary of Homeland Security, the Administrator of EPA, and the Secretary of Labor or their designated representatives at the Assistant Secretary level or higher, and comprised of senior representatives of other Federal departments, agencies, and offices. The Executive Order requires the Working Group to carry out a number of tasks whose overall goal is to prevent chemical accidents.

Section 6(a)(i) of Executive Order 13650 requires the Working Group to develop options for improved chemical facility safety and security that identify ''improvements to existing risk management practices through agency programs, private sector initiatives, Government guidance, outreach, standards, and regulations.'' Section 6(c) of Executive Order 13650 requires the Administrator of EPA to review the Risk Management Program. As part of this effort to solicit comments and information from the public regarding potential changes to EPA's RMP regulations (40 CFR part 68), on July 31, 2014, EPA published an RFI (79 FR 44604).

EPA believes that the RMP regulations have been effective in preventing and mitigating chemical accidents in the United States; however, EPA believes that revisions could further protect human health and the environment from chemical hazards through advancement of PSM based on lessons learned. These revisions are a result of a review of the existing Risk Management Program and information gathered from the comments on the proposed rulemaking, SBAR panel, public hearing, RFI, and Executive Order listening sessions, and are finalized under the statutory authority provided by CAA section 112(r) as amended (42 U.S.C. 7412(r)).

2. Description of Alternatives to the Final Rule

EPA analyzed in the RIA the requirements finalized in this action as well as several alternatives for each.

a. Third-Party Audits (Program 2 §§ 68.58 and 68.59 and Program 3 §§ 68.79 and 68.80)

The existing rule requires Program 2 and Program 3 processes to conduct a compliance audit at least once every three years. The revised rule requires facilities to contract with an independent third-party, or assemble an audit team led by an independent third-party, to conduct the next scheduled compliance audit following an RMP reportable accident or after an implementing agency determines that certain circumstances exist that suggest a heightened risk for an accident. The third-party would have to be someone with whom the facility does not have an existing or recent relationship and who meets specific qualification criteria. The low cost alternative applies only for Program 2 and Program 3 processes after an RMP reportable accident or at the request of the implementing agency. The medium cost alternative applies every three years for all compliance audits conducted for all Program 3 processes. The high cost alternative applies every three years for all compliance audits conducted for Program 2 and Program 3 processes.

b. Incident Investigations/Root Cause Analysis (§§ 68.60 and 68.81)

The rule requires facilities to conduct a root cause analysis as part of an incident investigation following an RMP reportable accident or an incident that could reasonably have resulted in an RMP reportable accident (*i.e.,* ''near miss''). A root cause analysis is a formal process to identify underlying reasons for failures that lead to accidental releases. These analyses usually require someone trained in the technique. The low cost alternative applies the provision only to RMP reportable accidents or near misses in Program 3 processes. The medium/high cost alternative applies to RMP reportable accidents or near misses involving Program 2 and Program 3 processes.

c. STAA (§ 68.67)

Under the final rule, facilities in NAICS codes 322 (paper manufacturing), 324 (petroleum and coal products manufacturing), and 325 (chemical manufacturing) with Program 3 processes are required to conduct a STAA for each process as part of their PHA, which occurs every five years. The STAA includes two parts: The initial analysis to identify alternatives, and a practicability study to determine the costs and assess the reasonableness of implementing technology alternatives. The final rule is the low cost alternative, which applies to all facilities with Program 3 processes in NAICS codes 322, 324, and 325. The medium cost alternative applies the requirement to all Program 3 processes. The high cost alternative applies the requirement to all Program 3 processes and require facilities to implement practicable IST/ISD.

d. Emergency Response Program Coordination With Local Responders (§§ 68.90, New 68.93, and 68.95)

Under the final rule, all facilities with Program 2 or Program 3 processes are required to coordinate with local response agencies annually to determine how the source is addressed in the community emergency response plan and to ensure that local response organizations are aware of the regulated substances at the source, their quantities, the risks presented by covered processes, and the resources and capabilities at the facility to respond to an accidental release of a regulated substance. The owner or operator must document coordination activities.

Alternatives to this provision are similar to the finalized requirements. One alternative that imposes the same costs as the final rule option includes an option for local officials to request that a facility owner or operator comply with the emergency response program requirements of § 68.95. This would be analogous to the requirements under the Oil Pollution Prevention regulation (40 CFR part 112) where all facilities subject to the FRP provisions at § 112.20 are required to prepare and implement an emergency response plan for oil discharges into navigable waters or adjoining shorelines.

e. Facility Exercises (§ 68.96)

Notification exercises. All facilities with Program 2 or Program 3 processes are required to conduct a notification

exercise annually to ensure that the contact list to be used in an emergency is complete, accurate, and up-to-date.

Tabletop and field exercises. The rule requires responding facilities to conduct exercises of their emergency response plans and invite local emergency response officials to participate. Under the low cost alternative, facilities would conduct tabletop exercises every three years. Under the final rule, which is the medium cost alternative, facilities will establish the frequency of exercises in consultation with local emergency response officials, but at a minimum, full field exercises will be conducted at least once every ten years and tabletop exercises conducted at least once every three years. Responding facilities that have an RMP reportable accident, and document the response activities in an after-action report comparable to the exercise evaluation reports may use that response to satisfy the field exercise requirements. Furthermore, owner and operators of responding facilities that conduct exercises to meet other Federal, state or local exercise requirements may satisfy the RMP exercise requirements provided that the scope of the exercise includes the objectives of an RMP exercise. Under the high cost alternative, facilities would conduct full field exercises annually.

f. Information Availability (§ 68.210)

The rule requires all facilities to provide certain basic chemical hazard information to the public, upon request. The owner or operator of the facility shall provide ongoing notification of availability of information elements on a company Web site, social media platforms, or through some other publicly accessible means. The information to be disclosed includes names of regulated substances at the facility; SDS; accident history information; emergency response program information; and LEPC or local response agency contact information.

EPA proposed requirements for facilities to provide certain information to the LEPC, Tribal Emergency Planning Committee (TEPC) or other local emergency response agencies. However, rather than prescribe information elements that must be provided upon request, EPA is requiring the owner or operator of a stationary source to share information that is relevant to emergency response planning as part of the coordination activities that occur annually between facility representatives and local emergency response agencies.

Finally, the rule requires facilities to hold a public meeting for the local community within 90 days of an RMP reportable accident. The medium cost alternative would require Program 2 and Program 3 facilities to hold a public meeting at least once every five years and within 90 days of an RMP reportable accident. The high cost alternative would require all facilities (*i.e.,* including Program 1 facilities) to hold a public meeting at least once every five years and immediately following an RMP reportable accident.

3. Summary of Costs

Approximately 12,500 facilities have filed current RMPs with EPA and are potentially affected by the revised rule. These facilities range from petroleum refineries and large chemical manufacturers to water and wastewater treatment systems; chemical and petroleum wholesalers and terminals; food manufacturers, packing plants, and other cold storage facilities with ammonia refrigeration systems; agricultural chemical distributors; midstream gas plants; and a limited number of other sources that use RMP-regulated substances.

Table 15 presents the number of facilities according to the latest RMP reporting as of February 2015 by industrial sector and chemical use.

TABLE 15—NUMBER OF AFFECTED FACILITIES BY SECTOR

Sector	NAICS codes	Total facilities	Chemical uses
Administration of environmental quality programs (*i.e.,* governments).	924	1,923	Use chlorine and other chemicals for treatment.
Agricultural chemical distributors/wholesalers	111, 112, 115, 42491	3,667	Store ammonia for sale; some in NAICS 111 and 115 use ammonia as a refrigerant.
Chemical manufacturing	325	1,466	Manufacture, process, store.
Chemical wholesalers	4246	333	Store for sale.
Food and beverage manufacturing	311, 312	1,476	Use mostly ammonia as a refrigerant.
Oil and gas extraction	211	741	Intermediate processing (mostly regulated flammable substances and flammable mixtures).
Other	44, 45, 48, 54, 56, 61, 72	248	Use chemicals for wastewater treatment, refrigeration, store chemicals for sale.
Other manufacturing	313, 326, 327, 33	384	Use various chemicals in manufacturing process, waste treatment.
Other wholesale	423, 424	302	Use (mostly ammonia as a refrigerant).
Paper manufacturing	322	70	Use various chemicals in pulp and paper manufacturing.
Petroleum and coal products manufacturing	324	156	Manufacture, process, store (mostly regulated flammable substances and flammable mixtures).
Petroleum wholesalers	4247	276	Store for sale (mostly regulated flammable substances and flammable mixtures).
Utilities	221	445	Use chlorine (mostly for water treatment) and other chemicals.
Warehousing and storage	493	1,056	Use mostly ammonia as a refrigerant.
Total		12,542	

Table 16 presents a summary of the annualized costs estimated in the RIA. In total, EPA estimates annualized costs of $131.2 million at a 3% discount rate and $131.8 million at a 7% discount rate.

TABLE 16—SUMMARY OF ANNUALIZED COSTS

[Millions, 2015 dollars]

Provision	3%	7%
Third-party Audits	$9.8	$9.8
Incident Investigation/Root Cause	1.8	1.8
STAA	70.0	70.0
Coordination	16.0	16.0
Notification Exercises	1.4	1.4
Facility Exercises	24.7	24.7
Information Sharing (Public)	3.1	3.1
Public Meeting	0.4	0.4
Rule Familiarization	3.9	4.6
Total Cost *	131.2	131.8

* Totals may not sum due to rounding.

The largest average annual cost of the final rule is the STAA costs ($70.0 million), followed by the exercise costs ($24.7 million), coordination ($16 million), and third-party audits ($9.8 million). The remaining provisions impose average annual costs under $5 million each, including rule familiarization ($3.9 to 4.6 million), information sharing (public) ($3.1 million), incident investigation/root cause analysis ($1.8 million), notification exercises ($1.4 million), and public meetings ($0.4 million).

The rule includes three prevention program provisions—third-party audits, root cause analysis, and STAA—involving information collection and analysis activities that can lead to a wide range of outcomes, and therefore costs, if and when the owner acts upon the findings and/or recommendations generated by the audit, investigation, or analysis. Although resolving audit and investigation findings is required under the existing rule provisions, and the rule does not require implementation of practicable IST alternatives, EPA believes it is possible that there may be costs associated with resolving findings from the third-party audit and root cause analysis provisions that go beyond the costs of the existing provisions, and that some owners or operators may have additional costs due to voluntary implementation of IST. EPA acknowledged the wide range of outcomes from these provisions and the significant uncertainties associated with their costs, and requested information in the proposed rulemaking on whether these costs should accrue to the rule. EPA did not receive any data from commenters that illustrates the: Types of costs that result from independent audits (other than the cost of the audit) that are different from self-audit costs; the types of costs that result from root cause investigations as compared to non-root-cause investigations; and for the STAA provisions, information to project what changes facilities are likely to voluntarily undertake (*e.g.,* cost data or studies for implementation of IST changes).

4. Summary of Potential Benefits

EPA anticipates that implementation of this rule will result in a reduction of the frequency and magnitude of damages from releases. Accidents and releases from RMP facilities occur every year, resulting in fires and explosions, property damage, acute and chronic exposures of workers and nearby residents to hazardous materials, and resultant damages to health. Although we are unable to quantify what specific damage reductions may occur as a result of these revisions, we are able to present data on the total damages that currently occur at RMP facilities each year. The data presented are based on a 10-year baseline period, summarizing RMP accident impacts and, when possible, monetizing them. EPA expects that some portion of future damages would be prevented through implementation of this rule. Table 17 presents a summary of the quantified damages identified in the analysis.

TABLE 17—SUMMARY OF QUANTIFIED DAMAGES

[Millions, 2015 dollars]

	Unit value	10-Year total	Average/year	Average/accident
On-site				
Fatalities	$8.6	$497.8	$49.8	$0.33
Injuries	0.05	105.2	10.5	0.69
Property Damage	.....	2,054.9	205.5	1.4
On-site Total	.....	2,657.9	265.8	1.8
Offsite				
Fatalities	8.6	8.6	0.86	0.01
Hospitalizations	0.4	6.8	0.68	0.004
Medical Treatment	0.001	14.8	1.5	0.01
Evacuations *	0.0	7.0	0.70	0.004
Sheltering in Place *	0.0	40.9	4.1	0.03
Property Damage	.....	11.4	1.1	0.007
Offsite Total	.....	89.5	8.9	0.06
Total	.....	2,747.3	274.7	1.8

* The unit value for evacuations is less than two hundred dollars and for sheltering in place is less than one hundred dollars so when expressed in rounded millions the value represented in the table is zero.

EPA monetized both on-site and offsite damages. EPA estimated total average annual on-site damages of $265.8 million. The largest monetized average annual on-site damage was on-site property damage, which resulted in average annual damage of approximately $205.5 million. The next largest impact was on-site fatalities ($49.8 million) and injuries ($10.5 million).

EPA estimated total average annual offsite damages of $8.9 million. The largest monetized average annual offsite damage was from sheltering in place ($4.1 million), followed by medical treatment ($1.5 million), property damage ($1.1 million), fatalities ($0.86 million), evacuations ($0.7 million), and hospitalizations ($0.68 million).

In total, EPA estimated monetized damages from RMP facility accidents of $274.7 million per year. However, the monetized impacts omit many important categories of accident impacts including lost productivity, the costs of emergency response, transaction costs, property value impacts in the surrounding community (that overlap with other benefit categories), and environmental impacts. Also not reflected in the 10-year baseline costs are the impacts of non-RMP accidents at RMP facilities and any potential impacts of rare high consequence catastrophes. A final omission is related to the information provision. Reducing the probability of chemical accidents and the severity of their impacts, and improving information disclosure by chemical facilities, as the provisions intend, would provide benefits to potentially affected members of society.

Table 18 summarizes four broad social benefit categories related to accident prevention and mitigation including prevention of RMP accidents, mitigation of RMP accidents, prevention and mitigation of non-RMP accidents at RMP facilities, and prevention of major catastrophes. The table explains each and identifies ten associated specific benefit categories, ranging from avoided fatalities to avoided emergency response costs. Table 18 also highlights and explains the information disclosure benefit category and identifies two specific benefits associated with it: Improved efficiency of property markets and allocation of emergency resources.

TABLE 18—SUMMARY OF SOCIAL BENEFITS OF FINAL RULE PROVISIONS

Broad benefit category	Explanation	Specific benefit categories
Accident Prevention	Prevention of future RMP facility accidents	• Reduced Fatalities.
Accident Mitigation	Mitigation of future RMP facility accidents	• Reduced Injuries.
Non-RMP accident prevention and mitigation	Prevention and mitigation of future non-RMP accidents at RMP facilities.	• Reduced Property Damage.
Avoided Catastrophes	Prevention of rare but extremely high consequence events.	• Fewer People Sheltered in Place.
		• Fewer Evacuations.
		• Avoided Lost Productivity.
		• Avoided Emergency Response Costs.
		• Avoided Transaction Costs.
		• Avoided Property Value Impacts.*
		• Avoided Environmental Impacts.
Information Disclosure	Provision of information to the public	• Improved efficiency of property markets.
		• Improved emergency response resource allocation.

* These impacts partially overlap with several other categories such as reduced health and environmental impacts.

5. Discussion of Comments on Estimated Costs and Benefits

a. General Comments

EPA costs underestimated or based on outdated information. Several commenters stated that EPA's cost estimates in the RIA for the proposed rulemaking were generally inaccurate and underestimated the true costs that facilities will face. Some commenters indicated that EPA's estimated labor rates were based on outdated (2014) information. Several commenters representing industry trade associations and regulated facilities expressed specific concerns about the estimated costs of each individual proposed rulemaking element, as well as EPA's estimate of the costs of rule familiarization. Some of these commenters provided specific cost information or estimates to support their claims.

EPA considered this information and made substantial adjustments to the cost estimates for every rule provision, including rule familiarization. In addition to adjusting the cost estimate for the final rule to incorporate cost information submitted by commenters, EPA also adjusted the estimate to delete costs associated with proposed rulemaking provisions that were not included in the final rule (*e.g.,* Information availability to LEPCs), and to account for structural changes between proposed and final rule provisions for certain rule elements (*e.g.,* the final rule requires emergency field and tabletop exercises to be conducted less frequently than EPA had proposed). EPA also updated its estimated labor rates to the most recent (2015) values available from the Bureau of Labor Statistics.

Benefit concerns. Several commenters also addressed EPA's assessment of benefits in their public comment submissions. While some commenters indicated that the proposed requirements would improve safety and prevent chemical releases, other commenters stated that the proposed requirements would not provide any benefits, or that the costs associated with the rule would severely outweigh any benefits. Other commenters indicated that EPA had failed to quantify any benefits of the rule, making a cost-benefit comparison impossible. Other commenters stated that EPA overestimated benefits or inappropriately counted benefits that actually accrue from OSHA's PSM standard as benefits of the proposed rulemaking. One commenter also stated that EPA's benefit categories would be offset by unstated additional costs, including losses in reputation or brand value, higher insurance premiums, and difficulty hiring and retaining workers that facilities may incur as a result of an accident.

EPA disagrees that the proposed rulemaking would not provide benefits or that the costs of the rule would necessarily outweigh its benefits. As EPA explains in the RIA for the final rule, the benefits of the final rule include reductions in the number of people killed, injured, and evacuated or otherwise inconvenienced by sheltering in place; reductions in the damage caused to property on-site and offsite including product, equipment, and buildings; reductions in damages to the

environment and ecosystems; and reductions in resources diverted to extinguish fires and clean up affected areas. The final rule also provides other benefits, such as increased public information, which in addition to helping to minimize the impacts of accidents on the offsite public, may also lead to more efficient property markets in areas near RMP facilities.

EPA acknowledges that it is not possible to estimate quantitative benefits for the final rule. EPA has no data to project the specific impact on accidents made by each final rule provision. The accidents themselves have highly variable impacts that are difficult to predict. However, it is clear from the RMP accident data and other available data that chemical accidents can impose substantial costs on firms, employees, emergency responders, the community, and the broader economy. Reducing the risk of such accidents and the severity of the impacts when accidents occur, and improving information provision, as the final rule intends, provides benefits to the potentially affected members of society.

EPA disagrees that the final rule takes credit for benefits that should accrue to the OSHA PSM standard. None of the provisions contained in the final rule are duplicated in the OSHA PSM standard. EPA also disagrees that regulated facilities will suffer losses in reputation or brand value, higher insurance premiums, or have difficulty hiring and retaining workers as a result of the final rule. If, as EPA expects, the final rule results in the prevention of accidents, then it should have the opposite of these effects, to the extent they relate to chemical accidents.

b. Estimate of Rule Familiarization Costs

Several industry trade associations stated that EPA's estimate of the costs of rule familiarization were too low. These commenters stated that EPA's estimate only included time spent by management level employees but should be expanded to include the cost of training all relevant facility employees. Some of these commenters recommended alternate approaches to estimating the costs of rule familiarization that included estimates of time spent by additional labor categories (*e.g.,* attorneys, engineers, production staff, etc.). One commenter also recommended that EPA consider adjusting its rule familiarization estimate to better track with the estimate used by the NJ DEP for revisions to the NJ TCPA regulations.

EPA agrees with these comments, and adjusted its rule familiarization estimate accordingly, resulting in an increase of the estimated costs of rule familiarization.

c. Third-Party Audit Costs

Many commenters including industry trade associations and facilities stated that EPA's estimate of the costs of third-party audits was too low. Many commenters also stated that third-party auditor fees will be much higher than EPA's estimate, partially due to the low availability of qualified auditors. Several commenters submitted cost information from external audits to support their estimates.

EPA generally agrees with these comments. Shortly after the proposed rulemaking was published, EPA received cost information relating to a series of third-party audits conducted by a facility as a result of an enforcement action taken by EPA under CAA section 112(r). The average cost of these audits was approximately double EPA's estimate in the proposed rulemaking, and comparable to cost estimates submitted by commenters. Therefore, EPA adjusted its cost estimate for this provision of the final rule accordingly, resulting in the estimated costs of third-party audits under the final rule nearly doubling. EPA notes that the third-party audit provisions of the final rule also relaxed, to some extent, the independence and competency criteria for third-party auditors. The Agency believes that these changes will increase the availability of qualified auditors, and therefore make such audits less costly than might otherwise have been the case.

d. Incident Investigation/Root Cause Costs

Several commenters stated that EPA's estimate of costs of incident investigations and root cause analysis was inaccurately low. Some of these commenters suggested that the required number of investigations will increase significantly as a result of EPA's proposal to re-define the term ''catastrophic release,'' and that this would cause the cost of this rule element to increase substantially. Other commenters stated that incident investigations require more labor hours than were accounted for in EPA's cost estimate, and that the Agency needs to significantly raise its estimate in order to account for these issues. Some of these commenters submitted cost information to support their estimates.

Although EPA disagrees that its proposed changes to the definition of ''catastrophic release'' would have increased the number of investigations required under the rule, the Agency elected not to finalize the proposed changes to that definition, so no increase in incident investigation costs will result from it. Regarding commenters' concerns that EPA had not accounted for enough labor hours for investigations in the RIA for the proposed rulemaking, after considering these comments, the Agency generally agrees that its estimate was too low. EPA incorporated the cost information submitted by commenters into its estimate for the final rule. EPA also notes that unlike the estimate for the proposed rulemaking, the final rule economic estimate did not assume that investigations of near misses would require fewer labor hours than investigations of actual release events. This change also accounted for some of the increase in the estimated cost of this rule element. Overall, these changes resulted in the estimated cost of this rule element approximately doubling for the final rule.

e. STAA Costs

STAA costs too low. EPA received several comments stating that the Agency's estimate of costs for the proposed STAA provisions was too low. Most of these comments addressed both EPA's estimate of the cost of the initial study of safer technology options, as well as the Agency's estimate of costs for the required evaluation of the practicability of IST considered during the STAA.[121] Some commenters submitted alternate cost estimate information for both the initial analysis of options and the practicability study.

EPA notes that in general, commenter's cost estimates for the initial analysis were higher than EPA's estimates, although not in every case. EPA incorporated these estimates into the RIA as appropriate—the Agency assumed that cost estimates for the STAA initial analysis submitted by trade associations representing a particular category of facilities (*e.g.,* refineries, complex chemical manufacturers, etc.) were the best representation of estimated costs for those categories of facilities, and adjusted its own estimate accordingly. In most cases, this cause the estimated costs for the STAA initial analysis to increase.

Practicability study costs. For the practicability study, several commenters stated that EPA's estimate was far too low, and indicated that EPA should adopt an alternate approach that estimated the cost of the practicability study as a fixed fraction of the cost of the project being considered.

[121] EPA used the term ''feasible'' rather than ''practicability'' in the proposed rulemaking.

After reviewing these comments, EPA conducted additional research on this subject which confirmed that these commenters were generally correct on this point. EPA therefore adjusted its approach to estimating the costs of practicability studies accordingly, which resulted in a significant increase for the cost of this provision. EPA's research on this topic and the resulting cost estimation approach is explained in detail in Appendix D to the RIA for the final rule.

STAA implementation. EPA also received several comments stating that the Agency should assume that the STAA provision will result in some facilities implementing safer technologies, and include the costs associated with such implementation in its economic estimate.

EPA disagrees with these comments. While the Agency agrees that some facilities may elect to implement IST, the final rule does not require facilities to do so. Therefore, the Agency believes that implementation of IST will result from the owner or operator's own judgement that it is beneficial for the source, after considering all relevant factors. The STAA required under this rule may facilitate such decision making, but does not require it.

f. Emergency Response Program Coordination With Local Responders' Costs

Emergency response program costs. The Agency received several comments relating to the proposed emergency coordination provisions. Some of the comments on this topic related to the Agency's projected estimate of the cost for some sources to develop an emergency response program, stating that EPA's estimate of these costs was too low.

EPA is not finalizing the proposed rulemaking provisions that it believes would have resulted in many sources developing emergency response programs. Therefore, these ''new responder'' costs were not included in the RIA for the final rule.

Annual coordination burden. EPA also received comments that stated its estimate of burden for the annual coordination provision, a modified form of which is included in the final rule, were too low. One commenter provided emergency coordination cost information for large complex facilities, which was substantially higher than EPA's estimate for the category of facilities.

EPA incorporated the emergency coordination cost information into the revised economic estimate in the RIA for the final rule. EPA also revised its estimate for this element to account for the fact that changes to the annual coordination provision in the final rule, as well as the Agency's decision not to finalize a portion of the information availability provisions of the proposed rulemaking, may result in greater information exchange occurring during annual coordination meetings than was estimated under the proposed rulemaking. Under the information availability provisions of the proposed rulemaking, the owner or operator would have been required to annually provide certain information to local emergency responders. The final rule does not include this provision; however, the annual coordination provisions in the final rule require the owner or operator to provide local response officials with information relevant to emergency planning upon request. The net effect of these changes was to more than double the estimated costs of the annual emergency response coordination provision of the final rule.

g. Facility Exercise Costs

Several commenters disagreed with EPA's approach to estimating the costs of emergency response exercises, and in general, characterized EPA's estimate as too low. Two of these commenters submitted alternate cost estimates for this provision. However, the cost estimate provided by one commenter did not appear to apply to facilities represented by the commenter's industry association. The information submitted by the other commenter appeared credible, but projected costs for large complex facilities that were lower than EPA's estimate.

As a result of these comments EPA determined that its NPRM cost estimate for large complex facilities was inflated, and lowered its estimate to better reflect industry experience. The Agency also notes that the final rule requires emergency exercises to be conducted less frequently than was proposed in the NPRM. The net effect of the structural changes to the final rule and EPA's adjustment of its cost estimation approach resulting from public comments was to substantially reduce the estimated costs of this rule provision.

h. Information Availability Costs

EPA received some comments stating that EPA's estimate of costs for the proposed rulemaking's information availability provisions was too low. These commenters indicated that EPA underestimated the time required for facilities to prepare information required to be disclosed to the public, and that EPA underestimated the cost of holding public meetings. One commenter indicated that renting space for a public meeting would cost as much as $10,000 per day.

Based on these comments, EPA increased its cost estimate for the public information availability provision for large complex facilities. EPA did not change its cost estimate for public meetings because commenter's high estimates of the costs of public meeting space did not comport with EPA's research and prior experience with the costs of public meetings.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2537.02 and OMB Control Number 2050–0216. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This ICR amends a previously approved ICR (1656.15), OMB Control No. 2050–0144. That ICR covers the risk management program rule, originally promulgated on June 20, 1996; the current rule, including previous amendments, is codified as 40 CFR part 68. This ICR addresses the following information requirements that are part of the revised rule:

(1) Make certain information related to the risk management program available to the public, upon request;

(2) Hold a public meeting within 90-days of an accident subject to reporting under § 68.42 (*i.e.,* an RMP reportable accident);

(3) Hire a third-party to perform or lead a compliance audit after an RMP reportable accident or after an implementing agency determines that conditions at the stationary source could lead to an accidental release of a regulated substance or identifies problems with the prior third-party audit;

(4) Conduct and document a root cause analysis after an RMP reportable accident or a near miss;

(5) Conduct and document a STAA for a subset of Program 3 facilities in North American Industrial Classification System (NAICS) codes 322 (paper manufacturing), 324 (petroleum and coal products manufacturing), and 325 (chemical manufacturing);

(6) Meet and coordinate with local responders annually to exchange emergency response planning information;

(7) Conduct an annual notification drill to verify emergency contact information; and

(8) Responding facilities conduct and document emergency response exercises including:

- A field exercise at least every ten years, and
- A tabletop exercise at least every three years.

EPA believes that the RMP regulations have been effective in preventing and mitigating chemical accidents in the United States. However, EPA is revising the rule to further protect human health and the environment from chemical hazards through advancement of PSM based on lessons learned—resulting in better coordination between facilities, LEPC's, and the public. State and local authorities will use the information in RMPs to modify and enhance their community response plans. The agencies implementing the RMP rule will use RMPs to evaluate compliance with part 68 and to identify sources for inspection because they may pose significant risks to the community. Citizens may use the information to assess and address chemical hazards in their communities and to respond appropriately in the event of a release of a regulated substance. These revisions are a result of a review of the existing Risk Management Program and are finalized under the statutory authority provided by section 112(r) of the CAA as amended (42 U.S.C. 7412(r)).

Some of the elements mandated in the regulation for the RMP may require the submittal of data viewed as proprietary, trade secret, or confidential. As described previously, EPA has adopted procedures for sources to claim certain information as confidential business information. EPA encourages facilities that have CBI claims to submit substantiation with the RMP.

Respondents/affected entities: Manufacturers, utilities, warehouses, wholesalers, food processors, ammonia retailers, and gas processors.

Respondent's obligation to respond: Mandatory (CAA sections 112(r)(7)(B)(i) and (ii), CAA section 112(r)(7)(B)(iii), 114(c), CAA 114(a)(1)).

Estimated number of respondents: 14,280.

Frequency of response: On occasion.

Total estimated burden: 1,778,244 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $130,578,842 (per year), includes $8,285,600 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 and 609(b) of the RFA the EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rulemaking and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rulemaking at 81 FR 13637, March 14, 2016.

As required by section 604 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rulemaking. The complete FRFA is available for review in the docket and is summarized here.

1. Statement of Need and Rule Objectives

The purpose of this action is to improve safety at facilities that use and distribute hazardous chemicals. In response to catastrophic chemical facility incidents in the United States, including the explosion that occurred at the West Fertilizer facility in West, Texas, on April 17, 2013 that killed 15 people (on May 11, 2016, ATF ruled that the fire was intentionally set),[122] President Obama issued Executive Order 13650, ''Improving Chemical Facility Safety and Security,'' on August 1, 2013. Section 6(a)(i) of Executive Order 13650 requires that various Federal agencies develop options for improved chemical facility safety and security, including modernizing regulations. As a result, EPA is finalizing revisions to the Risk Management Program (40 CFR part 68).[123]

EPA believes that the RMP regulations have been effective in preventing and mitigating chemical accidents in the United States; however, EPA believes that revisions could further protect human health and the environment from chemical hazards through the advancement of process safety based on lessons learned. These revisions are a result of a review of the existing Risk Management Program and information gathered from the comments on the proposed rulemaking, SBAR panel, public hearing, RFI, and Executive Order listening sessions, and are finalized under the statutory authority provided by CAA section 112(r) as amended (42 U.S.C. 7412(r)). For more information on the proposed rulemaking, SBAR panel and outreach efforts for this action, see the docket for this rulemaking (Docket ID Number EPA–HQ–OEM–2015–0725).

2. Significant Comments on the IRFA

a. General Comments

A Federal elected official, Federal agency, facility, and multiple industry trade associations commented that EPA is not fulfilling its obligations under the Regulatory Flexibility Act because the Agency did not provide itself with enough time to consider the comments of either the SBAR panel report or the SERs in the proposed rulemaking. Many of these commenters asked that the SBAR panel recommendations be incorporated in the final rule.

A facility stated that the proposed rulemaking will be burdensome to small facilities. An association of government agencies expressed concern that the costs of a more prescriptive risk management program will fall on small communities. An industry trade association and Federal agency claimed that the proposed rulemaking imposes a disproportionate burden on small facilities and asserted that EPA should eliminate impractical, unjustifiable, or non-cost-effective requirements. Several industry trade associations and a facility commented that the proposed rulemaking will result in more facilities being required to become responders, which will be costly and difficult for small businesses.

Multiple facilities commented that EPA should withdraw its proposed rulemaking and coordinate more closely with OSHA's PSM rulemaking. An industry trade association stated that OSHA's PSM program and EPA's RMP proposal is creating confusion for small entities in the water sector. The commenter asked that EPA update guidance documents and delay further development of RMP revisions until OSHA'S PSM SBAR panel process is complete.

[122] See ATF Announces $50,000 Reward in West, Texas Fatality Fire, *https://www.atf.gov/news/pr/atf-announces-50000-reward-west-texas-fatality-fire.*

[123] For more information on the Executive Order see *https://www.whitehouse.gov/the-press-office/2013/08/01/executive-order-improving-chemical-facility-safety-and-security.*

EPA disagrees that the Agency did not fulfill its obligations under the Regulatory Flexibility Act or that the Agency did not consider the comments of the SBAR panel and SERs in the proposed or final rules. In many locations throughout the proposed rulemaking, EPA discussed SBAR panel recommendations and requested public comments on regulatory alternatives recommended by the SBAR panel. EPA also made numerous adjustments to the final rule to incorporate regulatory alternatives that were suggested by SERs where those alternatives were also supported by public comments and were consistent with the Agency's policy goals. For example, EPA incorporated SBAR panel recommendations by relaxing the competency and independence criteria for third-party auditors; reducing the frequency for conducting facility exercises; and not finalizing the proposed revision to the definition of ''catastrophic release.''

EPA also disagrees that the final rule is disproportionately burdensome on small entities. In fact, the costliest final rule provisions—STAA and facility exercises—affect relatively few small entities. EPA minimized the effect of the STAA provisions on small entities by applying these requirements to a narrowly-defined set of facilities in three select industry sectors. EPA minimized the impact of the exercise requirements on small entities by applying these requirements only to responding facilities, which tend to more often be large facilities. EPA also removed language from the final rule that would potentially have required numerous small entities to become responding facilities.

Regarding comments requesting that EPA withdraw its rulemaking and coordinate more closely with OSHA, EPA notes that it did coordinate with OSHA in the development of the proposed and final rules, and that OSHA has also completed a SBAR panel as an initial step toward proposing potential changes to the PSM standard, which may include some changes that are similar to those in this rule. However, EPA does not believe it is necessary for the Agency to conduct its rulemaking on exactly the same timeline as OSHA. The 1990 CAA Amendments contained separate timelines for the initial OSHA and EPA rulemakings and has no provisions restricting timeframes for either agency amending its rules.

b. Third-Party Audits

A facility and an industry trade association stated that EPA's assertion that the proposed requirements for third-party audits will have ''fairly low impact on small businesses'' is false and the requirement should be withdrawn entirely. Another industry trade association commented that third-party audits will be especially costly to small facilities. An industry trade association commented that the requirement for third-party audits will lead to a lack of auditor availability, a particularly difficult problem for small businesses.

EPA disagrees that the final rule's third-party audit requirements have a disproportionately high impact on small businesses. EPA notes that the third-party audit provisions will only affect facilities that experience an RMP reportable accident. Over the last ten years, RMP facilities reported approximately 150 accidents per year, and over 75% of these accidents occurred at large businesses.[124] Based on comments expressed by SERS and others, EPA also relaxed the final rule's independence criteria to allow the owner or operator to use third-party audit teams that include some non-independent members, including employees of the stationary source being audited. Also, the final rule allows a third-party audit team to include retired employees of the facility being audited, if their sole continuing financial attachments to the owner or operator are employer-financed or managed retirement and/or health plans. The audit team can also include other persons who previously provided consulting services as an employee or contractor of the owner or operator, provided those services were not provided within the last two years (whereas the proposed rulemaking would have required a three-year prohibition on previous employment). EPA believes these changes will increase the availability of auditors and therefore make third-party audits more cost-effective for small business owners.

c. Facility Exercises

Multiple state agencies, facilities and a Federal agency commented that the increase in mandatory field exercises for Program 2 and Program 3 facilities would adversely affect small RMP facilities and small communities. An industry trade association stated that the proposed rulemaking for facility coordination with local responders should be more flexible based on the size of the community and its existing local response capabilities.

A consultant/engineer stated that small utilities who lack a local emergency agency with first responder capabilities will have difficulty meeting the proposed requirements. The commenter requested that EPA exempt small entities from the emergency response program requirement and offer increased assistance to LEPCs in small communities.

A Federal agency stated that LEPC concerns should be addressed in a guidance document instead of a rulemaking.

EPA notes that the final rule includes significant changes to the exercise requirements to address concerns expressed by the SBAR panel, individual SERs and other commenters. First, the final rule allows owners and operators to work with local response officials to establish an exercise schedule that works for both parties, provided the owner or operator holds a field exercise at least once every ten years, and a tabletop exercise at least once every three years. Second, the field and tabletop exercise requirements only apply to responding facilities, so non-responding facilities, which include the majority of small businesses regulated under the RMP rule, are not required to comply with them. Lastly, EPA did not finalize proposed rulemaking provisions that would have required many small businesses to become responding facilities.

d. Public Meetings and Information Disclosure

A Federal agency stated that the public meeting requirement should include small business flexibility, allowing small business to post the required information to be disclosed instead of organizing a public meeting.

While EPA did not implement the recommendation to allow small businesses to post required information in lieu of holding a public meeting, EPA notes that the public meeting requirement, like the third-party audit requirement, only applies to facilities after an RMP-reportable accident, which minimizes its impact on small businesses. Also, EPA revised the public meeting requirements to extend the timeframe within which the meeting must be held (from 30 to 90 days after an RMP reportable accident).

3. SBA Office of Advocacy Comments and EPA Response

The SBA Office of Advocacy comments urged EPA to consider small business concerns and provide flexibility to reduce the impact of the proposed rulemaking on small businesses. The following sections

[124] EPA, 2016. Regulatory Impact Analysis—Accidental Release Prevention Requirements: Risk Management Programs Under the Clean Air Act, Section 112(r)(7). Exhibit 7–9.

describe SBA recommendations and how EPA has revised the rule to provide additional flexibility that benefits small businesses.

a. Third-Party Audits

Duplicative of existing requirements. SBA suggested that third-party audits are too burdensome for small businesses and should be eliminated or reduced significantly in scope. SBA argued that the requirements are duplicative of the existing requirements for self-audits and incident investigations and suggested that EPA waive the requirements if an implementing agency conducts an inspection as a result of a reportable release or facility noncompliance.

EPA disagrees that third-party audits are duplicative of existing requirements. Following an accident, incident investigations often reveal that facilities have deficiencies in some prevention program requirements related to that process. Incident investigations generally only evaluate the affected process, and do not necessarily address all covered processes at a facility, or even all prevention program elements for the affected process. However, compliance audits entail a systematic evaluation of the full prevention program for all covered processes, and EPA expects that third-party audits should identify deficiencies in any other covered processes at such facilities.

Additionally, EPA does not agree that third-party audits should be waived if EPA conducts an inspection. Third-party audits do not constitute enforcement, nor do they substitute for inspections by implementing agencies. The audits are designed primarily to benefit owners or operators by assisting them to identify both actual noncompliance as well as operational or equipment deficiencies, previously unidentified risk factors, and accident release and/or regulatory noncompliance precursor conditions which, if uncorrected, could lead to releases and/or enforcement actions. Proactively addressing deficiencies, risk factors, and precursor conditions to accidental releases and regulatory noncompliance will provide financial, regulatory, and environmental benefits for facility owners and operators, including small businesses, and communities.

Finally, EPA has reasonably targeted third-party audit requirements at facilities that have had RMP reportable incidents that may demonstrate weaknesses in prior self-assessments and at facilities of heightened concern for implementing agencies. Most small businesses do not have RMP reportable releases and the implementing agency criterion focuses on conditions with the potential to lead to accidental releases, rather than authorizing implementing agencies to require third-party audits under a potentially wide range of circumstances, including minor noncompliance. Therefore, EPA does not expect that this provision will be burdensome for small facilities.

Applicability. SBA recommended that EPA limit the requirement to Program 3 facilities with major accidents with offsite impacts.

EPA disagrees with this approach. EPA based applicability of third-party audits on whether a source had an RMP reportable accident or whether conditions exist that could lead to an accidental release. EPA believes that these criteria are potential indicators for noncompliance with prevention program requirements and therefore warrant an evaluation by a third-party.

Auditor qualifications. SBA expressed concerns with the auditor qualifications in the proposed rulemaking arguing that it would be difficult to find auditors with no financial connection to the facility (such as retirees). SBA recommended that EPA allow small businesses with less than 250 employees to submit a waiver request of the independence criteria based on limited availability of independent auditors. SBA also expressed concern over the PE criterion for third-party auditors and recommended that EPA consider other accreditations[125] to satisfy the competency criterion for third-party auditors. SBA recommended EPA consider other criteria in place of the PE criterion to allow additional flexibility such as years of experience, number of audits conducted at a specific facility type, and active involvement in developing industry standards.

In order to address concerns about the availability of auditors, EPA modified the third-party auditor qualification criteria in the final rule to enable more firms and individuals to qualify as third-party auditors or third-party audit team leaders. The most significant modification to the third-party auditor qualification criteria is that only employees of the independent third-party audit firm must meet the independence criteria of § 68.59(c)(2) and/or § 68.80(c)(2). For third-party audit teams, the team leader must meet both the competency and independence criteria of § 68.59(c) and/or § 68.80(c) and all other employees of the third-party auditor firm that participate on the team need only meet the independence criteria. Third-party audit teams may also include other personnel, such as consultants or facility employees and these personnel are not subject to the third-party qualification criteria of the final rule.

EPA also revised the timeframe within which third-party auditors cannot provide business or consulting services to two years. EPA added language indicating that if a third-party-firm employs personnel who have provided business or consulting services to the facility within the prescribed timeframe (*i.e.* within two years of the audit) then the third-party audit firm must ensure that these personnel do not participate on the audit team. Additionally, EPA clarified in regulatory language the circumstances in which a retired employee may participate in a third-party audit and deleted the PE requirement from the final rule. Viewed as a whole, these changes serve to increase the types of personnel who may potentially serve as independent third-party auditors. Therefore, EPA believes it will be unnecessary for facility owners or operators to petition for a relaxation of auditor qualifications.

b. Incident Investigations and Root Cause Analysis

SBA recommended that EPA limit the scope of this requirement to apply only to reportable releases in order to reduce the burden on small businesses. SBA further recommended that EPA retain the existing definition of ''catastrophic release.''

EPA is finalizing the scope of the incident investigation requirement to apply to an incident that resulted in a catastrophic release or could reasonably have resulted in a catastrophic release (*i.e.* a near miss). However, EPA is not finalizing the proposed definition for catastrophic release and is instead maintaining the existing definition. In the final rule, EPA is clarifying what we mean by near miss to address uncertainty about the term.

c. STAA

SBA recommended mandating an IST analysis only at the design stage of new processes. Alternatively, to reduce the burden for small entities, SBA recommended delaying the provision for small firms (with less than 250 employees) until three years after the rule's compliance date for larger firms in order to allow EPA a chance to review the utility of the provision. SBA

[125] SERs suggested other accreditations including: degreed chemists, degreed chemical engineers, Certified Safety Professionals (CSP), Certified Industrial Hygienists (CIH), Certified Fire Protection Specialists (CFPS), Certified Hazardous Materials Managers (CHMM), Certified Professional Environmental Auditors (CPEA) or Certified Process Safety Auditors (CPSA).

also recommended that EPA exclude processes that are governed by specifications established by a government agency or by a customer through a contractual relationship.

EPA is finalizing the STAA provision as proposed. EPA disagrees that STAA analyses should only be required during the initial design phase of a facility. While the greatest potential opportunities for using IST occur early in process design and development, many IST options may still be practicable after the initial design phase. Furthermore, STAA involves more than just IST. Safer technology alternatives also include passive measures, active measures, and procedural measures, and these measures can be modified and improved after the initial design of a facility. EPA notes that many RMP-regulated facilities were originally constructed decades ago, yet major enhancements have been reported in some plants that have been operating for many years.[126] CCPS explains that inherently safer strategies can be evaluated throughout the lifecycle of a process, including operations, maintenance and modification, and EPA agrees with this approach.

EPA also disagrees with the suggestion to exempt certain groups (such as batch toll manufacturers) from the STAA requirement. Safer technology alternatives include many options beyond chemical substitution or minimization. Therefore, even where a contractual relationship or regulation requires a regulated batch toll manufacturing facility to use a particular regulated substance in specified quantities, owners and operators of batch toll manufacturing facilities may still consider other potential safer alternatives, such as passive, active, or procedural measures. Also, the final rule does not require regulated sources to implement IST or ISD considered, so there is no conflict between this final rule and other regulations that may apply to RMP-regulated facilities subject to STAA requirements. For example, an owner or operator would be in compliance with this rule if he or she determines that a chemical substitution is not practicable if the substitution is prohibited by another regulation.

Finally, EPA is not delaying compliance dates for small businesses to allow time for evaluating the provision at large facilities. STAA for a source is a site-specific determination and would be difficult to compare among facilities. EPA believes it would be impractical to gather/analyze information on STAA implementation to determine the utility of the provision for small facilities.

d. Emergency Response Program Coordination With Local Responders

SBA recommended that EPA adopt compliance flexibility for small businesses by limiting their responsibility to making good faith efforts to coordinate with local responders. SBA further suggested that EPA remove the provision to allow LEPCs to require sources to develop emergency response programs. SBA also suggested that EPA provide guidance to local responders, rather than expand existing regulations, and focus on implementing and enforcing emergency planning requirements for LEPCs. Finally, SBA recommended providing guidance on expectations for coordination between a facility and local responders as well as clarifying a facility's obligations for preparing an emergency response program.

EPA is not finalizing the provision that would have required the source to develop an emergency response program following a written request from the LEPCs or local response authorities. Furthermore, the final rule clarifies requirements for coordination activities between facility personnel and local responders. EPA understands some communities do not have functional LEPCs, but has accounted for this possibility by requiring coordination to be with ''local emergency planning and response organizations.'' This term is intended to encompass all manner of local public emergency planning and response organizations. In many cases this will be the LEPC, but in other cases it may be a local emergency management agency, a local fire department, or another local response organization. These non-LEPC planning entities can use this provision to obtain necessary planning information even when they lack the authority granted LEPCs under EPCRA 303(d)(3). Regardless of whether or not their community has an active LEPC, EPA expects owners and operators of regulated sources to make good faith efforts to carry out the coordination activities required in the final rule. If local emergency planning and response organizations decline to participate in coordination activities, or the owner or operator cannot identify any appropriate local emergency planning and response organization with which to coordinate, the owner or operator should document their coordination efforts, and continue to attempt to perform coordination activities at least annually.

The rule also clarifies requirements for facilities that must develop an emergency response program in accordance with § 68.95. Responding facilities must comply with all of the provisions of § 68.95, which include developing an emergency response plan, developing procedures for the use, inspection, and testing of emergency response equipment, conducting training for employees in relevant procedures, and updating the emergency response plan to reflect changes at the source. Any facility that plans to use its employees to take response actions beyond those specified in its emergency action plan under 29 CFR 1910.38 as a result of an accidental release at the source—which could include, for example, donning emergency air breathing apparatus in order to enter an area where a toxic gas leak has occurred with the intention of stopping or controlling the release—would be expected to have obtained appropriate equipment and training, and to address these activities in its emergency response program, even if the facility is also relying on local responders to supplement its own response, or to manage offsite response actions such as evacuations and sheltering-in-place.

e. Exercises

SBA recommends requiring small businesses to only conduct tabletop exercises and eliminate the field exercises requirement of the proposed rulemaking.

EPA is requiring that responding facilities conduct both tabletop and field exercises; however, we have revised the frequency to reduce the burden on all facilities. The rule requires the owner or operator to conduct both tabletop and field exercises involving a simulated accidental release of a regulated substance. As part of the coordination with local emergency response officials required by § 68.93, the owner or operator is required to consult with these local officials to establish an appropriate frequency for tabletop and field exercises. However, in all cases, the owner or operator must conduct a field exercise at least once every ten years and a tabletop exercises at least once every three years. Additionally, EPA encourages several nearby or adjacent facilities to conduct joint exercises, and this may prompt small facilities to pool their response resources, thereby reducing the exercise and emergency response burden on each facility.

[126] CCPS. 2009. Inherently Safer Chemical Processes: A Life Cycle Approach, 2nd ed., American Institute of Chemical Engineers, CCPS New York, Wiley, p. 25.

f. Information Availability

Availability of information for LEPCs. SBA suggests that EPA require a one-page summary of information relevant for emergency response to an accident at the facility. SBA also expressed concern with the recordkeeping requirement of the proposed provision and suggested that EPA require the information be provided within a reasonable time period after receiving a request to allow the facility time to develop the information.

EPA maintains that it is very important to ensure that LEPCs or local emergency response officials have the chemical information necessary for developing local emergency response plans, however, EPA believes it is unnecessary to specify in the RMP rule the types or format of information that LEPCs or emergency response officials may request. Therefore, EPA has eliminated this provision in the final rule. EPCRA section 303(d)(3) already provides the necessary authority to allow LEPCs to request information needed to develop the local emergency response plan. Additionally, EPCRA requires facilities to provide SDSs and inventory information to LEPCs to assist emergency planners and responders. Under EPCRA section 312(f), fire departments have the authority to inspect these facilities to better understand the risk associated with these chemicals and how to deal with those risk in the local emergency response plan.

EPA added language to the emergency response coordination provisions of § 68.93, which requires the owner or operator to provide ''any other information that local emergency planning and response organizations identify as relevant to local emergency planning.'' This approach will allow LEPCs and other local emergency officials to obtain the information they require to meet their emergency response planning needs. It will also allow local emergency planners and response officials to ask questions of facility personnel about the risks associated with the chemical hazards at the facility and about appropriate mitigation and response techniques to use in the event of a chemical release.

Availability of information for the public. SBA recommends that EPA improve public awareness of existing sources of information through its own Web site or other public forums rather than requiring small businesses to repackage existing information. Alternatively, SBA suggests requiring facilities to indicate where this information can be obtained.

The final rule requires the owner or operator to make certain chemical hazard information for all regulated processes at a stationary source available to the public upon request. The facility must provide ongoing notification to the public about what chemical hazard information is available upon request, how the public may obtain such information, and where to access any other available information on community emergency preparedness. The facility owner or operator must provide information to the requester within 45 days of receiving a request.

Public meetings. SBA recommends allowing small businesses to post information that would be disclosed at a public meeting rather than require them to host meetings. Furthermore, SBA suggests that EPA should provide a longer time period for holding a public meeting to allow the owner or operator more time to gather information and adequately prepare for the meeting.

In the final rule, EPA is requiring all facilities to hold a public meeting after an RMP-reportable accident, but is extending the timeframe for the public meeting to 90 days in response to comments. EPA believes that small businesses should host public meetings following an RMP reportable accident to allow community members an opportunity to talk with facility personnel. EPA encourages small businesses to find ways to reduce costs of public meetings such as by hosting the meetings at inexpensive venues, such as local schools, community centers, or churches.

4. Estimate of the Number of Small Entities to Which the Final Rule Applies

The RMP rule affects a broad range of sectors (296 separate NAICS codes are listed in RMP filings; 240 of these are associated with small entities). The RMP data include facility and parent company name, as well as the number of full time equivalents (FTE) for the facility and the NAICS codes. To develop an estimate of the number of small entities, the analysis required a series of reviews of the data to identify the large entities and the small entities that were part of small firms owning multiple facilities. For more information on the analysis to estimate the number of small entities, see section 7.2 of the RIA.

5. Projected Reporting, Recordkeeping and Other Compliance Requirements of the Final Rule

Under the final rule, all facilities are required to make certain information available to the public upon request. Program 2 and Program 3 facilities are also required to provide information upon request to local response officials during annual coordination meetings. Program 1 facilities will likely not have to spend more than an hour per year on this disclosure because the information disclosed to the public is information every facility should have readily available and because the additional information that will be provided, upon request, to local responders relates to provisions that do not apply to Program 1 facilities. Therefore, the FRFA has not considered Program 1 small facilities in the analysis of impacts.

Program 2 and Program 3 facilities will incur the same costs for the other provisions except for the STAA. Each facility will be required to update information to be disclosed annually, coordinate with the local responders, and conduct a notification drill annually. If the facility is a responder, it will have to hold exercises every three to ten years, including at least one full field exercise every ten years. Program 3 facilities in NAICS codes 322, 324, and 325 will have to conduct an STAA as part their PHA every five years.

If a facility has an accident, it will incur costs to hold a public meeting within 90 days of an RMP reportable accident. The facility will also incur costs for obtaining an independent third-party to conduct their next scheduled compliance audit and to conduct a root cause analysis as part of the incident investigation. In the event of a near miss, facilities will also be required to conduct a root cause investigation. Section 7.3.1 of the RIA describes the costs of the final rule for small entities.

6. Steps Taken To Minimize Economic Impact to Small Entities

The RIA analyzed the proposed new requirements and revisions to existing requirements as well as several alternatives for each. In most cases, EPA chose regulatory alternatives that had reduced impacts on small businesses relative to other alternatives that EPA considered. In this section, we discuss each final rule provision and explain how the provision minimizes impacts on small businesses and which of the SBAR Panel recommendations were implemented.

a. Third-Party Audits (Program 2 §§ 68.58 and 68.59 and Program 3 §§ 68.79 and 68.80)

EPA is finalizing a requirement for the owner or operator to engage a third-party auditor to conduct a compliance audit when required by an implementing agency due to conditions

at the stationary source that could lead to an accidental release of a regulated substance or following an RMP reportable accident. Limiting the applicability of this provision to sources that have had RMP reportable accidents minimizes its impact to the overall universe of RMP facilities, and particularly to small businesses. As indicated in Exhibit 5–18 of the RIA, the estimated cost of the high option ($196 million annualized) is nearly 20 times higher than the estimated costs of the preferred option ($9.9 million annualized). Furthermore, a majority of the costs for the option would likely be borne by large businesses as historically, most RMP accidents have occurred at facilities that do not meet SBA small business criteria. Table 19 shows the number of accidents from 2004—2013 that occurred at small and large facilities.

TABLE 19—PERCENTAGE OF ACCIDENTS AT SMALL AND LARGE RMP FACILITIES, 2004–2013

Sector	Program 1		Program 2		Program 3		Total
	Small	Large	Small	Large	Small	Large	
NAICS 325—Chemical Manufacturing	0	6	1	5	53	465	530
NAICS 311, 312—Food/Beverage Manufacturers	0	0	2	0	58	210	270
NAICS 322—Paper Manufacturing	0	0	0	0	9	37	46
NAICS 331, 332, 333, 334, 336, 339—Other Manufacturing	0	0	4	0	12	27	43
NAICS 11, 12, 15, 42491—Agricultural Chemical Distributors	0	0	0	0	91	65	156
NAICS 4246, 4247—Chemical/petroleum wholesale	0	2	0	0	7	29	38
NAICS 4244, 4245—Other wholesale	0	0	0	0	7	13	20
NAICS 493—Warehouse	0	1	0	0	18	53	72
NAICS 324—Petroleum and Coal Products Manufacturing	2	6	0	0	15	146	169
NAICS 22131, 22132—Water/POTW	0	0	14	20	17	24	75
NAICS 211—Oil/Gas exploration	4	4	1	0	10	34	53
Other	3	7	7	4	7	17	45
Total	9	26	29	29	304	1,120	1,517

While the third-party audit provision should have a fairly low impact on small businesses, the SBAR Panel made additional recommendations to further minimize the impacts of this provision on small businesses, which EPA considered for this final rule. Of the suggested recommendations, EPA revised the provision to require that only a third-party leading the audit team must meet the independence and competency criteria of the rule, and also by allowing that a retired employee of the source can participate in the audit. EPA also did not finalize the competency criterion that required a PE to participate in the audit.

b. Incident Investigation/Root Cause Analysis (§§ 68.60 and 68.81)

In the final rule, EPA is requiring a root cause investigation for any P2 or P3 reportable accident or near miss. Although the Agency chose the higher cost option, this provision is estimated to be one of the least costly provisions of the final rule. In fact, the costs for both options considered were nearly indistinguishable—as indicated in Exhibit 5–18 of the RIA, both the low and preferred options are estimated to cost approximately $1.8 million annually. Therefore, EPA believes that the additional safety benefit of requiring owners and operators of Program 2 processes to also conduct root cause analyses after incidents and near misses is warranted. Of the suggested SBAR recommendations, EPA clarified that near miss investigations are not intended to cover minor accidents or minor near misses that could not reasonably have resulted in a catastrophic release. EPA also chose not to finalize the proposed definition of ''catastrophic release,'' which some SERs had indicated could increase the number of investigations required.

c. STAA (§ 68.67)

For STAA, EPA is finalizing the least costly option. The final rule, which applies the STAA requirement to P3 processes in NAICS 322 (paper manufacturing), 324 (petroleum and coal products manufacturing), and 325 (chemical manufacturing), costs $80.0 million annually and is approximately $40 million less costly than the medium option ($120.4 million annually), which would have applied the requirement to all P3 processes, and likely far less costly than the high option, which would require implementation of practicable safer alternatives for all P3 processes. Although the SBAR panel provided recommendations, EPA finalized this provision as proposed, and estimates that it will affect relatively few small businesses given the narrow focus of the provision's applicability.

d. Emergency Response Program Coordination With Local Responders (§§ 68.90, 68.93, and 68.95)

The final rule requires all facilities with P2 or P3 processes to coordinate with local response agencies annually and document coordination activities. This provision does not have alternatives, but the SBAR panel did provide recommendations on streamlining the provision. In response to these and other recommendations, EPA modified the extent of required coordination, removed the requirement for the outcome of coordination to dictate whether a source must implement an emergency response program, and eliminated the ability for LEPCs to mandate sources' response capabilities.

e. Facility Exercises (§ 68.96)

Notification Exercises. The final rule requires all facilities with P2 or P3 processes to annually conduct an emergency notification exercise to ensure that their emergency contact list is complete, accurate, and up-to-date. This provision is expected to be one of the least costly rule provisions at $1.4 million annually (only the public meetings provision is estimated to cost less). Therefore, EPA did not consider any alternatives to reduce the impact of this provision on small businesses, nor did the SBAR panel make any such recommendations.

Tabletop and Field Exercises. The final rule requires responding facilities to conduct a full field exercise at least once every ten years and tabletop exercises triennially. As this provision only affects responding facilities, which tend to more often be large facilities (see Exhibit 3–7 in the RIA), EPA has

implemented a rule that mitigates the impact on small entities. EPA also considered a low option that would only require triennial tabletop exercises. This option would have saved approximately $8 million annually. EPA did not implement the low option because the Agency believes that periodic field exercises are an important component of a comprehensive emergency response program. In response to SBAR panel recommendations, EPA reduced the required frequency of exercises to minimize the impact of this provision on small businesses.

f. Information Availability (§ 68.210)

Under the final rule requirements, all facilities are required to make certain chemical hazard information available to the public, upon request. The owner or operator must provide an ongoing notification to the public that such information is available as well as instructions on how to request the information. Facilities are also required to hold public meetings within 90 days of any RMP reportable accident. Although EPA has not identified specific alternatives to minimize the impact of the information disclosure provisions on small businesses, the Agency believes that in general, smaller facilities will bear lower costs to comply with these provisions.

In response to the SBAR recommendations, EPA eliminated the proposed provision that would have had required specific information to be disclosed to LEPCs and extended the timeline for public meetings from 30 days to 90 days after an RMP reportable accident. In addition, information to be provided to the public is only required to be disclosed to the public upon request.

7. Small Business Compliance Guides

EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. EPA expects that this guide will be made available on the EPA Web site prior to March 15, 2021, when facilities will have to comply with new and revised data elements for the final rule.

D. Unfunded Mandates Reform Act (UMRA)

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under section 202 of UMRA. The statement is included in the docket for this action and briefly summarized here.

Over the 16 years of implementing the RMP program and, most recently through Executive Order 13650 listening sessions, webinars, consultations, and a public hearing, EPA has engaged states and local communities to discuss chemical safety issues. In the nine Executive Order 13650 Improving Chemical Facility Safety and Security listening sessions and webinars, held between November 2013 and January 2014, states and local communities identified lack of chemical facility participation and coordination in local emergency contingency planning as a key barrier to successful local community preparedness. Additionally, EPA has had consultations with states and local communities through participation in the National Association of SARA Title III Program Officials (NASTTPO) annual meetings to discuss key issues related to chemical facility and local community coordination and what areas of the RMP regulations need to be modernized to facilitate this coordination and improve local emergency preparedness and prevention. Key priority options discussed with NASTTPO states and local communities included: improving emergency response coordination between RMP facilities and LEPCs/first responder and requiring emergency response exercises of the RMP facility plan to involve LEPCs, first responders and emergency response personnel.

This action may significantly or uniquely affect small governments. The EPA consulted with small governments concerning the regulatory requirements that might significantly or uniquely affect them. Through the July 31, 2014, RFI (79 FR 44604), EPA sought feedback from governmental entities while formulating the proposed revisions in this action. Additionally, EPA participated in ongoing consultations with affected SERs (including small governmental entities) through the SBAR panel. EPA convened an SBAR panel in accordance with the requirements of the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). Finally, EPA hosted a public hearing on March 29, 2016 to provide interested parties the opportunity to present data, views or arguments concerning the rule.

Discussion of comments. EPA received comments concerning unfunded mandates. Several commenters, including state agencies and a professional organization, said that the proposed rulemaking adds to the unfunded mandate for LEPCs, which were never provided with any source of Federal funding. A few state agencies said that the proposed field exercises in particular will be a significant unfunded cost for LEPCs that choose to participate. A state agency, an industry trade association, and an association of government agencies commented that these additional costs will adversely affect smaller RMP facilities and smaller communities with municipal-owned RMP facilities. The industry trade association also suggested that EPA should consult with these municipal governments on the impact these proposed requirements will have on their operating budgets. A professional organization stated that very few LEPCs are able to support themselves with fees or other taxes on regulated facilities.

EPA disagrees that this final rule adds to the burden to LEPCs and local emergency response organizations. EPA believes that the amendments to the local coordination requirements clarifies existing requirements. LEPCs are required to develop community emergency response plans and the revisions to the RMP rule are intended to ensure that facility representatives coordinate with LEPC and local emergency response officials in developing those plans. Furthermore, EPA provided flexibility in the final rule to allow LEPC and local emergency response officials to participate as their schedules allow. LEPC and local emergency response officials are encouraged, but not required, to participate in facility exercises.

EPA agrees that the final rule will bear costs for small facilities and small governments; however, EPA has built flexibility into the rule provisions to allow facility owners and operators to tailor their risk management programs to their facility specific circumstances. Third-party compliance audits, and public meetings apply only following an RMP reportable accident, root cause analysis applies only after a catastrophic release (*e.g.* an RMP-reportable accident) or after an incident that could reasonably have resulted in a catastrophic release. STAA analyses are limited to specific NAICS codes, and exercises apply only to responding facilities. EPA has further revised information availability requirement to be provided only upon request by a member of the public. These provisions should minimize costs of the final rule for small facilities.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. The EPA believes, however, that these regulatory revisions may be of significant interest to local governments. Consistent with the EPA's

policy to promote communications between the EPA and state and local governments, and to better understand the concerns of local governments, EPA sought feedback through the July 31, 2014, RFI (79 FR 44604), through the SBREFA process, and a public hearing on March 29, 2016. EPA also hosted a conference call with governmental entities on May 4, 2016. A copy of the presentation and notes from the meeting are available in the docket for this action.[127]

EPA received comments pertaining to Federalism implications for this action. An industry trade association asserted that EPA's proposal to allow local authorities to request that the owner or operator assume emergency response obligations, which the commenter argues divorces these organizations from their Federal, state, and/or local legal obligations, raises Federalism issues by undermining the fundamental mission of those entities and state delegations of more (or less) authority to local emergency response organizations. Similarly, other industry trade associations commented that EPA's proposed delegation of authority to LEPCs to designate facilities as responding stationary sources raises significant separation of powers and federalism concerns. As the basis for this argument, the commenters relied primarily on the Supreme Court decisions in *Printz* v. *United States* (521 U.S. 898 (1997)) and *New York* v. *United States* (505 U.S. 144 (1992)), in which the court held that Federal agencies cannot ''commandeer'' local governments to implement Federal regulatory programs.

A few commenters, including an associations of government agencies and an industry trade association, commented that the Agency had missed a valuable opportunity to engage local governments prior to the rule's publication, which the commenter described as counter to EPA's internal ''Guidance on Executive Order 13132: Federalism'' (Nov. 2008) that specifies that States and local governments must be consulted on rules if they impose substantial compliance costs, preempt state or local laws, and/or have substantial direct effects on state and local governments. Because the commenter does not believe that EPA has adequately engaged local government agencies, an association of government agencies requested that EPA delay advancing the proposed rulemaking and perform a local government impact analysis and consultation with the nation's cities, counties, and mayors before finalizing the rule.

EPA is finalizing requirements for the stationary source owner or operator to coordinate annually with local emergency planning and response officials to ensure that the stationary source is included in the community emergency response plan (for toxic substances) and/or to coordinate response activities with local emergency responders (for flammable substances). However, after considering concerns raised by commenters related to providing LEPCs with the authority to require a stationary source to develop an emergency response program in accordance with § 68.95, EPA has eliminated this provision from the final rule. EPA did not intend this provision to undermine the fundamental mission of response agencies nor as a delegation of Federal authority. EPA expects that some stationary source owners or operators will self-identify a need to develop an emergency response program if the result of local coordination indicates that the stationary source is not included in the community emergency response plan (*e.g.,* when an LEPC is inactive and there is no community emergency response plan or the existing plan is outdated).

EPA disagrees with comments that suggest that EPA did not engage local governments prior to the rule's publication. EPA followed the agency's internal guidance on Executive Order 13132 when determining whether to initiate consultation with state and local governments. Furthermore, through Executive Order 13650 listening sessions, webinars, consultations, and a public hearing, EPA has engaged states and local communities to discuss chemical safety issues. Additionally, EPA has consulted with states and local communities through participation in the NASTTPO annual meetings to discuss key issues related to chemical facility and local community coordination and what areas of the RMP regulations need to be modernized to facilitate this coordination and improve local emergency preparedness and prevention.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. There are approximately 260 RMP facilities located on tribal lands. Tribes could be impacted by the final rule either as an owner or operator of an RMP-regulated facility or as a Tribal government when the Tribal government conducts emergency response or emergency preparedness activities under EPCRA.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. EPA hosted a public hearing on March 29, 2016 that was open to all interested parties and hosted a total of two conference calls for interested tribal representatives on April 20, 2016 and April 26, 2016. A summary of each conference call is available in the docket for this action.[128] EPA did not receive any written comments from tribal representatives.

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. The EPA believes that the proposed revisions to the Risk Management Program regulations would further protect human health, including the health of children, through advancement of process safety. EPA did not receive any comments associated with this issue.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action is not anticipated to have notable impacts on emissions, costs or energy supply decisions for the affected electric utility industry. EPA did not receive any comments associated with this issue.

I. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards. The EPA is requiring third-party auditors to be experienced with applicable RAGAGEP, which include

[127] *https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0425.*

[128] EPA–HQ–OEM–2015–0725–0419.

Voluntary Consensus Standards as well as other measures, for regulated processes being audited. Numerous different standards apply to processes regulated under the final rule and their application will vary depending on the particular process and chemicals involved. EPA is not listing all the various codes, standards and practices that would apply to the wide variety of chemical processes covered by this rule as doing so would be impracticable, given that this rule affects sectors across many industries and listing the applicable RAGAGEP measures would require the EPA to update that list every time there was a change in the industry standards or best practices. The final rule requires third-party auditors to be familiar with standards applicable to processes they audit, and to obtain their own copies of applicable standards where needed. Auditors must be knowledgeable of applicable consensus standards because the accident prevention program provisions of the existing rule (subparts C and D) require owners or operators to comply with RAGAGEP. Therefore, auditors must be knowledgeable of those practices in order to perform an effective audit. EPA did not receive any comments associated with this issue.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low income, or indigenous populations. The results of this evaluation are included in the RIA, located in the docket. EPA received multiple comments relating to environmental justice concerns.

Discussion of comments on access to information. Several groups stated that communities need better transparency and access to information on hazards and investigations, training on response plans, and access to inspection and incident reports. A few advocacy groups commented that the rule should include specific elements to address disproportionate impacts. A few advocacy groups said that EPA should create a centralized database available through a Web site and local community centers and libraries that provides this information. A facility commented that a Web site is a poor method to communicate information to individuals in poor or rural communities that may not have access to computers or the Internet. The commenter also said that LEPCs already hold public meetings to discuss emergency plans.

A couple advocacy groups stated that the RMP rule fails to ensure that at-risk communities near RMP facilities have the information they need to participate effectively in engagement with facilities. The groups also argued that the rule does not improve access to summaries of incident investigation reports, safety audits, and STAA, among other things, which are essential to ensuring fair treatment. Further, the groups commented that at-risk communities are not given access to information on prevention opportunities, and are not invited to participate in prevention analysis and planning. Another advocacy group said that the RMP rule should facilitate partnerships and interactions between facilities, local governments, and the community. A different group said that EPA should require a community meeting within 30 days of an incident, require publication of response and evacuation plans for affected areas, and establish an appeals process for communities to report when information and engagement opportunities are not provided as required, among other proposals.

EPA agrees with commenters that have requested better access to chemical hazard information at facilities in their communities and improved public transparency. EPA is finalizing a requirement for facility owners and operators to share information with the public that will assist neighboring communities to understand the hazards in their communities. Facility owners and operators must notify the public that specific information is available and provide instructions on how to request that information as well as how to access evacuation and shelter-in-place procedures for the community. Additionally, following an RMP reportable accident, facility owner and operators are required to host a public meeting within 90 days to communicate information about the accident. This allows sufficient time for facilities to gather information about the incident to share with the public. EPA believes that these provisions provides the public with more information that they can use to protect themselves and their families in the event of an accidental release at an RMP-regulated facility.

EPA has included other elements in the final rule that are intended to address disproportionate impacts of a release to surrounding communities. For example, EPA is requiring paper manufacturing, petroleum and coal products manufacturing, and chemical manufacturing facilities with Program 3 processes to analyze safer technologies for each process in order to consider ways to reduce and remove hazards. EPA is also encouraging better coordination between local emergency response organizations and facility representatives annually and during facility exercises which will lead to more effective community emergency response plans and mitigate the impacts of an accidental release to the surrounding community. EPA encourages facility representatives to attend LEPC meetings along with the public to facilitate partnerships among these representatives.

EPA disagrees with commenters that suggest creating a centralized database available through a Web site and local community centers and libraries to provide this information. Establishing such a centralized database would be costly, difficult to maintain, information would quickly become outdated, and a centralized database could create security vulnerabilities. See section VI.B of this preamble for more information on information availability to the public.

EPA recognizes that some community residents want to participate in prevention planning and have access to incident investigation reports, safety audits, and STAA. However, community input can be effective in other ways that relate to community planning. EPA encourages community residents to become active in their LEPCs who are already working to reduce hazards for local communities. Providing access to facility reports outside of existing community planning activities could result in duplicative work and increased burden for communities, emergency responders, and facility staff.

Furthermore, developing a risk management program involves process hazards analyses and hierarchies of controls developed by trained professionals. Investigation reports, safety audits and STAA are often complicated and contain technical jargon, which can be difficult to understand without the proper training. Information in these reports can also reveal security vulnerabilities which may put communities in greater danger of terrorism if released.

Discussion of comments on meaningful involvement. A few commenters, including advocacy groups, said that the only meaningful involvement EPA has facilitated included collecting input to shape the proposed rulemaking. The commenters said that there is no analysis in the rule on whether or how the rule would facilitate meaningful involvement by at-

risk or environmental justice (EJ) communities.

EPA believes there were numerous opportunities for the public to provide meaningful input on this final rule. This final rule was developed following extensive public feedback through Executive Order 13650 listening sessions, public comments on the RFI and the proposed rulemaking, and the public hearing held on March 29, 2016. EPA has incorporated requirements in the final rule to prevent accidental releases, mitigate the impacts of releases that do occur, and share chemical hazard information with the public.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 68

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 21, 2016.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 68, of the Code of Federal Regulations is amended as follows:

PART 68—CHEMICAL ACCIDENT PREVENTION PROVISIONS

■ 1. The authority citation for part 68 continues to read as follows:

Authority: 42 U.S.C. 7412(r), 7601(a)(1), 7661–7661f.

■ 2. Amend § 68.3 by adding in alphabetical order the definitions ''Active measures'', ''CBI'', ''Inherently safer technology or design'', ''LEPC'', ''Passive measures'', ''Practicability'', ''Procedural measures'', ''Root cause'', and ''Third-party audit'' to read as follows:

§ 68.3 Definitions.

* * * * *

Active measures mean risk management measures or engineering controls that rely on mechanical, or other energy input to detect and respond to process deviations. Examples of active measures include alarms, safety instrumented systems, and detection hardware (such as hydrocarbon sensors).

* * * * *

CBI means confidential business information.

* * * * *

Inherently safer technology or design means risk management measures that minimize the use of regulated substances, substitute less hazardous substances, moderate the use of regulated substances, or simplify covered processes in order to make accidental releases less likely, or the impacts of such releases less severe.

* * * * *

LEPC means local emergency planning committee as established under 42 U.S.C. 11001(c).

* * * * *

Passive measures mean risk management measures that use design features that reduce either the frequency or consequence of the hazard without human, mechanical, or other energy input. Examples of passive measures include pressure vessel designs, dikes, berms, and blast walls.

* * * * *

Practicability means the capability of being successfully accomplished within a reasonable time, accounting for economic, environmental, legal, social, and technological factors. Environmental factors would include consideration of potential transferred risks for new risk reduction measures.

Procedural measures mean risk management measures such as policies, operating procedures, training, administrative controls, and emergency response actions to prevent or minimize incidents.

* * * * *

Root cause means a fundamental, underlying, system-related reason why an incident occurred.

* * * * *

Third-party audit means a compliance audit conducted pursuant to the requirements of § 68.59 and/or § 68.80, performed or led by an entity (individual or firm) meeting the competency and independence described in § 68.59(c) or § 68.80(c).

* * * * *

■ 3. Amend § 68.10 by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) through (f) as paragraphs (f) through (j);

■ c. Adding new paragraphs (b) through (e); and

■ d. Revising the newly designated paragraph (f)(2).

The revisions and additions read as follow:

§ 68.10 Applicability.

(a) Except as provided in paragraphs (b) through (e) of this section, an owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process, as determined under § 68.115, shall comply with the requirements of this part no later than the latest of the following dates:

(1) June 21, 1999;

(2) Three years after the date on which a regulated substance is first listed under § 68.130;

(3) The date on which a regulated substance is first present above a threshold quantity in a process; or

(4) For any revisions to this part, the effective date of the final rule that revises this part.

(b) By March 14, 2018 the owner or operator of a stationary source shall comply with the emergency response coordination activities in § 68.93.

(c) Within three years of when the owner or operator determines that the stationary source is subject to the emergency response program requirements of § 68.95, pursuant to § 68.90(a), the owner or operator must develop and implement an emergency response program in accordance with § 68.95.

(d) By March 15, 2021, the owner or operator shall comply with the following provisions promulgated on January 13, 2017:

(1) Third-party audit provisions in §§ 68.58(f), 68.58(g), 68.58(h), 68.59, 68.79(f), 68.79(g), 68.79(h), and 68.80;

(2) Incident investigation root cause analysis provisions in §§ 68.60(d)(7) and 68.81(d)(7);

(3) Safer technology and alternatives analysis provisions in § 68.67(c)(8);

(4) Emergency response exercise provisions of § 68.96, and;

(5) Availability of information provisions in § 68.210(b) through (e).

(e) By March 14, 2022, the owner or operator shall comply with the risk management plan provisions of subpart G of this part promulgated on January 13, 2017.

(f) * * *

(2) The distance to a toxic or flammable endpoint for a worst-case release assessment conducted under subpart B and § 68.25 is less than the distance to any public receptor, as defined in § 68.3; and

* * * * *

■ 4. Amend § 68.12 by:

■ a. Revising paragraphs (c)(4) and (5), and adding paragraph (c)(6); and

■ b. Revising paragraphs (d)(4) and (5), and adding paragraph (d)(6).

The revisions and additions read as follows:

§ 68.12 General requirements.

* * * * *

(c) * * *

(4) Coordinate response actions with local emergency planning and response agencies as provided in § 68.93;

(5) Develop and implement an emergency response program, and conduct exercises, as provided in §§ 68.90 to 68.96; and

(6) Submit as part of the RMP the data on prevention program elements for Program 2 processes as provided in § 68.170.

(d) * * *

(4) Coordinate response actions with local emergency planning and response agencies as provided in § 68.93;

(5) Develop and implement an emergency response program, and conduct exercises, as provided in §§ 68.90 to 68.96; and

(6) Submit as part of the RMP the data on prevention program elements for Program 3 processes as provided in § 68.175.

■ 5. Amend § 68.48 by revising paragraph (a)(1) to read as follows:

§ 68.48 Safety information.

(a) * * *

(1) Safety Data Sheets (SDS) that meet the requirements of 29 CFR 1910.1200(g);

* * * * *

■ 6. Amend § 68.50 by revising paragraph (a)(2) to read as follows:

§ 68.50 Hazard review.

(a) * * *

(2) Opportunities for equipment malfunctions or human errors that could cause an accidental release, including findings from incident investigations;

* * * * *

■ 7. Amend § 68.54 by revising paragraphs (a), (b), and (d); and adding paragraph (e) to read as follows:

§ 68.54 Training.

(a) The owner or operator shall ensure that each employee presently involved in operating a process, and each employee newly assigned to a covered process have been trained or tested competent in the operating procedures provided in § 68.52 that pertain to their duties. For those employees already operating a process on June 21, 1999, the owner or operator may certify in writing that the employee has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities as provided in the operating procedures.

(b) *Refresher training.* Refresher training shall be provided at least every three years, and more often if necessary, to each employee involved in operating a process to ensure that the employee understands and adheres to the current operating procedures of the process. The owner or operator, in consultation with the employees operating the process, shall determine the appropriate frequency of refresher training.

* * * * *

(d) The owner or operator shall ensure that employees involved in operating a process are trained in any updated or new procedures prior to startup of a process after a major change.

(e) For the purposes of this section, the term employee also includes supervisors responsible for directing process operations.

■ 8. Amend § 68.58 by revising paragraph (a) and adding paragraphs (f) through (h) to read as follows:

§ 68.58 Compliance audits.

(a) The owner or operator shall certify that they have evaluated compliance with the provisions of this subpart for each covered process, at least every three years to verify that the procedures and practices developed under the rule are adequate and are being followed. When required as set forth in paragraph (f) of this section, the compliance audit shall be a third-party audit.

* * * * *

(f) *Third-party audit applicability.* The next required compliance audit shall be a third-party audit when one of the following conditions apply:

(1) An accidental release meeting the criteria in § 68.42(a) from a covered process at a stationary source has occurred; or

(2) An implementing agency requires a third-party audit due to conditions at the stationary source that could lead to an accidental release of a regulated substance, or when a previous third-party audit failed to meet the competency or independence criteria of § 68.59(c).

(g) *Implementing agency notification and appeals.* (1) If an implementing agency makes a preliminary determination that a third-party audit is necessary pursuant to paragraph (f)(2) of this section, the implementing agency will provide written notice to the owner or operator that describes the basis for this determination.

(2) Within 30 days of receipt of such written notice, the owner or operator may provide information and data to, and may consult with, the implementing agency on the determination. Thereafter, the implementing agency will provide a final determination to the owner or operator.

(3) If the final determination requires a third-party audit, the owner or operator shall comply with the requirements of § 68.59, pursuant to the schedule in paragraph (h) of this section.

(4) *Appeals.* The owner or operator may appeal a final determination made by an implementing agency under paragraph (g)(2) of this section within 30 days of receipt of the final determination. The appeal shall be made to the EPA Regional Administrator, or for determinations made by other implementing agencies, the administrator or director of such implementing agency. The appeal shall contain a clear and concise statement of the issues, facts in the case, and any relevant additional information. In reviewing the appeal, the implementing agency may request additional information from the owner or operator. The implementing agency will provide a written, final decision on the appeal to the owner or operator.

(h) *Schedule for conducting a third-party audit.* The audit and audit report shall be completed as follows, unless a different timeframe is specified by the implementing agency:

(1) For third-party audits required pursuant to paragraph (f)(1) of this section, within 12 months of the release; or

(2) For third-party audits required pursuant to paragraph (f)(2) of this section, within 12 months of the date of the final determination pursuant to paragraph (g)(3) of this section. However, if the final determination is appealed pursuant to paragraph (g)(4) of this section, within 12 months of the date of the final decision on the appeal.

■ 9. Section 68.59 is added to subpart C to read as follows:

§ 68.59 Third-party audits.

(a) *Applicability.* The owner or operator shall engage a third-party to conduct an audit that evaluates compliance with the provisions of this subpart in accordance with the requirements of this section when either criterion of § 68.58(f) is met.

(b) *Third-party auditors and auditing teams.* The owner or operator shall either:

(1) Engage a third-party auditor meeting all of the competency and independence criteria in paragraph (c) of this section; or

(2) Assemble an auditing team, led by a third-party auditor meeting all of the competency and independence criteria in paragraph (c) of this section. The team may include:

(i) Other employees of the third-party auditor firm meeting the independence criteria of paragraph (c)(2) of this section; and

(ii) Other personnel not employed by the third-party auditor firm, including facility personnel.

(c) Third-party auditor qualifications. The owner or operator shall determine and document that the third-party auditor(s) meet the following competency and independence requirements:

(1) *Competency requirements.* The third-party auditor(s) shall be:

(i) Knowledgeable with the requirements of this part;

(ii) Experienced with the stationary source type and processes being audited and applicable recognized and generally accepted good engineering practices; and

(iii) Trained and/or certified in proper auditing techniques.

(2) *Independence requirements.* The third-party auditor(s) shall:

(i) Act impartially when performing all activities under this section;

(ii) Receive no financial benefit from the outcome of the audit, apart from payment for auditing services. For purposes of this paragraph, retired employees who otherwise satisfy the third-party auditor independence criteria in this section may qualify as independent if their sole continuing financial attachments to the owner or operator are employer-financed or managed retirement and/or health plans;

(iii) Not have conducted past research, development, design, construction services, or consulting for the owner or operator within the last two years. For purposes of this requirement, consulting does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80. An audit firm with personnel who, before working for the auditor, conducted research, development, design, construction, or consulting services for the owner or operator within the last two years as an employee or contractor may meet the requirements of this subsection by ensuring such personnel do not participate in the audit, or manage or advise the audit team concerning the audit;

(iv) Not provide other business or consulting services to the owner or operator, including advice or assistance to implement the findings or recommendations in an audit report, for a period of at least two years following submission of the final audit report;

(v) Ensure that all third-party personnel involved in the audit sign and date a conflict of interest statement documenting that they meet the independence criteria of this paragraph; and

(vi) Ensure that all third-party personnel involved in the audit do not accept future employment with the owner or operator of the stationary source for a period of at least two years following submission of the final audit report. For purposes of this requirement, employment does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80.

(3) The auditor shall have written policies and procedures to ensure that all personnel comply with the competency and independence requirements of this section.

(d) *Third-party auditor responsibilities.* The owner or operator shall ensure that the third-party auditor:

(1) Manages the audit and participates in audit initiation, design, implementation, and reporting;

(2) Determines appropriate roles and responsibilities for the audit team members based on the qualifications of each team member;

(3) Prepares the audit report and where there is a team, documents the full audit team's views in the final audit report;

(4) Certifies the final audit report and its contents as meeting the requirements of this section; and

(5) Provides a copy of the audit report to the owner or operator.

(e) *Audit report.* The audit report shall:

(1) Identify all persons participating on the audit team, including names, titles, employers and/or affiliations, and summaries of qualifications. For third-party auditors, include information demonstrating that the competency requirements in paragraph (c)(1) of this section are met;

(2) Describe or incorporate by reference the policies and procedures required under paragraph (c)(3) of this section;

(3) Document the auditor's evaluation, for each covered process, of the owner or operator's compliance with the provisions of this subpart to determine whether the procedures and practices developed by the owner or operator under this rule are adequate and being followed;

(4) Document the findings of the audit, including any identified compliance or performance deficiencies;

(5) Summarize any significant revisions (if any) between draft and final versions of the report; and

(6) Include the following certification, signed and dated by the third-party auditor or third-party audit team member leading the audit:

I certify that this RMP compliance audit report was prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information upon which the audit is based. I further certify that the audit was conducted and this report was prepared pursuant to the requirements of subpart C of 40 CFR part 68 and all other applicable auditing, competency, independence, impartiality, and conflict of interest standards and protocols. Based on my personal knowledge and experience, and inquiry of personnel involved in the audit, the information submitted herein is true, accurate, and complete.

(f) *Third-party audit findings*—(1) *Findings response report.* As soon as possible, but no later than 90 days after receiving the final audit report, the owner or operator shall determine an appropriate response to each of the findings in the audit report, and develop a findings response report that includes:

(i) A copy of the final audit report;

(ii) An appropriate response to each of the audit report findings;

(iii) A schedule for promptly addressing deficiencies; and

(iv) A certification, signed and dated by a senior corporate officer, or an official in an equivalent position, of the owner or operator of the stationary source, stating:

I certify under penalty of law that I have engaged a third-party to perform or lead an audit team to conduct a third-party audit in accordance with the requirements of 40 CFR 68.59 and that the attached RMP compliance audit report was received, reviewed, and responded to under my direction or supervision by qualified personnel. I further certify that appropriate responses to the findings have been identified and deficiencies were corrected, or are being corrected, consistent with the requirements of subpart C of 40 CFR part 68, as documented herein. Based on my personal knowledge and experience, or inquiry of personnel involved in evaluating the report findings and determining appropriate responses to the findings, the information submitted herein is true, accurate, and complete. I am aware that there are significant penalties for making false material statements, representations, or certifications, including the possibility of fines and imprisonment for knowing violations.

(2) *Schedule implementation.* The owner or operator shall implement the schedule to address deficiencies identified in the audit findings response report in paragraph (f)(1)(iii) of this section and document the action taken to address each deficiency, along with the date completed.

(3) *Submission to Board of Directors.* The owner or operator shall immediately provide a copy of each document required under paragraphs (f)(1) and (2) of this section, when completed, to the owner or operator's

audit committee of the Board of Directors, or other comparable committee or individual, if applicable.

(g) *Recordkeeping.* The owner or operator shall retain at the stationary source, the two most recent final third-party audit reports, related findings response reports, documentation of actions taken to address deficiencies, and related records. This requirement does not apply to any document that is more than five years old.

■ 10. Amend § 68.60 by:
■ a. Revising paragraph (a);
■ b. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g);
■ c. Adding a new paragraph (c); and
■ d. Revising the newly designated paragraphs (d) and (g).

The revisions and additions read as follows:

§ 68.60 Incident investigation.

(a) The owner or operator shall investigate each incident that:

(1) Resulted in a catastrophic release (including when the affected process is decommissioned or destroyed following, or as the result of, an incident); or

(2) Could reasonably have resulted in a catastrophic release (*i.e.,* was a near miss).

* * * * *

(c) An incident investigation team shall be established and consist of at least one person knowledgeable in the process involved and other persons with appropriate knowledge and experience to thoroughly investigate and analyze the incident.

(d) A report shall be prepared at the conclusion of the investigation. The report shall be completed within 12 months of the incident, unless the implementing agency approves, in writing, an extension of time. The report shall include:

(1) Date, time, and location of incident;

(2) Date investigation began;

(3) A description of the incident, in chronological order, providing all relevant facts;

(4) The name and amount of the regulated substance involved in the release (*e.g.,* fire, explosion, toxic gas loss of containment) or near miss and the duration of the event;

(5) The consequences, if any, of the incident including, but not limited to: injuries, fatalities, the number of people evacuated, the number of people sheltered in place, and the impact on the environment;

(6) Emergency response actions taken;

(7) The factors that contributed to the incident including the initiating event, direct and indirect contributing factors, and root causes. Root causes shall be determined by conducting an analysis for each incident using a recognized method; and

(8) Any recommendations resulting from the investigation and a schedule for addressing them.

* * * * *

(g) Incident investigation reports shall be retained for five years.

■ 11. Amend § 68.65 by revising the first sentence of paragraph (a) and the note to paragraph (b) to read as follows:

§ 68.65 Process safety information.

(a) The owner or operator shall complete a compilation of written process safety information before conducting any process hazard analysis required by the rule, and shall keep process safety information up-to-date. * * *

(b) * * *

Note to paragraph (b): Safety Data Sheets (SDS) meeting the requirements of 29 CFR 1910.1200(g) may be used to comply with this requirement to the extent they contain the information required by paragraph (b) of this section.

* * * * *

■ 12. Amend § 68.67 by:
■ a. Revising paragraph (c)(2);
■ b. Amending paragraph (c)(6) by removing the word ''and;''
■ c. Amending paragraph (c)(7) by removing the period at the end of the paragraph and adding ''; and'' in its place; and
■ d. Adding paragraph (c)(8).

The revisions and additions read as follows:

§ 68.67 Process hazard analysis.

* * * * *

(c) * * *

(2) The findings from all incident investigations required under § 68.81, as well as any other potential failure scenarios;

* * * * *

(8) For processes in NAICS 322, 324, and 325, safer technology and alternative risk management measures applicable to eliminating or reducing risk from process hazards.

(i) The owner or operator shall consider, in the following order of preference inherently safer technology or design, passive measures, active measures, and procedural measures. A combination of risk management measures may be used to achieve the desired risk reduction.

(ii) The owner or operator shall determine the practicability of the inherently safer technologies and designs considered.

* * * * *

■ 13. Amend § 68.71 by adding paragraph (d) to read as follows:

§ 68.71 Training.

* * * * *

(d) For the purposes of this section, the term employee also includes supervisors with process operational responsibilities.

■ 14. Amend § 68.79 by revising paragraph (a) and adding paragraphs (f) through (h) to read as follows:

§ 68.79 Compliance audits.

(a) The owner or operator shall certify that they have evaluated compliance with the provisions of this subpart for each covered process, at least every three years to verify that the procedures and practices developed under the rule are adequate and are being followed. When required as set forth in paragraph (f) of this section, the compliance audit shall be a third-party audit.

* * * * *

(f) *Third-party audit applicability.* The next required compliance audit shall be a third-party audit when one of the following conditions apply:

(1) An accidental release meeting the criteria in § 68.42(a) from a covered process at a stationary source has occurred; or

(2) An implementing agency requires a third-party audit due to conditions at the stationary source that could lead to an accidental release of a regulated substance, or when a previous third-party audit failed to meet the competency or independence criteria of § 68.80(c).

(g) *Implementing agency notification and appeals.* (1) If an implementing agency makes a preliminary determination that a third-party audit is necessary pursuant to paragraph (f)(2) of this section, the implementing agency will provide written notice to the owner or operator that describes the basis for this determination.

(2) Within 30 days of receipt of such written notice, the owner or operator may provide information and data to, and may consult with, the implementing agency on the determination. Thereafter, the implementing agency will provide a final determination to the owner or operator.

(3) If the final determination requires a third-party audit, the owner or operator shall comply with the requirements of § 68.80, pursuant to the schedule in paragraph (h) of this section.

(4) *Appeals.* The owner or operator may appeal a final determination made by an implementing agency under paragraph (g)(2) of this section within

30 days of receipt of the final determination. The appeal shall be made to the EPA Regional Administrator, or for determinations made by other implementing agencies, the administrator or director of such implementing agency. The appeal shall contain a clear and concise statement of the issues, facts in the case, and any relevant additional information. In reviewing the appeal, the implementing agency may request additional information from the owner or operator. The implementing agency will provide a written, final decision on the appeal to the owner or operator.

(h) *Schedule for conducting a third-party audit.* The audit and audit report shall be completed as follows, unless a different timeframe is specified by the implementing agency:

(1) For third-party audits required pursuant to paragraph (f)(1) of this section, within 12 months of the release; or

(2) For third-party audits required pursuant to paragraph (f)(2) of this section, within 12 months of the date of the final determination pursuant to paragraph (g)(3) of this section. However, if the final determination is appealed pursuant to paragraph (g)(4) of this section, within 12 months of the date of the final decision on the appeal.

■ 15. Section 68.80 is added to subpart D to read as follows:

§ 68.80 Third-party audits.

(a) *Applicability.* The owner or operator shall engage a third-party to conduct an audit that evaluates compliance with the provisions of this subpart in accordance with the requirements of this section when either criterion of § 68.79(f) is met.

(b) *Third-party auditors and auditing teams.* The owner or operator shall either:

(1) Engage a third-party auditor meeting all of the competency and independence criteria in paragraph (c) of this section; or

(2) Assemble an auditing team, led by a third-party auditor meeting all of the competency and independence criteria in paragraph (c) of this section. The team may include:

(i) Other employees of the third-party auditor firm meeting the independence criteria of paragraph (c)(2) of this section; and

(ii) Other personnel not employed by the third-party auditor firm, including facility personnel.

(c) *Third-party auditor qualifications.* The owner or operator shall determine and document that the third-party auditor(s) meet the following competency and independence requirements:

(1) *Competency requirements.* The third-party auditor(s) shall be:

(i) Knowledgeable with the requirements of this part;

(ii) Experienced with the stationary source type and processes being audited and applicable recognized and generally accepted good engineering practices; and

(iii) Trained or certified in proper auditing techniques.

(2) *Independence requirements.* The third-party auditor(s) shall:

(i) Act impartially when performing all activities under this section;

(ii) Receive no financial benefit from the outcome of the audit, apart from payment for auditing services. For purposes of this paragraph, retired employees who otherwise satisfy the third-party auditor independence criteria in this section may qualify as independent if their sole continuing financial attachments to the owner or operator are employer-financed or managed retirement and/or health plans;

(iii) Not have conducted past research, development, design, construction services, or consulting for the owner or operator within the last two years. For purposes of this requirement, consulting does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80. An audit firm with personnel who, before working for the auditor, conducted research, development, design, construction, or consulting services for the owner or operator within the last two years as an employee or contractor may meet the requirements of this subsection by ensuring such personnel do not participate in the audit, or manage or advise the audit team concerning the audit;

(iv) Not provide other business or consulting services to the owner or operator, including advice or assistance to implement the findings or recommendations in an audit report, for a period of at least two years following submission of the final audit report;

(v) Ensure that all third-party personnel involved in the audit sign and date a conflict of interest statement documenting that they meet the independence criteria of this paragraph; and

(vi) Ensure that all third-party personnel involved in the audit do not accept future employment with the owner or operator of the stationary source for a period of at least two years following submission of the final audit report. For purposes of this requirement, employment does not include performing or participating in third-party audits pursuant to § 68.59 or § 68.80.

(3) The auditor shall have written policies and procedures to ensure that all personnel comply with the competency and independence requirements of this section.

(d) *Third-party auditor responsibilities.* The owner or operator shall ensure that the third-party auditor:

(1) Manages the audit and participates in audit initiation, design, implementation, and reporting;

(2) Determines appropriate roles and responsibilities for the audit team members based on the qualifications of each team member;

(3) Prepares the audit report and where there is a team, documents the full audit team's views in the final audit report;

(4) Certifies the final audit report and its contents as meeting the requirements of this section; and

(5) Provides a copy of the audit report to the owner or operator.

(e) *Audit report.* The audit report shall:

(1) Identify all persons participating on the audit team, including names, titles, employers and/or affiliations, and summaries of qualifications. For third-party auditors, include information demonstrating that the competency requirements in paragraph (c)(1) of this section are met;

(2) Describe or incorporate by reference the policies and procedures required under paragraph (c)(3) of this section;

(3) Document the auditor's evaluation, for each covered process, of the owner or operator's compliance with the provisions of this subpart to determine whether the procedures and practices developed by the owner or operator under this rule are adequate and being followed;

(4) Document the findings of the audit, including any identified compliance or performance deficiencies;

(5) Summarize any significant revisions (if any) between draft and final versions of the report; and

(6) Include the following certification, signed and dated by the third-party auditor or third-party audit team member leading the audit:

I certify that this RMP compliance audit report was prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information upon which the audit is based. I further certify that the audit was conducted and this report was prepared pursuant to the requirements of subpart D of 40 CFR part 68 and all other applicable auditing,

competency, independence, impartiality, and conflict of interest standards and protocols. Based on my personal knowledge and experience, and inquiry of personnel involved in the audit, the information submitted herein is true, accurate, and complete.

(f) *Third-party audit findings*—(1) *Findings response report.* As soon as possible, but no later than 90 days after receiving the final audit report, the owner or operator shall determine an appropriate response to each of the findings in the audit report, and develop a findings response report that includes:

(i) A copy of the final audit report;

(ii) An appropriate response to each of the audit report findings;

(iii) A schedule for promptly addressing deficiencies; and

(iv) A certification, signed and dated by a senior corporate officer, or an official in an equivalent position, of the owner or operator of the stationary source, stating:

I certify under penalty of law that I have engaged a third-party to perform or lead an audit team to conduct a third-party audit in accordance with the requirements of 40 CFR 68.80 and that the attached RMP compliance audit report was received, reviewed, and responded to under my direction or supervision by qualified personnel. I further certify that appropriate responses to the findings have been identified and deficiencies were corrected, or are being corrected, consistent with the requirements of subpart D of 40 CFR part 68, as documented herein. Based on my personal knowledge and experience, or inquiry of personnel involved in evaluating the report findings and determining appropriate responses to the findings, the information submitted herein is true, accurate, and complete. I am aware that there are significant penalties for making false material statements, representations, or certifications, including the possibility of fines and imprisonment for knowing violations.

(2) *Schedule implementation.* The owner or operator shall implement the schedule to address deficiencies identified in the audit findings response report in paragraph (f)(1)(iii) of this section and document the action taken to address each deficiency, along with the date completed.

(3) *Submission to Board of Directors.* The owner or operator shall immediately provide a copy of each document required under paragraphs (f)(1) and (2) of this section, when completed, to the owner or operator's audit committee of the Board of Directors, or other comparable committee or individual, if applicable.

(g) *Recordkeeping.* The owner or operator shall retain at the stationary source the two most recent final third-party audit reports, related findings response reports, documentation of actions taken to address deficiencies, and related records.

■ 16. Amend § 68.81 by revising paragraphs (a), (d) introductory text, (d)(1), (d)(3) through (5), and adding paragraphs (d)(6) through (8) to read as follows:

§ 68.81 Incident investigation.

(a) The owner or operator shall investigate each incident that:

(1) Resulted in a catastrophic release (including when the affected process is decommissioned or destroyed following, or as the result of, an incident); or

(2) Could reasonably have resulted in a catastrophic release (*i.e.,* was a near miss).

* * * * *

(d) A report shall be prepared at the conclusion of the investigation. The report shall be completed within 12 months of the incident, unless the implementing agency approves, in writing, an extension of time. The report shall include:

(1) Date, time, and location of incident;

* * * * *

(3) A description of the incident, in chronological order, providing all relevant facts;

(4) The name and amount of the regulated substance involved in the release (*e.g.,* fire, explosion, toxic gas loss of containment) or near miss and the duration of the event;

(5) The consequences, if any, of the incident including, but not limited to: injuries, fatalities, the number of people evacuated, the number of people sheltered in place, and the impact on the environment;

(6) Emergency response actions taken;

(7) The factors that contributed to the incident including the initiating event, direct and indirect contributing factors, and root causes. Root causes shall be determined by conducting an analysis for each incident using a recognized method; and

(8) Any recommendations resulting from the investigation and a schedule for addressing them.

* * * * *

■ 17. Revise § 68.90 to read as follows:

§ 68.90 Applicability.

(a) *Responding stationary source.* Except as provided in paragraph (b) of this section, the owner or operator of a stationary source with Program 2 and Program 3 processes shall comply with the requirements of §§ 68.93, 68.95, and 68.96.

(b) *Non-responding stationary source.* The owner or operator of a stationary source whose employees will not respond to accidental releases of regulated substances need not comply with § 68.95 of this part provided that:

(1) For stationary sources with any regulated toxic substance held in a process above the threshold quantity, the stationary source is included in the community emergency response plan developed under 42 U.S.C. 11003;

(2) For stationary sources with only regulated flammable substances held in a process above the threshold quantity, the owner or operator has coordinated response actions with the local fire department;

(3) Appropriate mechanisms are in place to notify emergency responders when there is a need for a response;

(4) The owner or operator performs the annual emergency response coordination activities required under § 68.93; and

(5) The owner or operator performs the annual notification exercises required under § 68.96(a).

■ 18. Section 68.93 is added to subpart E to read as follows:

§ 68.93 Emergency response coordination activities.

The owner or operator of a stationary source shall coordinate response needs with local emergency planning and response organizations to determine how the stationary source is addressed in the community emergency response plan and to ensure that local response organizations are aware of the regulated substances at the stationary source, their quantities, the risks presented by covered processes, and the resources and capabilities at the stationary source to respond to an accidental release of a regulated substance.

(a) Coordination shall occur at least annually, and more frequently if necessary, to address changes: At the stationary source; in the stationary source's emergency response and/or emergency action plan; and/or in the community emergency response plan.

(b) Coordination shall include providing to the local emergency planning and response organizations: The stationary source's emergency response plan if one exists; emergency action plan; updated emergency contact information; and any other information that local emergency planning and response organizations identify as relevant to local emergency response planning. For responding stationary sources, coordination shall also include consulting with local emergency response officials to establish appropriate schedules and plans for field and tabletop exercises required under § 68.96(b). The owner or operator

shall request an opportunity to meet with the local emergency planning committee (or equivalent) and/or local fire department as appropriate to review and discuss these materials.

(c) The owner or operator shall document coordination with local authorities, including: The names of individuals involved and their contact information (phone number, email address, and organizational affiliations); dates of coordination activities; and nature of coordination activities.

■ 19. Amend § 68.95 by:

■ a. Revising paragraph (a)(1)(i);

■ b. Adding a sentence to the end of paragraph (a)(4); and

■ c. Revising paragraph (c).

The revisions and addition read as follows:

68.95 Emergency response program.

(a) * * *

(1) * * *

(i) Procedures for informing the public and the appropriate Federal, state, and local emergency response agencies about accidental releases;

* * * * *

(4) * * * The owner or operator shall review and update the plan as appropriate based on changes at the stationary source or new information obtained from coordination activities, emergency response exercises, incident investigations, or other available information, and ensure that employees are informed of the changes.

* * * * *

(c) The emergency response plan developed under paragraph (a)(1) of this section shall be coordinated with the community emergency response plan developed under 42 U.S.C. 11003. Upon request of the LEPC or emergency response officials, the owner or operator shall promptly provide to the local emergency response officials information necessary for developing and implementing the community emergency response plan.

■ 20. Section 68.96 is added to subpart E to read as follows:

§ 68.96 Emergency response exercises.

(a) *Notification exercises.* At least once each calendar year, the owner or operator of a stationary source with any Program 2 or Program 3 process shall conduct an exercise of the stationary source's emergency response notification mechanisms required under § 68.90(a)(2) or § 68.95(a)(1)(i), as appropriate. Owners or operators of responding stationary sources may perform the notification exercise as part of the tabletop and field exercises required in paragraph (b) of this section. The owner/operator shall maintain a written record of each notification exercise conducted over the last five years.

(b) *Emergency response exercise program.* The owner or operator of a stationary source subject to the requirements of § 68.95 shall develop and implement an exercise program for its emergency response program, including the plan required under § 68.95(a)(1). Exercises shall involve facility emergency response personnel and, as appropriate, emergency response contractors. When planning emergency response field and tabletop exercises, the owner or operator shall coordinate with local public emergency response officials and invite them to participate in the exercise. The emergency response exercise program shall include:

(1) *Emergency response field exercises.* The owner or operator shall conduct field exercises involving the simulated accidental release of a regulated substance (*i.e.,* toxic substance release or release of a regulated flammable substance involving a fire and/or explosion).

(i) *Frequency.* As part of coordination with local emergency response officials required by § 68.93, the owner or operator shall consult with these officials to establish an appropriate frequency for field exercises, but at a minimum, shall conduct a field exercise at least once every ten years.

(ii) *Scope.* Field exercises shall include: Tests of procedures to notify the public and the appropriate Federal, state, and local emergency response agencies about an accidental release; tests of procedures and measures for emergency response actions including evacuations and medical treatment; tests of communications systems; mobilization of facility emergency response personnel, including contractors, as appropriate; coordination with local emergency responders; emergency response equipment deployment; and any other action identified in the emergency response program, as appropriate.

(2) *Tabletop exercises.* The owner or operator shall conduct a tabletop exercise involving the simulated accidental release of a regulated substance.

(i) *Frequency.* As part of coordination with local emergency response officials required by § 68.93, the owner or operator shall consult with these officials to establish an appropriate frequency for tabletop exercises, but at a minimum, shall conduct a field exercise at least once every three years.

(ii) *Scope.* The exercise shall include discussions of: Procedures to notify the public and the appropriate Federal, state, and local emergency response agencies; procedures and measures for emergency response including evacuations and medical treatment; identification of facility emergency response personnel and/or contractors and their responsibilities; coordination with local emergency responders; procedures for emergency response equipment deployment; and any other action identified in the emergency response plan, as appropriate.

(3) *Documentation.* The owner/operator shall prepare an evaluation report within 90 days of each exercise. The report shall include: A description of the exercise scenario; names and organizations of each participant; an evaluation of the exercise results including lessons learned; recommendations for improvement or revisions to the emergency response exercise program and emergency response program, and a schedule to promptly address and resolve recommendations.

(c) *Alternative means of meeting exercise requirements.* The owner or operator may satisfy the requirement to conduct notification, field and/or tabletop exercises through:

(1) Exercises conducted to meet other Federal, state or local exercise requirements, provided the exercise meets the requirements of paragraphs (a) and/or (b) of this section, as appropriate.

(2) Response to an accidental release, provided the response includes the actions indicated in paragraphs (a) and/or (b) of this section, as appropriate. When used to meet field and/or tabletop exercise requirements, the owner or operator shall prepare an after-action report comparable to the exercise evaluation report required in paragraph (b)(3) of this section, within 90 days of the incident.

■ 21. Amend § 68.130 by:

■ a. In Table 1, ''List of Regulated Toxic Substances and Threshold Quantities for Accidental Release Prevention'', under second column entitled ''CAS No.'', removing the number ''107–18–61'' adding ''107–18–6'' in its place; and

■ b. Revising Table 4, ''List of Regulated Flammable Substances and Threshold Quantities for Accidental Release Prevention''.

The revisions read as follows:

§ 68.130 List of substances.

* * * * *

TABLE 4 TO § 68.130—LIST OF REGULATED FLAMMABLE SUBSTANCES [1] AND THRESHOLD QUANTITIES FOR ACCIDENTAL RELEASE PREVENTION

[CAS Number Order—63 Substances]

CAS No.	Chemical name	Threshold quantity (lbs)	Basis for listing
60–29–7	Ethyl ether [Ethane, 1,1′-oxybis-]	10,000	g
74–82–8	Methane	10,000	f
74–84–0	Ethane	10,000	f
74–85–1	Ethylene [Ethene]	10,000	f
74–86–2	Acetylene [Ethyne]	10,000	f
74–89–5	Methylamine [Methanamine]	10,000	f
74–98–6	Propane	10,000	f
74–99–7	Propyne [1-Propyne]	10,000	f
75–00–3	Ethyl chloride [Ethane, chloro-]	10,000	f
75–01–4	Vinyl chloride [Ethene, chloro-]	10,000	a, f
75–02–5	Vinyl fluoride [Ethene, fluoro-]	10,000	f
75–04–7	Ethylamine [Ethanamine]	10,000	f
75–07–0	Acetaldehyde	10,000	g
75–08–1	Ethyl mercaptan [Ethanethiol]	10,000	g
75–19–4	Cyclopropane	10,000	f
75–28–5	Isobutane [Propane, 2-methyl]	10,000	f
75–29–6	Isopropyl chloride [Propane, 2-chloro-]	10,000	g
75–31–0	Isopropylamine [2-Propanamine]	10,000	g
75–35–4	Vinylidene chloride [Ethene, 1,1-dichloro-]	10,000	g
75–37–6	Difluoroethane [Ethane, 1,1-difluoro-]	10,000	f
75–38–7	Vinylidene fluoride [Ethene, 1,1-difluoro-]	10,000	f
75–50–3	Trimethylamine [Methanamine, N, N-dimethyl-]	10,000	f
75–76–3	Tetramethylsilane [Silane, tetramethyl-]	10,000	g
78–78–4	Isopentane [Butane, 2-methyl-]	10,000	g
78–79–5	Isoprene [1,3,-Butadiene, 2-methyl-]	10,000	g
79–38–9	Trifluorochloroethylene [Ethene, chlorotrifluoro-]	10,000	f
106–97–8	Butane	10,000	f
106–98–9	1-Butene	10,000	f
106–99–0	1,3-Butadiene	10,000	f
107–00–6	Ethyl acetylene [1-Butyne]	10,000	f
107–01–7	2-Butene	10,000	f
107–25–5	Vinyl methyl ether [Ethene, methoxy-]	10,000	f
107–31–3	Methyl formate [Formic acid, methyl ester]	10,000	g
109–66–0	Pentane	10,000	g
109–67–1	1-Pentene	10,000	g
109–92–2	Vinyl ethyl ether [Ethene, ethoxy-]	10,000	g
109–95–5	Ethyl nitrite [Nitrous acid, ethyl ester]	10,000	f
115–07–1	Propylene [1-Propene]	10,000	f
115–10–6	Methyl ether [Methane, oxybis-]	10,000	f
115–11–7	2-Methylpropene [1-Propene, 2-methyl-]	10,000	f
116–14–3	Tetrafluoroethylene [Ethene, tetrafluoro-]	10,000	f
124–40–3	Dimethylamine [Methanamine, N-methyl-]	10,000	f
460–19–5	Cyanogen [Ethanedinitrile]	10,000	f
463–49–0	Propadiene [1,2-Propadiene]	10,000	f
463–58–1	Carbon oxysulfide [Carbon oxide sulfide (COS)]	10,000	f
463–82–1	2,2-Dimethylpropane [Propane, 2,2-dimethyl-]	10,000	f
504–60–9	1,3-Pentadiene	10,000	f
557–98–2	2-Chloropropylene [1-Propene, 2-chloro-]	10,000	g
563–45–1	3-Methyl-1-butene	10,000	f
563–46–2	2-Methyl-1-butene	10,000	g
590–18–1	2-Butene-cis	10,000	f
590–21–6	1-Chloropropylene [1-Propene, 1-chloro-]	10,000	g
598–73–2	Bromotrifluorethylene [Ethene, bromotrifluoro-]	10,000	f
624–64–6	2-Butene-trans [2-Butene, (E)]	10,000	f
627–20–3	2-Pentene, (Z)-	10,000	g
646–04–8	2-Pentene, (E)-	10,000	g
689–97–4	Vinyl acetylene [1-Buten-3-yne]	10,000	f
1333–74–0	Hydrogen	10,000	f
4109–96–0	Dichlorosilane [Silane, dichloro-]	10,000	f
7791–21–1	Chlorine monoxide [Chlorine oxide]	10,000	f
7803–62–5	Silane	10,000	f
10025–78–2	Trichlorosilane [Silane, trichloro-]	10,000	g
25167–67–3	Butene	10,000	f

[1] A flammable substance when used as a fuel or held for sale as a fuel at a retail facility is excluded from all provisions of this part (see § 68.126).

Note: Basis for Listing:

[a] Mandated for listing by Congress.

[f] Flammable gas.

[g] Volatile flammable liquid.

■ 22. Amend § 68.160 by adding paragraphs (b)(21) and (22) to read as follows:

§ 68.160 Registration.

* * * * *

(b) * * *

(21) Method of communication and location of the notification that chemical hazard information is

available to the public, pursuant to § 68.210(c); and

(22) Whether a public meeting has been held following an RMP reportable accident, pursuant to § 68.210(e).

■ 23. Amend § 68.170 by revising paragraphs (i) and (j) to read as follows:

§ 68.170 Prevention program/Program 2.

* * * * *

(i) The date of the most recent compliance audit, the expected date of completion of any changes resulting from the compliance audit, and identify whether the most recent compliance audit was a third-party audit, pursuant to §§ 68.58 and 68.59.

(j) The completion date of the most recent incident investigation and the expected date of completion of any changes resulting from the investigation.

* * * * *

■ 24. Amend § 68.175 by:

■ a. Revising the introductory text of paragraph (e), and paragraphs (e)(1), (5), and (6);

■ b. Adding paragraph (e)(7); and

■ c. Revising paragraphs (k) and (l).

The revisions and addition read as follows:

§ 68.175 Prevention program/Program 3.

* * * * *

(e) The most recent process hazard analysis (PHA) or PHA update and revalidation information, pursuant to § 68.67, including:

(1) The date of completion of the most recent PHA or update and the technique used;

* * * * *

(5) Monitoring and detection systems in use;

(6) Changes since the last PHA; and

(7) Inherently safer technology or design measures implemented since the last PHA, if any, and the technology category (substitution, minimization, simplification and/or moderation).

* * * * *

(k) The date of the most recent compliance audit, the expected date of completion of any changes resulting from the compliance audit, and identify whether the most recent compliance audit was a third-party audit, pursuant to §§ 68.79 and 68.80.

(l) The completion date of the most recent incident investigation and the expected date of completion of any changes resulting from the investigation.

* * * * *

■ 25. Revise § 68.180 to read as follows:

§ 68.180 Emergency response program and exercises.

(a) The owner or operator shall provide in the RMP:

(1) Name, organizational affiliation, phone number, and email address of local emergency planning and response organizations with which the stationary source last coordinated emergency response efforts, pursuant to § 68.10(f)(3) or § 68.93;

(2) The date of the most recent coordination with the local emergency response organizations, pursuant to § 68.93 and

(3) A list of Federal or state emergency plan requirements to which the stationary source is subject.

(b) The owner or operator shall identify in the RMP whether the facility is a responding stationary source or a non-responding stationary source, pursuant to § 68.90.

(1) For non-responding stationary sources, the owner or operator shall identify:

(i) For stationary sources with any regulated toxic substance held in a process above the threshold quantity, whether the stationary source is included in the community emergency response plan developed under 42 U.S.C. 11003, pursuant to § 68.90(b)(1);

(ii) For stationary sources with only regulated flammable substances held in a process above the threshold quantity, the date of the most recent coordination with the local fire department, pursuant to § 68.90(b)(2);

(iii) What mechanisms are in place to notify the public and emergency responders when there is a need for emergency response; and

(iv) The date of the most recent notification exercise, as required in § 68.96(a).

(2) For responding stationary sources, the owner or operator shall identify:

(i) The date of the most recent review and update of the emergency response plan, pursuant to § 68.95(a)(4);

(ii) The date of the most recent notification exercise, as required in § 68.96(a);

(iii) The date of the most recent field exercise, as required in § 68.96(b)(1); and

(iv) The date of the most recent tabletop exercise, as required in § 68.96(b)(2).

■ 26. Amend § 68.190 by adding a sentence at the end of paragraph (c) to read as follows:

§ 68.190 Updates.

* * * * *

(c) * * * Prior to de-registration the owner or operator shall meet applicable reporting and incident investigation requirements in accordance with §§ 68.42, 68.60, and/or 68.81.

* * * * *

■ 27. Revise § 68.200 to read as follows:

§ 68.200 Recordkeeping.

The owner or operator shall maintain records supporting the implementation of this part at the stationary source for five years, unless otherwise provided in subpart D of this part.

■ 28. Revise § 68.210 to read as follows:

§ 68.210 Availability of information to the public.

(a) *RMP availability.* The RMP required under subpart G of this part shall be available to the public under 42 U.S.C. 7414(c) and 40 CFR part 1400.

(b) *Chemical hazard information.* The owner or operator of a stationary source shall provide, upon request by any member of the public, the following chemical hazard information for all regulated processes, as applicable:

(1) Regulated substances information. Names of regulated substances held in a process;

(2) Safety data sheets (SDS). SDSs for all regulated substances located at the facility;

(3) Accident history information. Provide the five-year accident history information required to be reported under § 68.42;

(4) Emergency response program. The following summary information concerning the stationary source's compliance with § 68.10(f)(3) or the emergency response provisions of subpart E:

(i) Whether the stationary source is a responding stationary source or a non-responding stationary source;

(ii) Name and phone number of local emergency response organizations with which the owner or operator last coordinated emergency response efforts, pursuant to § 68.180; and

(iii) For stationary sources subject to § 68.95, procedures for informing the public and local emergency response agencies about accidental releases;

(5) Exercises. A list of scheduled exercises required under § 68.96; and

(6) LEPC contact information. Include LEPC name, phone number, and web address as available.

(c) *Notification of availability of information.* The owner or operator shall provide ongoing notification on a company Web site, social media platforms, or through other publicly accessible means that:

(1) Information specified in paragraph (b) of this section is available to the public upon request. The notification shall:

(i) Specify the information elements, identified in paragraph (b) of this section, that can be requested; and

(ii) Provide instructions for how to request the information (*e.g.* email,

mailing address, and/or telephone or Web site request);

(2) Identify where to access information on community preparedness, if available, including shelter-in-place and evacuation procedures.

(d) *Timeframe to provide requested information.* The owner or operator shall provide the requested information under paragraph (b) of this section within 45 days of receiving a request from any member of the public.

(e) *Public meetings.* The owner or operator of a stationary source shall hold a public meeting to provide information required under § 68.42 as well as other relevant chemical hazard information, such as that described in paragraph (b) of this section, no later than 90 days after any accident subject to reporting under § 68.42.

(f) *Classified information.* The disclosure of information classified by the Department of Defense or other Federal agencies or contractors of such agencies shall be controlled by applicable laws, regulations, or executive orders concerning the release of classified information.

(g) *CBI.* An owner or operator asserting CBI for information required under this section shall provide a sanitized version to the public. Assertion of claims of CBI and substantiation of CBI claims shall be in the same manner as required in §§ 68.151 and 68.152 for information contained in the RMP required under subpart G of this part. As provided under § 68.151(b)(3), an owner or operator of a stationary source may not claim five-year accident history information as CBI. As provided in § 68.151(c)(2), an owner or operator of a stationary source asserting that a chemical name is CBI shall provide a generic category or class name as a substitute.

[FR Doc. 2016–31426 Filed 1–12–17; 8:45 am]

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Part V

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1

Federal Acquisition Regulation; Federal Acquisition Circular 2005–95; Introduction; Uniform Use of Line Items; Acquisition Threshold for Special Emergency Procurement Authority; Contractor Employee Internal Confidentiality Agreements or Statements; Contracts Under the Small Business Administration 8(a) Program; Prohibition on Reimbursement for Congressional Investigations and Inquiries; and Federal Acquisition Circular 2005–95; Small Entity Compliance Guide; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2016–0051, Sequence No. 9]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–95; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2005–95. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC. The FAC, including the SECG, is available via the Internet at *http://www.regulations.gov.*

DATES: For effective dates see the separate documents, which follow.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to the FAR case. Please cite FAC 2005–95 and the specific FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2005–95

Item	Subject	FAR Case	Analyst
I	Uniform Use of Line Items	2013–014	Francis.
II	Acquisition Threshold for Special Emergency Procurement Authority	2016–004	Francis.
III	Contractor Employee Internal Confidentiality Agreements or Statements	2015–012	Davis.
IV	Contracts Under the Small Business Administration 8(a) Program	2012–022	Uddowla.
V	Prohibition on Reimbursement for Congressional Investigations and Inquiries	2015–016	Delgado.

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–95 amends the FAR as follows:

Item I—Uniform Use of Line Items (FAR Case 2013–014)

This final rule amends the FAR to establish standards for the uniform use of line items in Federal procurement. These standards are designed to improve the accuracy, traceability, and usability of procurement data. The implementation of these standards will facilitate the identification and traceability of spending from appropriation through expenditure, supporting automated collection of information using key identifiers. The implementation date for FAR 4.1002 through 4.1008 will be October 1, 2019.

The requirements in the rule have the potential to impact any entity, small or large, that does business with the Federal Government because the proposed rule would apply to purchases of items, including commercial items and commercially available off-the-shelf items, and purchases under the simplified acquisition threshold. Any small business that contracts with a Federal agency could be impacted to at least some extent.

Item II—Acquisition Threshold for Special Emergency Procurement Authority (FAR Case 2016–004)

This final rule amends the FAR by increasing the simplified acquisition threshold (SAT) for special emergency procurement authority from $300,000 to $750,000 (within the United States) and from $1 million to $1.5 million (outside the United States) for acquisitions of supplies or services that, as determined by the head of the agency, are to be used to support a contingency operation or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack. This change implements Section 816 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92). This rule provides contracting officers with more flexibility when contracting in support of contingency operations.

The rule is not anticipated to have a significant economic impact on small business entities, because the rule raises the SAT for special emergency procurements, an arena in which a smaller percentage of small businesses participate, as compared to larger businesses. This final rule does not place any new requirements on small entities.

Item III—Contractor Employee Internal Confidentiality Agreements or Statements (FAR Case 2015–012)

This final rule revises the FAR to implement section 743 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and successor provisions in subsequent appropriations acts. Section 743 prohibits the use of funds appropriated or otherwise made available by Division E or any other act, for a contract with an entity that requires employees and subcontractors of such entity to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse, to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.,* agency office of the Inspector General). This rule is not expected to have a significant impact on small entities contracting with the Government.

Item IV—Contracts Under the Small Business Administration 8(a) Program (FAR Case 2012–022)

This final rule amends the Federal Acquisition Regulation (FAR) to implement clarifications made by the Small Business Administration in its final rule, which published in the **Federal Register** at 76 FR 8222 on February 11, 2011. This final rule clarifies in the FAR the procedures and requirements used when contracting under the 8(a) program. Clarifications include the evaluation, offering, and acceptance process, procedures for acquiring SBA's consent to procure an

8(a) requirement outside the 8(a) program, and the impact of exiting the 8(a) program in terms of the firm's ability to receive future 8(a) requirements and its current contractual commitments.

This final rule does not place any new requirements, financial or otherwise, on small entities, and serves mainly to provide more explicit guidance to Federal contracting officials.

Item V—Prohibition on Reimbursement for Congressional Investigations and Inquiries (FAR Case 2015–016)

This rule amends the FAR to implement section 857 of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015. Section 857 imposes additional requirements relative to the allowability of costs incurred by a contractor in connection with a congressional investigation or inquiry. Contracting officers need to be aware of these new restrictions on certain costs, which cannot be charged under contracts. Although small businesses subject to FAR part 31 will need to maintain accounting records, this rule does not place any new requirements on small entities.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2005–95 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2005–95 is effective January 13, 2017 except for item III, which is effective January 19, 2017.

Dated: December 21, 2016.

Claire M. Grady,

Director, Defense Procurement and Acquisition Policy.

Dated: December 21, 2016.

William F. Clark,

Acting, Senior Procurement Executive, Office of Acquisition Policy, U.S. General Services Administration.

Dated: December 19, 2016.

William P. McNally,

Assistant Administrator, Office of Procurement National Aeronautics and Space Administration.

[FR Doc. 2016–31494 Filed 1–12–17; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 3, 4, 5, 7, 8, 9, 12, 14, 15, 16, 17, 27, 32, 42, 48, 49, and 52

[FAC 2005–95; FAR Case 2013–014; Item I; Docket No. 2013–0014, Sequence No. 1]

RIN 9000–AM73

Federal Acquisition Regulation; Uniform Use of Line Items

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to establish uniform use of line items in Federal procurement.

DATES: *Effective:* January 13, 2017. In order to provide agencies with time to transition their information systems, agencies have until October 1, 2019, to apply the requirements of FAR 4.1002 through 4.1008 of subpart 4.10.

FOR FURTHER INFORMATION CONTACT: Ms. Camara Francis, Procurement Analyst, at 202–550–0935 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–95, FAR Case 2013–014.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 79 FR 45408 on August 5, 2014, to establish uniform use of line items in Federal procurement. The uniform line item structure is designed to improve the accuracy, traceability, and usability of procurement data. The need for this rule stems from the lack of access to reliable and comprehensive data on Federal procurement actions that is essential to management and program decisions that result in delivering services to taxpayers in the most efficient and effective manner. Lack of standards for identifying and tracing tax dollars across the acquisition contributes to duplication in spending, gaps in reporting, and inefficiencies in management decisions. The implementation of these standards will facilitate the identification and traceability of spending from appropriation through expenditure, supporting automated collection of information using key identifiers. Three respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes From the Proposed Rule

1. The rule provides agencies time to transition their information systems and appropriately train the workforce. Accordingly, agencies have until October 1, 2019, to apply the requirements of FAR 4.1002 through 4.1008 of subpart 4.10.

2. The term ''line item unique identifier'' was removed and replaced with ''line item number'' for consistency with the current version of the FAR text. The term ''unique'' is no longer necessary due to changes made by the Uniform Procurement Identification rule (FAR Case 2012–023) published in the **Federal Register** at 79 FR 61739 on October 14, 2014.

B. Analysis of Public Comments

1. Alternative Line Item Structure

Comment: One respondent suggested removing text that would allow offerors to propose their own alternative line item structure, because this would be counterproductive to the goal of standardized reporting.

Response: The language on alternative line items was intended to allow flexibility, consistent with the requirements at FAR subpart 4.10. To clarify that the Government is not requesting contractors to create line items inconsistent with the rule, the clause is renamed ''Alternative Line Item Proposal'' and the explanatory text will no longer use the term ''structure,'' as this seemed to be the cause of some confusion.

2. Accounting Classification Citation

Comment: One respondent asked if each subline item is expected to have its own accounting classification citation.

Response: It is not a requirement for each subline item to have its own accounting classification citation. However, each deliverable subline item is expected to have its own accounting classification citation. This should not be construed to mean that the same

accounting classification citation cannot apply to multiple line items.

Comment: One respondent opined that a contract line item number or subline item number should not be created for the sole purpose of addressing an accounting classification, because this information is already tracked in financial systems. The respondent also questioned the specificity of the required accounting data on subline item numbers, because this data could not be gathered effectively through automated means.

Response: Only a deliverable subline item is expected to have its own accounting classification citation. While it is true that some Government systems are integrated to trace accounting classification citations to specific line items, this is not the case for all systems and this rule allows for linking accounting classification citations directly to line items in contract writing systems.

3. Exceptions

Comment: One respondent recommended adding exceptions to the text related to the requirement to include accounting classification citations on line items.

Response: There is no need for an exception to include accounting classification citations on line items, as this is not required, but is allowed. The text at FAR 4.1003(c) is modified to make it clear that multiple accounting classification citations can be provided on a line item.

4. Implementation

Comment: One respondent requested pushing the implementation date of the line item requirement further into the future, beyond October 1, 2016, due to the associated burden.

Response: The implementation date of this requirement for uniform line item use is now set for October 1, 2019.

5. Contract Milestone

Comment: One respondent inquired if a contact milestone will be considered a deliverable for the purpose of assigning contract line item numbers, based on the proposed definition of ''line item'' in FAR 2.101.

Response: Yes, a deliverable line item can be created for a contract milestone, but it is not required to be used for this purpose.

6. Existing Systems

Comment: One respondent challenged the background of the case ''funding traceability is limited to contract-level information'' by pointing out that NASA has systems in place that can capture financial data with great detail, including units and prices, descriptions, and accounting line information.

Response: This may be the case for some existing systems; however, not all Government systems have these capabilities.

Comment: One respondent pointed out that accounting information is already collected in Federal Procurement Data System—Next Generation (FPDS–NG) for appropriated funds, and questioned the need to gather more explicit accounting information that would burden contractors with tracking Government accounting lines.

Response: FPDS–NG captures data related to the preponderance of the spending on a contract, not details on contract line items. This rule does not require contractors to track any new information.

7. Delete Text (FAR 4.1003 & 4.1005(a)(4))

Comment: One respondent suggested removing the proposed text at FAR 4.1003(c) and 4.1005–1(a)(4), because contractors do not need to be informed of Government accounting information and because this information is already available to the Government in accounting and contract reporting systems.

Response: While some Government systems are capable of tracing accounting data to specific line items through other means, most of them are not. The recommended text is not removed from the final rule.

8. Exhibit Line Item

Comment: One respondent asked if the FAR Council plans to address exhibit lines and formally define them as part of the Governmentwide initiative for standardized line item structures.

Response: No, not at this time.

9. Acronyms

Comment: One respondent asked if the FAR Council intends to minimize the use of acronyms, specifically CLIN, SLIN, and ELIN.

Response: The FAR currently does not use SLIN or ELIN. The instances where the FAR uses CLIN were removed by this rule. Accordingly, there is no intent to address the use of these acronyms in this rule.

10. Defense Federal Acquisition Regulation Supplement (DFARS) Procedure, Guidance, and Information (PGI)

Comment: One respondent asked if there is a plan to incorporate the entire DFARS PGI in the FAR for Governmentwide use, beyond DoD.

Response: This is outside the scope of this rule.

C. Other Changes

1. The definition of ''line item'' is modified to clarify that this term is inclusive of subline items when it is applicable.

2. The term ''line item number'' is now defined to clarify that a line item may be identified in a numeric or alphanumeric format.

3. FAR 4.1003(c) and 4.1005–1(a)(4) are modified to note that multiple accounting classification citations can be provided on a single line item.

4. FAR 4.1004 is modified to clarify that the characteristics in 4.1003 apply to subline items that are deliverable but not informational subline items.

5. The requirement to include the national stock number or special item number at FAR 8.406–4(c)(3)(i)(C) is removed.

6. FAR 15.203(a)(2) is amended to clarify the process for allowing and evaluating proposals with alternative line item structures.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This final rule establishes uniform use of line items in Federal procurement. The uniform use of line items is designed to improve the accuracy, traceability, and usability of procurement data. This rule continues Federal procurement efforts to more robustly implement the objectives of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109–282), including promoting achievement of rigorous

accountability of procurement dollars and processes.

The requirements in this rule have the potential to have an impact on any entity, small or large, that does business with the Federal Government, because the rule would apply to purchases of items, including commercial items and commercially available off-the-shelf items, and purchases under the simplified acquisition threshold. However, line item pricing is a common commercial practice; therefore, the impact may not be significant.

None of the public comments addressed the initial regulatory flexibility analysis.

Any small business that contracts with a Federal agency could be impacted to at least some extent. Using data from the Federal Procurement Data System, there were 107,172 such small entities in fiscal year (FY) 2010, 97,626 in FY 2011, 85,749 in FY 2012, and 73,987 in FY 2013 doing business with the Federal Government.

The rule could require some contractors to restructure their proposal pricing process as well as their systems to accommodate the line item identification system. This change may also require contractors to make changes to their pricing and electronic systems. Contractors may also have to develop more extensive pricing data to conform to a new line item structure. However, this consistent line item identification policy should be beneficial to contractors doing business with executive branch agencies. This is especially true if contractors already have contracts with the Department of Defense (DoD), because these identification standards are already in use. Accordingly, contractors that currently contract with DoD will not be impacted. There is no data at this time on cost impacts to contractors in making this change.

The rule contains no reporting, recordkeeping, or other compliance requirements on the vendor community.

DoD, GSA, and NASA have not identified any significant alternatives to accomplish the stated objectives of this rule that would reduce impact on small entities.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 2, 3, 4, 5, 7, 8, 9, 12, 14, 15, 16, 17, 27, 32, 42, 48, 49, and 52

Government procurement.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 2, 3, 4, 5, 7, 8, 9, 12, 14, 15, 16, 17, 27, 32, 42, 48, 49, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 3, 4, 5, 7, 8, 9, 12, 14, 15, 16, 17, 27, 32, 42, 48, 49, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 2—DEFINITION OF WORDS AND TERMS

■ 2. Amend section 2.101 in paragraph (b)(2) by adding, in alphabetical order, the definitions ''Line item'', ''Line item number'', and ''Subline item'' to read as follows:

2.101 Definitions.

* * * * *

(b) * * *

(2) * * *

Line item means the basic structural element in a procurement instrument that describes and organizes the required product or service for pricing, delivery, inspection, acceptance, invoicing, and payment. The use of the term ''line item'' includes ''subline item,'' as applicable.

Line item number means either a numeric or alphanumeric format to identify a line item.

* * * * *

Subline item means a subset of a line item.

* * * * *

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

3.302 [Amended]

■ 3. Amend section 3.302 by removing the definition ''Line item''.

PART 4—ADMINISTRATIVE MATTERS

■ 4. Revise subpart 4.10 to read as follows:

Subpart 4.10—Uniform Use of Line Items

Sec.

4.1000 Scope.
4.1001 Policy.
4.1002 Applicability.
4.1003 Establishing line items.
4.1004 Establishing subline items.
4.1005 Data elements for line items and subline items.
4.1005–1 Required data elements.
4.1005–2 Exceptions.
4.1006 Modifications.
4.1007 Solicitation alternative line item proposal.
4.1008 Solicitation provision.

SUBPART 4.10—Uniform Use of Line Items

4.1000 Scope.

This subpart prescribes policies and procedures for assigning line items and subline items and their identifiers. However, in order to provide agencies with time to transition their information systems, agencies have until October 1, 2019, to apply the requirements of 4.1002 through 4.1008.

4.1001 Policy.

In order to improve the accuracy, traceability, and usability of procurement data, procurement instruments shall identify the supplies or services to be acquired as separately identified line items and, as needed, subline items.

(a) Line items are established to define deliverables or organize information about deliverables. Each line item describes characteristics for the item purchased, *e.g.,* pricing, delivery, and funding information.

(b) Each line item may be subdivided into separate unique subsets (called subline items) to ease administration. If a line item has deliverable subline items, the line item is informational. Subline items differentiate between or among certain characteristics of the line item, such as colors or sizes, dates of delivery, destinations, or places of performance. Subline items are established to define deliverables or organize information about deliverables.

4.1002 Applicability.

The policies of this subpart shall apply to the following procurement instruments, to include amendments, modifications, and change orders thereto:

(a) Solicitations.

(b) Contracts, including, but not limited to, Governmentwide acquisition contracts (GWACs), multi-agency contracts (MACs), Federal Supply Schedule (FSS) contracts, indefinite-delivery contracts, and purchase orders.

(c) Agreements that include pre-priced supplies or services.

(d) Task and delivery orders.

4.1003 Establishing line items.

Establish separate line items for deliverables that have the following characteristics except as provided at 4.1005–2:

(a) Separately identifiable.

(1) A supply is separately identifiable if it has its own identification (*e.g.,* national stock number (NSN), item

description, manufacturer's part number).

(2) Services are separately identifiable if they have no more than one statement of work or performance work statement.

(3) If the procurement instrument involves a first article (see subpart 9.3), establish a separate line item for each item requiring a separate approval. If the first article consists of a lot composed of a mixture of items that will be approved as a single lot, a single line item may be used.

(b) Single unit price or total price.

(c) Single accounting classification citation. A single deliverable may be funded by multiple accounting classifications when the deliverable effort cannot be otherwise subdivided.

(d) Separate delivery schedule, destination, period of performance, or place of performance.

(e) Single contract pricing type (*e.g.,* fixed-price or cost-reimbursement).

4.1004 Establishing subline items.

Subline items may be used to facilitate tracking of performance, deliverables, payment, and contract funds accounting or for other management purposes. Subline items may be either deliverable or informational. The list of characteristics at 4.1003 applies to deliverable subline items, but it is not applicable to informational subline items. A line item with subline items shall contain only that information that is common to all subline items thereunder. All subline items under one line item shall be the same contract type as the line item.

(a) *Deliverable subline items.* Deliverable subline items may be used for several related items that require separate identification. For example, instead of establishing multiple separate line items, subline items may be established for—

(1) Items that are basically the same, except for minor variations such as—

(i) Size or color;

(ii) Accounting classification, but see also 4.1005–1(a)(4); or

(iii) Date of delivery, destination, or period or place of performance;

(2) Separately priced collateral functions that relate to the primary product, such as packaging and handling, or transportation; or

(3) Items to be separately identified at the time of shipment or performance.

(b) *Informational subline items.* (1) Informational subline items may be used by agencies for administrative purposes. This type of subline item identifies information that relates directly to the line item and is an integral part of it (*e.g.,* parts of an assembly or parts of a kit).

(2) Position informational subline items within the line item description, not in the quantity or price fields.

4.1005 Data elements for line items and subline items.

4.1005–1 Required data elements.

(a) Except as provided in 4.1005–2, each line item or subline item shall include in the schedule (described at 12.303(b)(4), 14.201–2, or 15.204–2, or in a comparable section of the procurement instrument), at a minimum, the following information as separate, distinct data elements:

(1) Line item or subline item number established in accordance with agency procedures.

(2) Description of what is being purchased.

(3) Product or Service Code (PSC).

(4) Accounting classification citation.

(i) Line items or deliverable subline items. If multiple accounting classifications for a single deliverable apply, include the dollar amount for each accounting classification in the schedule (or a comparable section of the procurement instrument).

(ii) Informational subline items. An accounting classification citation is not required. (See 4.1004).

(5)(i) For fixed-price line items:

(A) Unit of measure.

(B) Quantity.

(C) Unit price.

(D) Total price.

(ii) For cost-reimbursement line items:

(A) Unit of measure.

(B) Quantity.

(C) Estimated cost.

(D) Fee (if any).

(E) Total estimated cost plus any fee.

(b) If a contract contains a combination of fixed-price, time-and-materials, labor-hour, or cost-reimbursable line items, identify the contract type for each line item in the schedule (or a comparable section of the procurement instrument) to facilitate payment.

(c) Each deliverable line item or deliverable subline item shall have its own delivery schedule, destination, period of performance, or place of performance expressly stated in the appropriate section of the procurement instrument (''as required'' constitutes an expressly stated delivery term). When a line item has deliverable subline items, the delivery schedule, destination, period of performance, or place of performance shall be identified at the subline item level, rather than the line item level.

(d) Terms and conditions in other sections of the contract (such as contract clauses or payment instructions) shall also specify applicability to individual line items if not applicable to the contract as a whole.

4.1005–2 Exceptions.

(a) *Indefinite-delivery contracts*—(1) *General.* The following required data elements are not known at time of issuance of an indefinite-delivery contract, but shall be provided in each order at the time of issuance: Accounting classification, delivery date and destination, or period and place of performance.

(2) *Indefinite-delivery indefinite-quantity (IDIQ) and requirements contracts.* IDIQ and requirements contracts may omit the quantity at the line item level for the base award provided that the total contract minimum and maximum, or the estimate, respectively, is stated.

(b) *Item description and PSC.* These data elements are not required in the line item if there are associated deliverable subline items that include the actual detailed identification. When this exception applies, use a general narrative description for the line item.

(c) *Single unit price or single total price.* The requirement for a single unit price or single total price at the line item level does not apply if any of the following conditions are present:

(1) There are associated deliverable subline items that are priced.

(2) The line item or subline item is not separately priced.

(3) The supplies or services are being acquired on a cost-reimbursement, time-and-materials, or labor-hour basis.

(4) The procurement instrument is for services and firm prices have been established for elements of the total price, but the actual number of the elements is not known until performance (*e.g.,* a labor-hour contract for maintenance/repair). The contracting officer may structure these procurement instruments to reflect a firm or estimated total amount for each line item.

4.1006 Modifications.

(a) When a new item (such as an increased quantity) is added to the procurement instrument, assign a new line item number.

(b) If the modification relates to existing line items, the modification shall refer to those items.

4.1007 Solicitation alternative line item proposal.

Solicitations should be structured to allow offerors to propose alternative line items (see 4.1008 and 52.212–1(e)). For example, when soliciting certain items using units of measure such as kit, set,

or lot, the offeror may not be able to group and deliver all items in a single shipment.

4.1008 Solicitation provision.

Insert the provision at 52.204–22, Alternative Line Item Proposal, in all solicitations.

PART 5—PUBLICIZING CONTRACT ACTIONS

5.207 [Amended]

■ 5. Amend section 5.207 by removing from paragraph (a)(13) the word ''Contract''.

PART 7—ACQUISITION PLANNING

■ 6. Amend section 7.105 by revising paragraph (b)(5)(iv) to read as follows:

7.105 Contents of written acquisition plans.

* * * * *

(b) * * *

(5) * * *

(iv) For each contract (and order) contemplated, discuss the strategy to transition to firm-fixed-price contracts to the maximum extent practicable. During the requirements development stage, consider structuring the contract requirements, *i.e.,* line items, in a manner that will permit some, if not all, of the requirements to be awarded on a firm-fixed-price basis, either in the current contract, future option years, or follow-on contracts. This will facilitate an easier transition to a firm-fixed-price contract, because a cost history will be developed for a recurring definitive requirement.

* * * * *

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

■ 7. Amend section 8.402 by revising paragraph (f)(3) to read as follows:

8.402 General.

* * * * *

(f) * * *

(3) The items are clearly labeled on the order as items not on the Federal Supply Schedule and they conform to the rules for numbering line items at subpart 4.10; and

* * * * *

■ 8. Amend section 8.404 by adding paragraph (j) to read as follows:

8.404 Use of Federal Supply Schedules.

* * * * *

(j) *Line items.* When placing orders or establishing BPAs, ordering activities shall reference the special item number and the corresponding line or subline item awarded (established per 4.1005) in the schedule. If an ordering activity contracting officer adds an item not on the Federal Supply Schedule in accordance with 8.402(f), establish a new line item in accordance with subpart 4.10.

■ 9. Amend section 8.406–1 by—

■ a. Redesignating paragraphs (d)(8) through (16) as paragraphs (d)(9) through (17), respectively; and

■ b. Adding a new paragraph (d)(8).

The addition reads as follows:

8.406–1 Order placement.

* * * * *

(d) * * *

(8) Line item or subline item.

* * * * *

■ 10. Amend section 8.406–4 by revising paragraph (c)(3)(i)(C) to read as follows:

8.406–4 Termination for cause.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(C) Line item number(s) and a brief description of the item(s).

* * * * *

PART 9—CONTRACTOR QUALIFICATIONS

9.307 [Amended]

■ 11. Amend section 9.307 by removing from third sentence of paragraph (b) ''contract line item number'' and adding ''line item number'' in its place.

PART 12—ACQUISITION OF COMMERCIAL ITEMS

12.303 [Amended]

■ 12. Amend section 12.303 by removing from paragraph (b)(3) the word ''contract''.

■ 13. Amend section 12.603 by revising paragraph (c)(2)(v) to read as follows:

12.603 Streamlined solicitation for commercial items.

* * * * *

(c) * * *

(2) * * *

(v) A list of line item number(s) and items, quantities, and units of measure (including option(s), if applicable).

* * * * *

PART 14—SEALED BIDDING

■ 14. Amend section 14.201—2 by revising the first sentence of paragraph (b) to read as follows:

14.201–2 Part I—The Schedule.

* * * * *

(b) * * * Include a brief description of the supplies or services; *e.g.,* line item number, national stock number/part number if applicable, title or name identifying the supplies or services, and quantities (see part 11). * * *

* * * * *

■ 15. Amend section 14.201–9 by revising paragraphs (b) introductory text and (b)(1) to read as follows:

14.201–9 Simplified contract format.

* * * * *

(b) *Contract schedule.* Include the following for each line item:

(1) Line item number.

* * * * *

PART 15—CONTRACTING BY NEGOTIATION

■ 16. Amend section 15.203 by revising paragraph (a)(2) to read as follows:

15.203 Requests for proposals.

(a) * * *

(2) Anticipated terms and conditions that will apply to the contract. The solicitation may authorize offerors to propose alternative terms and conditions. If the solicitation permits offerors to submit one or more additional proposals with alternative line items (see 52.204–22 or 52.212–1(e)), the evaluation approach should consider the potential impact of the alternative line items on other terms and conditions or the requirement (*e.g.,* place of performance or payment and funding requirements) (see 15.206);

* * * * *

■ 17. Amend section 15.404–1 by revising the second sentence of paragraph (g)(1) to read as follows:

15.404–1 Proposal analysis techniques.

* * * * *

(g) * * *

(1) * * * Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly over or understated as indicated by the application of cost or price analysis techniques. * * *

* * * * *

■ 18. Amend section 15.408 in Table 15–2 by—

■ a. Under the heading *I. General Instructions,* revising the first sentence of paragraph D. and removing from paragraph E. the word ''contract''; and

■ b. Under the heading *II. Cost Elements,* removing from the first sentence of paragraph A. the word ''contract''.

The revision reads as follows:

15.408 Solicitation provisions and contract clauses.

* * * * *

Table 15–2—Instructions for Submitting Cost/Price Proposals When Certified Cost or Pricing Data Are Required

* * * * *

I. General Instructions

* * * * *

D. You must show the relationship between line item prices and the total contract price. * * *

* * * * *

PART 16—TYPES OF CONTRACTS

16.203–4 [Amended]

■ 19. Amend section 16.203–4 by removing from paragraph (b)(4) ''contract line items'' and adding ''line items'' in its place.

■ 20. Amend section 16.505 by revising paragraph (a)(7)(iii) to read as follows:

16.505 Ordering.

(a) * * *

(7) * * *

(iii) For supplies and services, line item number, subline item number (if applicable), description, quantity, and unit price or estimated cost and fee (as applicable). The corresponding line item number and subline item number from the base contract shall also be included.

* * * * *

PART 17—SPECIAL CONTRACTING METHODS

17.106–1 [Amended]

■ 21. Amend section 17.106–1 by removing from the fifth sentence of paragraph (c)(1), ''Table 15–2, Formats for Submission of Line Items'' and adding ''Table 15–2, III. Formats for Submission of Line Item'' in its place.

17.203 [Amended]

■ 22. Amend section 17.203 by removing from paragraph (g)(2) ''contract line item'' and adding ''line item'' in its place.

17.208 [Amended]

■ 23. Amend section 17.208 by removing from paragraph (e) ''basic contract line item'' and adding ''line item'' in its place.

PART 27—PATENTS, DATA, AND COPYRIGHTS

27.406–1 [Amended]

■ 24. Amend section 27.406–1 by removing from the second sentence of paragraph (b) ''contract line items'' and adding ''line items'' in its place.

PART 32—CONTRACT FINANCING

32.903 [Amended]

■ 25. Amend section 32.903 by removing from paragraph (b) introductory text ''contract line item'' and adding ''line item'' in its place.

32.905 [Amended]

■ 26. Amend section 32.905 by removing from paragraph (b)(1)(iii) ''contract line item'' and adding ''line item'' in its place.

32.1004 [Amended]

■ 27. Amend section 32.1004 by removing from the introductory text and paragraph (a)(2)(v) ''contract line item'' and adding ''line item'' in their places (three times).

32.1110 [Amended]

■ 28. Amend section 32.1110 by removing from paragraph (f) ''contract line item'' and adding ''line item'' in its place.

PART 42—CONTRACT ADMINISTRATION AND AUDIT SERVICES

42.302 [Amended]

■ 29. Amend section 42.302 by removing from paragraph (b)(9) ''contract line item'' and adding ''line item'' in its place.

PART 48—VALUE ENGINEERING

48.104–2 [Amended]

■ 30. Amend section 48.104–2 by removing from paragraph (a)(4) ''contract line item'' and adding ''line item'' in its place.

PART 49—TERMINATION OF CONTRACTS

49.601–2 [Amended]

■ 31. Amend section 49.601–2 by removing from the introductory text of the Notice of Termination to Prime Contractors ''*items, etc.*'' and adding ''*line items, etc.*'' in its place.

49.603–2 [Amended]

■ 32. Amend section 49.603–2 by removing from paragraph (b)(1) ''(*i*) *item*'' and adding ''(*i*) *line item*'' in its place.

49.603–5 [Amended]

■ 33. Amend section 49.603–5 by removing from paragraph (b)(1) ''(*i*) *item*'' and adding ''(*i*) *line item*'' in its place.

49.603–7 [Amended]

■ 34. Amend section 49.603–7 by removing from paragraph (b)(1) ''(*i*) *item*'' and adding ''(*i*) *line item*'' in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 35. Add section 52.204–22 to read as follows:

52.204–22 Alternative Line Item Proposal.

As prescribed in 4.1008, insert the following provision:

Alternative Line Item Proposal (JAN 2017)

(a) The Government recognizes that the line items established in this solicitation may not conform to the Offeror's practices. Failure to correct these issues can result in difficulties in acceptance of deliverables and processing payments. Therefore, the Offeror is invited to propose alternative line items for which bids, proposals, or quotes are requested in this solicitation to ensure that the resulting contract is economically and administratively advantageous to the Government and the Offeror.

(b) The Offeror may submit one or more additional proposals with alternative line items, provided that alternative line items are consistent with subpart 4.10 of the Federal Acquisition Regulation. However, acceptance of an alternative proposal is a unilateral decision made solely at the discretion of the Government. Offers that do not comply with the line items specified in this solicitation may be determined to be nonresponsive or unacceptable.

(End of provision)

■ 36. Amend section 52.212–1 by revising the date of the provision and paragraph (e) to read as follows:

52.212–1 Instructions to Offerors—Commercial Items.

* * * * *

Instructions to Offerors—Commercial Items (JAN 2017)

* * * * *

(e) *Multiple offers.* Offerors are encouraged to submit multiple offers presenting alternative terms and conditions, including alternative line items (provided that the alternative line items are consistent with subpart 4.10 of the Federal Acquisition Regulation), or alternative commercial items for satisfying the requirements of this solicitation. Each offer submitted will be evaluated separately.

* * * * *

■ 37. Amend section 52.212–4 by—

■ a. Revising the date of the clause;

■ b. Removing from paragraph (g)(1)(iii) ''contract line item'' and adding ''line item'' in its place;

■ c. Removing from paragraph (i)(5)(i)(C) the word ''contract''; and

■ d. In Alternate I—

■ 1. Revising the date of Alternate I; and

■ 2. Removing from paragraph (i)(5)(i)(C) the word ''contract''.

The revisions read as follows:

52.212–4 Contract Terms and Conditions—Commercial Items.

* * * * *

Contract Terms and Conditions—Commercial Items (JAN 2017)

* * * * *

Alternate I (JAN 2017)* * *

* * * * *

■ 38. Amend section 52.212–5 by revising the date of the clause and paragraph (b)(55) to read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (JAN 2017)

* * * * *

(b) * * *

____(55) 52.232–30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

* * * * *

■ 39. Amend section 52.213–4 by revising the date of the clause and paragraph (a)(2)(iv) to read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other than Commercial Items (JAN 2017)

* * * * *

(a) * * *

(2) * * *

(iv) 52.232–25, Prompt Payment (JAN 2017)

* * * * *

■ 40. Amend section 52.214–21 in Alternate I by revising the date of the alternate and removing from paragraph (f) ''Contract line'' and adding ''Line'' in its place to read as follows:

52.214–21 Descriptive Literature.

* * * * *

Alternate I (JAN 2017)* * *

* * * * *

■ 41. Amend section 52.215–1 by revising the date of the provision and removing from the second sentence of paragraph (f)(8) the word ''contract'' to read as follows:

52.215–1 Instructions to Offerors—Competitive Acquisition.

* * * * *

Instructions to Offerors—Competitive Acquisition (JAN 2017)

* * * * *

■ 42. Amend section 52.216–4 by revising the date of the clause and removing from the second sentence of paragraph (c)(3) the word ''contract'' to read as follows:

52.216–4 Economic Price Adjustment—Labor and Material.

* * * * *

Economic Price Adjustment—Labor and Material (JAN 2017)

* * * * *

■ 43. Amend section 52.222–32 by revising the date of the clause and removing from the fourth sentence of paragraph (f)(2) ''contract line item'' and adding ''line item'' in its place'' to read as follows:

52.222–32 Construction Wage Rate Requirements—Price Adjustment (Actual Method).

* * * * *

Construction Wage Rate Requirements—Price Adjustment (Actual Method) (JAN 2017)

* * * * *

■ 44. Amend section 52.232–25 by—

■ a. Revising the date of the clause;

■ b. Removing from paragraph (a)(3)(iii) ''contract line item'' and adding ''line item'' in its place; and

■ c. Removing from paragraph (d)(1)(iii) ''contract line item'' and adding ''line item'' in its place.

The revision reads as follows:

52.232–25 Prompt Payment.

* * * * *

Prompt Payment (JAN 2017)

* * * * *

■ 45. Amend section 52.232–26 by—

■ a. Revising the section heading and the date of the clause;

■ b. Removing from paragraph (a)(2)(iii) ''contract line item'' and adding ''line item'' in its place; and

■ c. Removing from paragraph (c)(1)(iii) ''contract line item'' and adding ''line item'' in its place.

The revision reads as follows:

52.232–26 Prompt Payment for Fixed-Price Architect-Engineer Contracts.

* * * * *

Prompt Payment for Fixed-Price Architect-Engineer Contracts (JAN 2017)

* * * * *

■ 46. Amend section 52.232–27 by—

■ a. Revising the section heading and the date of the clause;

■ b. Removing from paragraph (a)(2)(iii) ''contract line item'' and adding ''line item'' in its place; and

■ c. Removing from paragraph (l)(1)(iii) ''contract line item'' and adding ''line item'' in its place.

The revision reads as follows:

52.232–27 Prompt Payment for Construction Contracts.

* * * * *

Prompt Payment for Construction Contracts (JAN 2017)

* * * * *

■ 47. Amend section 52.232–30 by—

■ a. Revising the date of the clause;

■ b. Removing from paragraph (b) introductory text ''contract line item'' and adding ''line item'' in its place;

■ c. Removing from paragraph (b)(1) ''contract line item'' and adding ''line item'' in their places (six times);

■ d. Removing from paragraph (b)(2) ''contract line item'' and adding ''line item'' in its place;

■ e. Removing from paragraph (b)(3) ''contract line item'' and adding ''line item'' in their places (three times);

■ f. Removing from paragraph (b)(4) ''contract line item'' and adding ''line item'' in its place;

■ g. Removing from paragraph (e) ''contract line item'' and adding ''line item'' in its place; and

■ h. Removing from paragraph (i)(4) ''contract line item'' and adding ''line item'' in its place;

The revision reads as follows:

52.232–30 Installment Payments for Commercial Items.

* * * * *

Installment Payments for Commercial Items (JAN 2017)

* * * * *

■ 48. Amend section 52.243–7 by revising the date of the clause and removing from paragraph (b)(5)(i) ''contract line items'' and adding ''line items'' in its place to read as follows:

52.243–7 Notification of Changes.

* * * * *

Notification of Changes (JAN 2017)

* * * * *

■ 49. Amend section 52.245–1 by revising the date of the clause and removing from paragraph (e)(3) ''contract line items'' and adding ''line items'' in its place to read as follows:

52.245–1 Government Property.

* * * * *

Government Property (JAN 2017)

* * * * *

■ 50. Amend section 52.247–60 by revising the date of the clause and adding a sentence to the end of paragraph (a)(1)(xi) to read as follows:

52.247–60 Guaranteed Shipping Characteristics.

* * * * *

Guaranteed Shipping Characteristics (JAN 2017)

(a) * * *

(1) * * *

(xi) * * *

Number of complete units (line item) to be shipped in carrier's equipment.

* * * * *

■ 51. Amend section 52.248–1 in Alternate II by revising the date of the alternate and removing from paragraph (a) ''contract line items'' and adding ''line items'' in its place to read as follows:

52.248–1 Value Engineering.

* * * * *

Alternate II (JAN 2017) * * *

* * * * *

[FR Doc. 2016–31495 Filed 1–12–17; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 13, and 19

[FAC 2005–95; FAR Case 2016–004; Item II; Docket No. 2016–0004, Sequence No. 1]

RIN 9000–AN18

Federal Acquisition Regulation; Acquisition Threshold for Special Emergency Procurement Authority

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 to raise the simplified acquisition threshold for special emergency procurement authority.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Camara Francis, Procurement Analyst, at 202–550–0935, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–95, FAR Case 2016–004.

SUPPLEMENTARY INFORMATION:

I. Background

DOD, GSA, and NASA published a proposed rule in the **Federal Register** at 81 FR 39882 on June 20, 2016, to implement section 816 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92). FAR 2.101, 13.003, 19.203, and 19.502–2 are being revised to increase the simplified acquisition threshold for special emergency procurement authority from $300,000 to $750,000 (within the United States) and from $1 million to $1.5 million (outside the United States). The rule would apply to acquisitions of supplies or services that, as determined by the head of the agency, are to be used to support a contingency operation or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack. Two respondents provided comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the comments in the development of the final rule. A discussion of the comments is provided.

A. Summary of Changes

There was no change made to the rule as a result of the comments received. There were no comments on the Initial Regulatory Flexibility Analysis.

B. Analysis of Public Comments

1. Small Business

Comment: The respondent identified that the proposed rule did not recognize that the automatic set-asides for small business would apply up to the threshold in paragraph (1)(ii) of the simplified acquisition threshold definition at FAR 2.101 in the case of an emergency acquisition in an outlying area as defined in FAR 2.101.

Response: The proposed rule did not address the issue of the outlying areas. While the comment is out of scope of this rule, the Councils will take the comment under consideration.

2. Increased Simplified Acquisition Threshold

Comment: The respondent opposes the increase in the special emergency procurement threshold, because increases to the acquisition threshold threaten to compromise the integrity of the Berry amendment, outsource critical portions of the domestic industrial base, and hurt American manufacturers.

Response: The Councils appreciate the comment and acknowledge the concern; however, the increase in the special emergency procurement threshold is statutory in nature.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This final rule implements section 816 of the National Authorization Act for Fiscal Year (FY) 2016, Public Law 114–92. Therefore, the FAR is revised to raise the simplified acquisition thresholds for special emergency procurement authority.

The objective of this final rule is to increase the simplified acquisition thresholds for special emergency procurement authority from $300,000 to $750,000 (within the United States) and $1 million to $1.5 million (outside the United States) for acquisitions of supplies or services that, as determined by the head of the agency, are to be used to support a contingency operation or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack.

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule.

There was no change made to the rule as a result of the comments received. There were no comments on the Regulatory Flexibility Analysis.

DoD, GSA, and NASA do not expect this final rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule raises the simplified acquisition threshold for special emergency procurements, an arena in which a smaller percentage of small businesses participate, as compared to larger businesses. Between $300,000 and the increase to $750,000, 188 total awards were made of which 45 or 24 percent were to small businesses in FY 2014, and 219 total awards were made of which 66 or 30 percent were to small businesses in FY

2015. Between $1 million and the increase to $1.5 million, 56 total awards were made of which 10 or 17 percent were to small businesses in FY 2014, and 29 total awards were made of which 9 or 31 percent were to small businesses in FY 2015.

The final rule imposes no reporting, recordkeeping, or other information collection requirements.

There are no known significant alternatives to the rule. The impact of this final rule on small business is not expected to be significant.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 2, 13, and 19

Government procurement.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 2, 13, and 19 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 13, and 19 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 2—DEFINITIONS WORDS AND TERMS

2.101 [Amended]

■ 2. Amend section 2.101, in paragraph (b)(2), in the definition ''Simplified acquisition threshold'' by removing from paragraphs (1)(i) and (ii) ''$300,000'' and ''$1 million'' and adding ''$750,000'' and ''$1.5 million'' in their places, respectively.

PART 13—SIMPLIFIED ACQUISITION PROCEDURES

13.003 [Amended]

■ 3. Amend section 13.003 by removing from paragraph (b)(1) ''$300,000'' and adding ''$750,000'' in its place.

PART 19—SMALL BUSINESS PROGRAMS

19.203 [Amended]

■ 4. Amend section 19.203 by removing from paragraph (b) ''$300,000'' and adding ''$750,000'' in its place.

19.502–2 [Amended]

■ 5. Amend section 19.502–2 by removing from paragraph (a) ''$300,000'' and adding ''$750,000'' in its place.

[FR Doc. 2016–31496 Filed 1–12–17; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 3, 4, and 52

[FAC 2005–95; FAR Case 2015–012; Item III; Docket No. 2015–0012, Sequence No. 1]

RIN 9000–AN04

Federal Acquisition Regulation; Contractor Employee Internal Confidentiality Agreements or Statements

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the Consolidated and Further Continuing Appropriations Act, 2015, that prohibits the use of funds, appropriated or otherwise made available, for a contract with an entity that requires employees or subcontractors to sign an internal confidentiality agreement that restricts such employees or subcontractors from lawfully reporting waste, fraud, or abuse to a designated Government representative authorized to receive such information.

DATES: *Effective:* January 19, 2017.

Applicability: This rule applies to all solicitations and contracts, using fiscal year 2015 or subsequent fiscal year funds that do not already contain a comparable provision/clause.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at 202–219–0202 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–95, FAR Case 2015–012.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 81 FR 3763 on January 22, 2016, to implement section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) (*i.e.,* section 743 of Division E of Pub. L. 114–113). Section 743 prohibits the use of funds appropriated or otherwise made available by Division E or any other Act for a contract, grant, or cooperative agreement with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

Four respondents submitted comments on the interim rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes From the Proposed Rule

The following significant changes are included in the final rule:

- Adds definitions of ''internal confidentiality agreement or statement,'' ''subcontract,'' and ''subcontractor'' (FAR 3.901, 52.203–18(a), and 52.203–19(a)).
- Clarifies that the representation applies to future internal confidentiality agreements or statements that restrict reporting of waste, fraud, or abuse related to the performance of a Government contract, and specifically cites the agency Office of the Inspector General as a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (FAR 3.909–2, 52.203–18(d), 52.203–19(b), and 52.212–3(s)(3)).

• Clarifies that the contractor is required to give notice only to current employees and subcontractors that any prohibitions and restrictions of any preexisting confidentiality agreements or statements covered by the clause are no longer in effect, to the extent that such prohibitions and restrictions are in conflict with the prohibitions of the clause (FAR 52.203–19(c)).

B. Analysis of Public Comments

1. General Support for the Rule

Comment: All respondents were in general support of the rule. For example, one respondent stated its support of the intent of section 743 and the proposed rule to provide appropriate protection for employees looking to report waste, fraud, or abuse.

Response: Noted.

2. Internal Confidentiality Agreement or Statement

Several respondents raised questions about the meaning of ''internal confidentiality agreements or statement'' and their scope.

Comment: One respondent questioned use of the term ''internal confidentiality agreement'' to apply to an agreement with a subcontractor, because ''internal'' would imply an agreement with employees of the company.

The respondent questioned how the rule applies to subcontractors and subcontracts and suggested that the application to subcontractors is only through flowdown, rather than direct application to the prime contractor.

Response: Notwithstanding the word ''internal,'' which would normally apply to inside the company, the statute specifically addresses the situation in which the contractor requires employees or subcontractors to sign internal confidentiality agreements or statements.

The clause does flow down to subcontracts, but it also prohibits the prime contractor from requiring subcontractors to sign internal confidentiality agreements or statements.

Comment: One respondent asked whether the rule covers confidentiality agreements arising out of civil litigation. The respondent also questioned whether it applies to confidentiality agreements that employees sign at the behest of a Federal agency.

Response: A definition of ''internal confidentiality agreement or statement'' has been added to the final rule. This definition excludes confidentiality agreements arising out of civil litigation or confidentiality agreements that contractor employees or subcontractors sign at the behest of a Federal agency.

3. Definitions of ''Entity,'' ''Employee,'' and ''Subcontractor''

a. ''Entity''

Comment: One respondent noted that the proposed rule did not define ''entity'' and sometimes used the term ''contractor'' or ''offeror'' in a manner that appears to be intended to mean ''entity.''

Response: The term ''entity'' is a well-known legal term, frequently used in the FAR with its standard dictionary meaning, and does not require further definition in the acquisition regulations. According to Black's Law Dictionary, ''entity'' is a generic term inclusive of a person, partnership, organization, or business, which can be legally bound, and is uniquely identifiable from any other entity. All offerors and contractors are entities, but not all entities are offerors or contractors. The statute prohibits making funds available to entities that require employees or subcontractors to sign certain confidentiality agreements or statements due to this prohibition. Therefore, it is very possible that such entities will not submit offers or be awarded contracts. The terms ''offeror'' and ''contractor'' are used when the rule is specifically addressing an entity that has submitted an offer or bid or an entity that has been awarded a contract.

b. ''Employee''

Comment: One respondent requested a definition of the term ''employee.'' The respondent suggested the term be defined to mean ''any officer, partner, employee, or agent of a prime contractor,'' consistent with the definition of ''prime contractor employee'' at FAR 3.502–1. The respondent noted that this definition would clarify that the term encompasses only current employees, reducing the burden of who would be covered for purposes of implementing the rule.

Response: The term ''employee'' is used throughout the FAR, generally without definition. The definition of ''prime contractor employee'' at FAR 3.502–1 was first included in the FAR in FAC 84–24 (February 6, 1987), to implement the Anti-Kickback Enforcement Act of 1986. According to the Senate Report 99–435, the statute added a definition of ''prime contractor employee'' to parallel the language of 41 U.S.C. 51, which prohibits payments to any prime contractor, or to any officer, partner, employee, or agent of a prime contractor. All of these separate terms were included in the expanded definition of ''prime contractor employee'' in order to cover all those persons that might be acting to benefit or on behalf of the prime contractor when participating in a kick-back scheme. In general usage, an ''officer'' is an employee, but a ''partner'' is a co-owner, not an employee. An ''agent'' also is not necessarily an employee and instead is frequently a subcontractor. More importantly, the difference between an employee and an independent contractor is not an issue in this rule, because the rule equally covers both employees and subcontractors (including consultants).

However, the rule has been modified at FAR 52.203–19(c) to specify that the contractor is only required to notify current employees and subcontractors.

c. ''Subcontractor''

Comment: Several respondents were concerned about limiting the meaning of the term subcontractor. One respondent stated that ''subcontractor'' should cover only current subcontractors that have fully executed subcontracts under which work is currently being performed. Both respondents commented that the subcontract should be directly in support of a Government contract. The respondents consider that it would be a substantial burden to cover subcontractors that they do business with commercially that do not operate under a Government contract (*e.g.,* cafeteria and lawn services).

Response: Definitions of ''subcontract'' and ''subcontractor'' have been added to the final rule to specify that the term ''subcontract'' applies to contracts entered into by a prime contractor or by a subcontractor ''to furnish supplies or services for performance of a prime contract or subcontract.'' ''Subcontractor'' means any supplier, distributor, vendor, or firm (including a consultant) that furnishes supplies or services to or for a prime contractor or another subcontractor.

As stated in the responses in section II.B.2.b. of this preamble, the rule has been modified at FAR 52.203–19(c) to specify that the contractor is only required to notify current employees and subcontractors.

4. Clarify Scope of Representation

Comment: One respondent was concerned that the rule as proposed could be construed in a manner broader than the stated policy for the proposed rule. The policy states that the proposed rule is intended to reduce waste, fraud, and abuse in all Federal acquisitions. The respondent recommended that the rule be clarified that it only addresses those agreements or statements involving the employees or contractors

directly performing work on a Federal contract.

Response: The definition of ''subcontractor'' limits the applicability of the rule to subcontracts under the Government contract. However, the statute focuses on reporting of waste, fraud, and abuse related to the performance of a Government contract. It is very possible that employees of the contractor not directly employed on the Government contract may have information to report relating to waste, fraud, or abuse on such contract. Therefore, the prohibition applies to all employees of the contractor, whether or not they are directly employed on the Government contract.

5. Timeframe of Representation

One respondent recommended that the representation be revised to provide for prospective applicability.

Retrospective representation would require offerors to locate and review all of its employee and subcontract agreements, which could be a time-consuming and costly task. The respondent recommended that the rule be revised to require offerors to represent that ''they have no such agreements in place with regard to current employees and current subcontracts used for performance of government contracts and it agrees that it will not enter into any new confidentiality agreements or statements that include prohibited limitations on reporting.''

Response: The rule does not require retrospective representation. It allows contractors to make a blanket notice of nonenforcement (FAR 52.203–19(b)). The respondent's proposed wording requiring contractors to represent they have no such agreements in place with current employees or subcontractors appears more burdensome that the current rule. However, the representation has been modified to accept the latter part of the recommendation, changing it to read that the offeror ''will not require its employees or subcontractors'' to sign such internal confidentiality agreements or statements.

6. Reporting

Comment: One respondent recommended that the FAR clause be modified so that the scope of the reporting is limited to waste, fraud, and abuse related to the execution of Government contracts.

Response: The final rule has been amended at FAR 3.909–2 to specify that the policy applies to the reporting of waste, fraud, or abuse related to the performance of a Government contract. The same change is also incorporated in the associated provision and clause.

Comment: Another respondent recommended that the rule should more precisely identify the ''designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.'' The respondent recommended that clarification would avoid creating a situation such as where the report is inadvertently made to the wrong agency, or to entities that have no responsibility for the procurement.

Response: The purpose of the quoted phrase is to eliminate protection for disclosures to unauthorized people. The final rule has been amended to add ''(*e.g.,* agency Office of the Inspector General)'' at the end of FAR 52.203–18(d) and 52.203–19(b).

Comment: One respondent was concerned that the proposed rule does not apply to disclosures made to Congress.

Response: Other statutes cover disclosures to Congress (see *e.g.,* the whistleblower rights at FAR 3.907 and 3.908). This statute does not address disclosure to Congress.

7. Notice Requirements

Comment: One respondent recommended that the preamble be amended to validate more flexible forms of notification, other than email, that could be selected by the contractor/offeror.

Response: The rule does not specify how the notification is to be made. The preamble to the proposed rule only used email as an example, stating that ''This notice could be accomplished through normal business communication channels, such as email.''

8. Protection of Controlled Unclassified Information

Comment: One respondent recommended that the rule should address the interplay with procedures for handling controlled unclassified information. An employee or subcontractor who wished to report fraud, waste, or abuse, should still be responsible for the proper protection and handling of controlled unclassified information. When an agency has a reason to limit the reporting of waste, fraud, or abuse to a limited chain of individuals, the rule should be revised to respect those limits.

Another respondent stated concern that the rule does not acknowledge that contractors have a legitimate interest in protecting their privileged and confidential information. The respondent recommended a change to the clauses to acknowledge the ability of contractors to protect this information.

Response: Information that is reported to the agency Office of the Inspector General is protected from further disclosure outside of the Government, respecting all markings on any data or confidential information that is received.

9. Safe Harbor

Comment: One respondent requested examples of or guidance about confidentiality agreements or statements that would help contractors comply. The respondent recommended that the rule should include definitive guidance as to language to be included in a confidentiality statement or agreement that would comply with the requirements of the statute. The respondent suggested the following:

''Neither the confidentiality provision contained in the _____ [insert title of agreement, statement, policy], nor confidentiality provisions contained in any existing employment or contract with _____ [insert name of contractor] shall be construed to prohibit or otherwise restrict you, as an employee or {sub}contractor of _____ [insert name of contractor] from lawfully reporting waste, fraud, or abuse to a designated investigative or law enforcement representative of a federal department or agency authorized to receive such information under the procurement.''

Response: Although the Councils do not consider it appropriate to prescribe specific language in the regulations, the language provided by the respondent is provided in full text in the preamble. The Councils concur that the sample contains appropriate language that could be included in an internal confidentiality agreement or statement, and could be tailored for use in the notice required by FAR 52.203–19(c).

10. Applicability to Contracts Valued at or Below the Simplified Acquisition Threshold (SAT) and for the Acquisition of Commercial Items

Comment: One respondent was pleased that the rule also applies to contracts and subcontracts for acquisitions in amounts not greater than the simplified acquisition threshold, and to contracts and subcontracts for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items.

Response: Noted.

Comment: Another respondent recommended that the rule be revised to exclude contracts for commercial items, including COTS items, and purchases

below the simplified acquisition threshold.

• This rule would interfere with customary commercial practices and may deter certain valued commercial vendors from participating in Government procedures.

• Nothing in the statute indicates that commercial items or purchases below the simplified acquisition threshold are a significant source of this type of waste, fraud, or abuse.

• Government should determine whether commercial item suppliers routinely enter into such restrictive confidentiality agreements with their employees and subcontractors.

• The conclusion that the burdens imposed by this rule are minimal does not acknowledge the due diligence and effort necessary before a contractor can accurately represent compliance. According to the respondent, contractors will be required to review current internal confidentiality agreements, identify any conflicts with the regulatory requirement, and modify or enter into new confidentiality agreements to the extent necessary to ensure compliance.

• At a minimum, the clause should not require flowdown to commercial item subcontractors.

Response: This is an appropriations act restriction on use of funds, passed by Congress to protect the Government's interests in preventing waste, fraud, and abuse on Federal contracts. The FAR signatories and the Administrator for Federal Procurement Policy have determined that it would not be in the best interest of the Government to waive applicability of this statute to acquisitions valued at or below the SAT and contracts and subcontracts for the acquisition of commercial items (including COTS items). In response to the specific comments of the respondent, the Government has no insight into when a contractor requires internal confidentiality agreements or statements from its employees and subcontractors. The concern that this rule will interfere with common commercial practice implies that it is common commercial practice to require internal confidentiality agreements or statements. Nothing in the statute indicates that acquisitions below the SAT and for the acquisition of commercial items are not a significant source of waste, fraud, and abuse. (See also section IV of this preamble.) Furthermore, the rule imposes far less burden than envisioned by the respondent (see response to the comments in section II.B.11. of this preamble.)

Although the preamble for the proposed rule stated the clear intent to flow the clause down to subcontracts for the acquisition of commercial items, the rule did not actually implement this flowdown. The final rule implemented the flowdown requirement by adding the FAR clause 52.203–19 to the lists at 52.212–5(e) and 52.244–6.

11. Implementation Burden

Comment: Several respondents commented that implementation of the proposed requirements would be immensely burdensome, without implementation of the recommended changes to limit scope and applicability. In particular, one respondent was especially concerned about the significant burden for contractors to track and trace all existing confidentiality agreements and statements, which may be freestanding or incorporated into other agreements. According to the respondent, an offeror would have to review each agreement and statement to determine whether it would be covered and compliant.

Response: There is no requirement to track and trace all existing internal confidentiality agreements and statements. That is the purpose of the notification at FAR 52.203–19(c), to override the prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by the clause that are in conflict with the new requirement.

12. Law Does Not Go Far Enough

Comment: One respondent was concerned that the law does not go far enough and should be expanded to—

• Eliminate ''nondisclosure agreements'' to hide any criminal activity, including but not limited to fraud, waste, and abuse;

• Be worldwide; and

• Not be limited to just businesses with Government contracts.

Response:

The final rule implements the requirements of the statute. The Councils note that—

• Certain crimes are covered by existing whistleblower statutes; see FAR 3.908–3 and 3.907;

• Agreements are covered worldwide, but only for agreements applying to disclosures made to U.S. Federal officials; and

• The FAR cannot cover businesses that do not have Government contracts.

C. Other Changes

The title of the FAR provision 52.203–18 and clause 52.203–19 were changed to include ''or Statements'' and the clause title was revised from ''Prohibition on Contracting with Entities that Require . . .'' to ''Prohibition on Requiring . . .'' (since the contract has already been awarded).

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf (COTS) Items

Based on determinations by the FAR signatories (DoD, GSA, and NASA) and the Administrator for Federal Procurement Policy, in accordance with 41 U.S.C. 1905, 1906, and 1907, this rule applies to all solicitations and resultant contracts that are funded with fiscal year (FY) 2015 funds or subsequent FY funds that are subject to the same prohibition on confidentiality agreements, including contracts and subcontracts for acquisitions in amounts not greater than the SAT, and contracts and subcontracts for the acquisition of commercial items, (including COTS items). This is an appropriations act restriction that prohibits use of funds appropriated or otherwise made available by Division E of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 112–235), or any other act, for a contract with an entity that requires employees or subcontractors to sign certain internal confidentiality agreements or statements. It is not in the best interest of the Federal Government to waive the applicability of section 743 to contracts and subcontracts in amounts not greater than the SAT, or for the acquisition of commercial items (including COTS items). In FY 2015, about 90 percent of all awards were below the SAT, and commercial procedures were used in more than 50 percent of all awards, so that excluding these awards from

application of the law would seriously weaken the impact of the law.

Because the emphasis of section 743 is to prohibit restrictions on the ability of employees and subcontractors to report waste, fraud, or abuse to appropriate Government authorities, it is not in the best interest of the Federal Government to waive the applicability of section 743 to contracts and subcontracts in amounts not greater than the SAT. The suggested exception would exclude a significant number of acquisitions and thereby further limit the number of contractor/subcontractor employees protected by section 743. Furthermore, this rule imposes a minimal burden on offerors and contractors, requiring only that offerors represent by submission of the offer that they will not require certain internal confidentiality agreements. Contractors only need to notify employees that the prohibition and restrictions of any preexisting internal confidentiality agreements covered by the clause, are no longer in effect to the extent that the restrictions are inconsistent with the prohibitions of the clause.

Therefore, contractors are not required to conduct an exhaustive and burdensome search of all preexisting agreements to conform to the rule.

V. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule implements section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and successor provisions in subsequent appropriations acts (and as extended in continuing resolutions). Section 743 prohibits the use of funds appropriated or otherwise made available by Division E or any other Act for a contract, grant, or cooperative agreement with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

The objective of the rule is to remove restrictions on the ability of employees and subcontractors to report waste, fraud, or abuse to the appropriate Government authorities.

The legal basis for the rule is the above-cited statute.

There were no public comments in response to the initial regulatory flexibility analysis.

This rule will apply to all small entities that receive Government contracts awarded using funds subject to the restriction of section 743, or successor provisions in subsequent appropriations acts with the same prohibition (and as extended in continuing resolutions). Based on FPDS data for FY 2014, this rule may affect up to 108,500 small entities per year (75,000 small entities receiving new awards, 33,500 modifications). However, it is doubtful that most small entities have any such prohibited internal confidentiality agreements with their employees and subcontractors.

There are no reporting or recordkeeping burdens associated with this rule and the other compliance requirements do not have significant impact, because the rule does not impose any significant burdens—it merely requires that contractors (1) not prohibit their employees and subcontractors from reporting fraud, waste, or abuse to appropriate Government authorities; and (2) notify employees previously subject to such agreements, that the prohibited sections of the agreements are no longer in effect (*e.g.,* an email to all affected employees).

The rule has no significant economic impact on small entities. DoD, GSA, and NASA did not identify any significant alternatives that would reduce the impact on small entities and still meet the objectives of the statute.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat. The Regulatory Secretariat has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 3, 4, and 52

Government procurement.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 3, 4, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 3, 4, and 52 continues to read as follows;

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTERESTS

■ 2. Amend section 3.900 by—

■ a. Removing from the introductory text ''three different'' and adding ''various'' in its place;

■ b. Redesignating paragraph (c) as paragraph (d); and

■ c. Adding a new paragraph (c).

The addition reads as follows:

3.900 Scope of subpart.

* * * * *

(c) Section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), implemented in 3.909, applicable to all agencies.

* * * * *

■ 3. Amend section 3.901 by adding, in alphabetical order, definitions for ''Internal confidentiality agreement or statement'', ''Subcontract'', and ''Subcontractor'' to read as follows:

3.901 Definitions.

* * * * *

Internal confidentiality agreement or statement means a confidentiality agreement or any other written statement that the contractor requires any of its employees or subcontractors to sign regarding nondisclosure of contractor information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that contractor employees or subcontractors sign at the behest of a Federal agency.

Subcontract means any contract as defined in subpart 2.1 entered into by a subcontractor to furnish supplies or services for performance of a prime contract or a subcontract. It includes but is not limited to purchase orders, and changes and modifications to purchase orders.

Subcontractor means any supplier, distributor, vendor, or firm (including a consultant) that furnishes supplies or services to or for a prime contractor or another subcontractor.

■ 4. Add sections 3.909, 3.909–1, 3.909–2, and 3.909–3 to read as follows:

3.909 Prohibition on providing funds to an entity that requires certain internal confidentiality agreements or statements.

3.909–1 Prohibition.

(a) The Government is prohibited from using fiscal year 2015 and subsequent fiscal year funds for a contract with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law

enforcement representative of a Federal department or agency authorized to receive such information. See section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions.)

(b) The prohibition in paragraph (a) of this section does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

3.909–2 Representation by the offeror.

(a) In order to be eligible for contract award, an offeror must represent that it will not require its employees or subcontractors to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.,* agency Office of the Inspector General). Any offeror that does not so represent is ineligible for award of a contract.

(b) The contracting officer may rely on an offeror's representation unless the contracting officer has reason to question the representation.

3.909–3 Solicitation provision and contract clause.

When using funding subject to the prohibitions in 3.909–1(a), the contracting officer shall—

(a)(1) Include the provision at 52.203–18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation, in all solicitations, except as provided in paragraph (a)(2) of this section; and

(2) Do not insert the provision in solicitations for a personal services contract with an individual if the services are to be performed entirely by the individual, rather than by an employee of the contractor or a subcontractor.

(b)(1) Include the clause at 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements, in all solicitations and resultant contracts, other than personal services contracts with individuals.

(2) Modify existing contracts, other than personal services contracts with individuals, to include the clause before obligating FY 2015 or subsequent FY funds that are subject to the same prohibition on internal confidentiality agreements or statements.

PART 4—ADMINISTRATIVE MATTERS

■ 5. Amend section 4.1202 by—

■ a. Redesignating paragraphs (a)(3) through (33) as paragraphs (a)(4) through (34), respectively;

■ b. Revising the heading and first sentence of the Note in newly redesignated paragraph (a)(22); and

■ c. Adding new paragraph (a)(3).

The addition and revision reads as follows:

4.1202 Solicitation provision and contract clause.

(a) * * *

(3) 52.203–18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation.

* * * * *

(22) * * *

Note to paragraph (a)(22): By a court order issued on October 24, 2016, this paragraph (a)(22) is enjoined indefinitely as of the date of the order.

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Add sections 52.203–18 and 52.203–19 to read as follows:

52.203–18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation.

As prescribed in 3.909–3(a), insert the following provision:

Prohibition on Contracting With Entities That Require Certain Internal Confidentiality Agreements or Statements—Representation (JAN 2017)

(a) *Definition.* As used in this provision—

Internal confidentiality agreement or statement, subcontract, and *subcontractor,* are defined in the clause at 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

(b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d) *Representation.* By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.,* agency Office of the Inspector General).

(End of provision)

52.203–19 Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

As prescribed in 3.909–3(b), insert the following clause:

Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017)

(a) *Definitions.* As used in this clause—

Internal confidentiality agreement or statement means a confidentiality agreement or any other written statement that the contractor requires any of its employees or subcontractors to sign regarding nondisclosure of contractor information, except that it does not include confidentiality agreements arising out of civil litigation or confidentiality agreements that contractor employees or subcontractors sign at the behest of a Federal agency.

Subcontract means any contract as defined in subpart 2.1 entered into by a subcontractor to furnish supplies or services for performance of a prime contract or a subcontract. It includes but is not limited to purchase orders, and changes and modifications to purchase orders.

Subcontractor means any supplier, distributor, vendor, or firm (including a consultant) that furnishes supplies or services to or for a prime contractor or another subcontractor.

(b) The Contractor shall not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement

representative of a Federal department or agency authorized to receive such information (*e.g.,* agency Office of the Inspector General).

(c) The Contractor shall notify current employees and subcontractors that prohibitions and restrictions of any preexisting internal confidentiality agreements or statements covered by this clause, to the extent that such prohibitions and restrictions are inconsistent with the prohibitions of this clause, are no longer in effect.

(d) The prohibition in paragraph (b) of this clause does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(e) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015, (Pub. L. 113–235), and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions) use of funds appropriated (or otherwise made available) is prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(f) The Contractor shall include the substance of this clause, including this paragraph (f), in subcontracts under such contracts.

(End of clause)

■ 7. Amend section 52.204–8 by—

■ a. Revising the date of the provision;

■ b. Redesignating paragraphs (c)(1)(iii) through (xxiv) as paragraphs (c)(1)(iv) through (xxv), respectively;

■ c. In the note to newly redesignated paragraph (c)(1)(xvi), remove ''paragraph (c)(1)(xv)'' and add ''paragraph (c)(1)(xvi)'' in its place; and

■ d. Adding a new paragraph (c)(1)(iii).

The revision and addition reads as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (JAN 2017)

* * * * *

(c)(1) * * *

(iii) 52.203–18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation. This provision applies to all solicitations.

* * * * *

■ 8. Amend section 52.212–3 by—

■ a. Revising the date of provision;

■ b. Removing from the introductory text of the provision ''through (t)'' and adding ''through (u)'' in its place;

■ c. Removing from paragraph (b)(2), in the bracketed paragraph, ''through (t)'' and adding ''through (u)'' in its place; and

■ d. Adding paragraph (u).

The revision and addition reads as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offeror Representations and Certifications—Commercial Items (JAN 2017)

* * * * *

(u)(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use appropriated (or otherwise made available) funds for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(2) The prohibition in paragraph (u)(1) of this provision does not contravene requirements applicable to Standard Form 312 (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(3) *Representation.* By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.,* agency Office of the Inspector General).

■ 9. Amend section 52.212–5 by—

■ a. Revising the date of clause;

■ b. Redesignating paragraphs (a)(1) through (3) as paragraphs (a)(2) through (4), respectively;

■ c. Adding a new paragraph (a)(1);

■ d. Redesignating paragraphs (e)(1)(ii) through (xxii) as (e)(1)(iii) through (xxiii), respectively;

■ e. In the note to newly redesignated paragraph (e)(1)(xvii), remove ''paragraph (e)(1)(xvi)'' and add ''paragraph (e)(1)(xvii)'' in its place; and

■ f. Adding a new paragraph (e)(1)(ii).

The revision and additions read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes of Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (JAN 2017)

* * * * *

(a) * * *

(1) 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

* * * * *

(e) * * *

(1) * * *

(ii) 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

* * * * *

■ 10. Amend section 52.213–4—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (a)(1)(i) through (vi) as (a)(1)(ii) through (vii), respectively;

■ c. Adding a new paragraph (a)(1)(i); and

■ d. Revising paragraph (a)(2)(viii).

The revisions and addition reads as follows:

52.213–4 Terms and Conditions-simplified Acquisitions (Other Than Commercial Items).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (JAN 2017)

(a) * * *

(1) * * *

(i) 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

* * * * *

(2) * * *

(viii) 52.244–6, Subcontracts for Commercial Items (JAN 2017).

* * * * *

■ 11. Amend section 52.244–6 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (c)(1)(iii) through (xix) as paragraphs (c)(1)(iv) through (c)(1)(xx);

■ c. In the note to newly redesignated paragraph (c)(1)(xiv), remove ''paragraph (c)(1)(xiii)'' and add ''paragraph (c)(1)(xiv)'' in its place; and

■ d. Adding a new paragraph (c)(1)(iii).

The revision and addition reads as follows:

52.244–6 Subcontracts for Commercial Items.

* * * * *

Subcontracts for Commercial Items (JAN 2017)

* * * * *

(c) * * *

(1) * * *

(iii) 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017).

* * * * *

[FR Doc. 2016–31497 Filed 1–12–17; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 5, 6, 18, 19 and 52

[FAC 2005–95; FAR Case 2012–022; Item IV; Docket No. 2012–0022, Sequence No. 1]

RIN 9000–AM68

Federal Acquisition Regulation; Contracts Under the Small Business Administration 8(a) Program

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement regulatory clarifications made by the Small Business Administration regarding the 8(a) program.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, at 703–605–2868, or by email at *mahruba.uddowla@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–95, FAR Case 2012–022.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 79 FR 6135 on February 3, 2014, soliciting public comments regarding the implementation of regulatory clarifications made by the Small Business Administration (SBA) under section 8(a) of the Small Business Act (15 U.S.C. 637(a)). The proposed rule provided additional guidance for the evaluation, offering, and acceptance process; procedures for releasing a requirement for non-8(a) procurement; and information on the effect exiting the 8(a) program will have on its current contractual obligations and the firm's ability to receive new 8(a) requirements. Six respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the comments in the development of the final rule. A discussion of the comments is provided.

A. Summary of Significant Changes

The final rule contains revisions to the language at FAR 19.804–6(a) to clarify that offers and acceptances are required for individual orders under multiple-award contracts that were not set aside for competition among 8(a) contractors. The final rule also revises the language at FAR 19.814(a) to indicate that the SBA Inspector General can request a formal size determination. In addition, the final rule revises the language at FAR 19.815 regarding the release of requirements from the 8(a) program. Language has been added to clarify that any follow-on 8(a) requirement shall remain in the 8(a) program unless there is a mandatory source for the requirement pursuant to FAR 8.002 or 8.003 or SBA agrees to release the requirement for procurement outside the 8(a) program.

B. Analysis of Public Comments

1. Support Proposed Changes

Comment: One respondent stated support for the changes made in the proposed rule.

Response: The Councils acknowledge receipt of this comment.

2. Potential Conflict With Other Statutorily Mandated Socioeconomic Programs

Comment: Two respondents expressed concern that the proposed language at FAR 19.815 appeared to be in conflict with other socioeconomic programs, such as the Javits-Wagner-O'Day (JWOD) Act (now codified at 41 U.S.C. chapter 85). The proposed rule at FAR section 19.815, Release for non-8(a) procurement, implies that the SBA Associate Administrator for Business Development will only consider releasing requirements from the 8(a) program when there are assurances that the requirement will be procured under another small business program. However, the proposed rule does not mention that another reason a requirement must be released is when it can be procured under a statutory authority other than the Small Business Act. For example, if the requirement has been placed on the Procurement List by the Committee for Purchase from People Who are Blind or Severely Disabled (AbilityOne), it must, by law, be procured under JWOD, using the procedures at FAR subpart 8.7. These respondents asked for further clarification of this point in the FAR.

Response: The purpose of FAR 19.815 is to clarify that the contracting officer must submit a formal request to the SBA Associate Administrator for the release of a requirement that is currently accepted into the 8(a) program, if he or she intends to procure the item from a non-8(a) source. It further clarifies the factors SBA will take into consideration when determining whether to release the requirement from the 8(a) program.

This clarification does not conflict or eliminate an agency's obligation to follow the procedures at FAR 8.002, Priorities for use of mandatory Government sources, and FAR 8.003, Use of other mandatory sources. As stated in these sections of the FAR, an agency may consider satisfying its requirement(s) through a commercial source, such as a small business, only after it has exhausted the possibility of fulfilling its requirement through one of the mandatory sources identified in FAR 8.002 or 8.003. However, new language has been added at FAR 19.815(a) and (b), to clarify that a requirement accepted into the 8(a) program shall remain in the 8(a) program unless the requirement can be satisfied through one of the mandatory sources listed at FAR 8.002 or 8.003 or the SBA Associate Administrator for Business Development agrees to release it.

3. The Rule Gives Preference to 8(a)Program Participants Over Other Small Businesses or Other Small Business Socioeconomic Programs

Comment: One respondent remarked that FAR 19.800(d) appears to give preferential treatment to 8(a) awards over other small business or other socioeconomic goals. FAR 19.800(d) of the proposed rule states the following: ''the contracting officer shall consider 8(a) set-asides or sole source awards before considering small business set-asides . . . .'' This respondent stated that each agency should have autonomy in achieving its own socioeconomic goals.

Response: The language in question already existed in the FAR as 19.800(e), but was renumbered as 19.800(d) by the proposed rule. The intent of the language at FAR 19.800(d) of the proposed rule is to further convey the policy established at FAR 19.203(c), *i.e.,* for acquisitions above the simplified acquisition threshold (SAT), the contracting officer shall first consider small business socioeconomic contracting programs, such as the HUBZone program, the service-disabled veteran-owned small business (SDVOSB) program, the women-owned small business program (WOSB), and the 8(a) program, before considering a small business set-aside, thus allowing agencies to independently tailor acquisition strategies based on their small business and small business socioeconomic goaling achievements. Similar language appears in FAR subparts 19.13, 19.14, and 19.15, though it is adapted to suit the specific socioeconomic program under discussion, *i.e.,* HUBZone, SDVOSB program, or the WOSB program. For further information on the socioeconomic parity rules within the small business programs, refer to the final rule for FAR case 2011–004, Socioeconomic Program Parity, published in the **Federal Register** at 77 FR 12930 on March 2, 2012.

4. Further Clarification of 8(a) Offer and Acceptance Procedures Is Needed

Comment: A respondent recommended that the language at FAR 19.804–3(c)(2), which discusses sole source awards where the contracting officer has not nominated a specific 8(a) participant, be amended to allow the contracting officer to have input in the selection process and the opportunity to concur with SBA's selection.

Response: The guidance provided in the FAR for ''open'' sole source requirements is consistent with SBA's regulations at 13 CFR part 124. In open sole source requirements, the agency provides input into the selection through its offering letter, including such criteria as the special capabilities or disciplines needed for contract performance. Concurrence with SBA's selection is evidenced by the contracting officer's signature on the tripartite agreement or, where SBA has delegated 8(a) contract execution functions to an agency, the contracting officer's signature on the contract award document.

Comment: One respondent requested additional guidance to clarify when the contracting office may assume SBA's acceptance of a requirement valued below the SAT that is not offered on behalf of a specific 8(a) participant. For acquisitions at or below the SAT, FAR 19.804–3(a)(2) states that the contracting office may assume SBA's acceptance has occurred within two working days when the offer was made on behalf of a specific 8(a) participant; however, the FAR is silent regarding when the contracting officer may assume SBA's acceptance of a requirement that was not offered on behalf of a specific 8(a) participant.

Response: Although the proposed rule contained minor editorial revisions in this paragraph, the basic guidance was not changed because it is consistent with SBA's regulations. In order for SBA to make the decision to accept an offer of a requirement into the 8(a) program, it must have reasonable assurance that an eligible 8(a) participant is available.

In the case of a sole source requirement at or below the SAT, when the contracting officer has identified a specific 8(a) participant, SBA will normally respond within two working days. This quick turnaround is attributed to the fact that SBA will usually accept the requirement on behalf of the 8(a) program in support of the specific participant nominated in the offering letter. However, when a contracting officer submits an open requirement to SBA, *i.e.,* does not identify a specific participant for the performance of the sole source requirement, the matching process is more complicated, and SBA will require variable amounts of time to pair the offered requirement with an 8(a) participant possessing the competencies needed for successful performance. For this reason, a definitive time frame for assuming SBA's acceptance of an open requirement below the SAT is not provided in the FAR.

5. Editorial Recommendations

Comment: One respondent recommended the inclusion of a definitions section, rather than defining all the terms at FAR 19.800(a). This respondent suggested that the new Definitions section should define the terms ''offering letter'' and ''competitive threshold.''

Response: The intent of the rule is to provide needed clarification of certain aspects of the 8(a) program relating to Federal procurement. In its present format, the definitions of certain terms such as ''offering letter'' and ''competitive threshold'' occur in the FAR section where the phrase is introduced and the primary discussion of these subjects takes place. For example, the meaning of the term ''offering letter'' is explained in FAR 19.804–2, Agency offering, which is the area where the subject matter is introduced and where the primary discussion of offering letters is located. Similarly, the discussion of ''competitive threshold'' occurs in two back-to-back sections of FAR subpart 19.8, where the term is defined and its primary discussion takes place.

Comment: One respondent stated that the language at FAR 19.816(a) pertaining to an 8(a) contractor's eligibility to receive contracts after exiting the 8(a) program requires further explanation, since it appears to conflict with FAR 19.804–6 as well as section 19.816(c). This respondent suggested that the verbiage ''except as provided in FAR 19.804–6 and paragraph 19.816(c) . . .'' be added to ensure these exceptions are made clear.

Response: FAR 19.816(a) has been revised to add ''[e]xcept as provided in 19.816(c) . . . .'' However, FAR 19.804–6 addresses different subject matter. FAR 19.804–6 discusses the conditions by which an 8(a) prime contractor may continue to accept new orders under its existing multiple-award, indefinite-delivery, indefinite-quantity contract. On the other hand, FAR 19.816 discusses the contractual obligations upon exiting the 8(a) program.

Comment: One respondent stated that the language at FAR 19.816(c) pertaining to a contractor's eligibility to receive contracts after exiting the program should be further clarified. Based on the assumption that an 8(a) contractor would necessarily have new North American Industry Classification System (NAICS) code applicability upon exiting the program, the respondent recommended that additional language be added to stipulate that the contractor must have been eligible for contract award in the specific NAICS code(s) identified in the contract on the initial date specified for receipt of offers.

Response: The recommended change is unnecessary since 8(a) program

eligibility is already addressed in FAR sections 19.802, 19.803, and 19.805 of the rule.

Comment: Two respondents suggested a few minor editorial changes.

Response: All suggested minor editorial changes have been incorporated.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This final rule amends the FAR to implement regulatory changes that SBA made to the 8(a) program. The final rule clarifies procedures and requirements used when agencies are contracting under the 8(a) Program. Among other issues, these changes include clarification of the evaluation, offering, and acceptance process; procedures for acquiring SBA's consent to procure an 8(a) requirement outside the 8(a) program; and the impact of exiting the 8(a) program in terms of the firm's ability to receive future 8(a) requirements and its current contractual commitments. These revisions do not place any new requirements, financial or otherwise, on small entities, and serve mainly to provide more explicit guidance to Federal contracting officials.

There were no significant issues raised by the public in response to the Initial Regulatory Flexibility Analysis provided in the proposed rule.

Currently, the 8(a) Program has approximately 6,885 active Participants, and of these, approximately 1,289 are owned by Native Americans. These entities may be economically impacted by the changes addressed in this final rule.

This rule does not impose any new information collection requirements on small businesses. The rule will have no direct negative impact on any small business concern, since it merely provides clarification of existing procedures and requirements used by agencies when contracting under the 8(a) Program.

There are no alternative approaches that will accomplish the stated objectives of the rule.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 5, 6, 18, 19 and 52.

Government procurement.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 5, 6, 18, 19 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 5, 6, 18, 19 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 5—PUBLICIZING CONTRACT ACTIONS

■ 2. Amend section 5.205 by revising paragraph (f) to read as follows:

5.205 Special situations.

* * * * *

(f) *Section 8(a) competitive acquisition.* When a national buy requirement is being considered for competitive acquisition limited to eligible 8(a) participants under subpart 19.8, the contracting officer must transmit a synopsis of the proposed contract action to the GPE. The synopsis may be transmitted to the GPE concurrent with submission of the agency offering (see 19.804–2) to the Small Business Administration (SBA). The synopsis should also include information—

(1) Advising that the acquisition is being offered for competition limited to eligible 8(a) participants;

(2) Specifying the North American Industry Classification System (NAICS) code;

(3) Advising that eligibility to participate may be restricted to 8(a) participants in either the developmental stage or the developmental and transitional stages; and

(4) Encouraging interested 8(a) participants to request a copy of the solicitation as expeditiously as possible since the solicitation will be issued without further notice upon SBA acceptance of the requirement for the section 8(a) program.

* * * * *

PART 6—COMPETITION REQUIREMENTS

■ 3. Revise section 6.204 to read as follows:

6.204 Section 8(a) competition.

(a) To fulfill statutory requirements relating to section 8(a) of the Small Business Act, as amended by Public Law 100–656, contracting officers may limit competition to eligible 8(a) participants (see subpart 19.8).

(b) No separate justification or determination and findings is required under this part to limit competition to eligible 8(a) participants. (But see 6.302–5 and 6.303–1 for sole source 8(a) awards over $22 million.)

PART 18—EMERGENCY ACQUISITIONS

18.114 [Amended]

■ 4. Amend section 18.114 by removing ''firms'' and adding ''participants'' in its place.

PART 19—SMALL BUSINESS PROGRAMS

19.000 [Amended]

■ 5. Amend section 19.000 by removing from paragraph (a)(3) ''business development''.

■ 6. Revise section 19.800 to read as follows:

19.800 General.

(a) Section 8(a) of the Small Business Act (15 U.S.C. 637(a)) established a program that authorizes the Small Business Administration (SBA) to enter into all types of contracts with other agencies and award subcontracts for performing those contracts to firms eligible for program participation. This program is the ''8(a) Business Development Program,'' commonly referred to as the ''8(a) program.'' A small business that is accepted into the 8(a) program is known as a ''participant.'' SBA's subcontractors are referred to as ''8(a) contractors.'' As used in this subpart, an 8(a) contractor is an 8(a) participant that is currently performing on a Federal contract or order that was set aside for 8(a) participants.

(b) Contracts may be awarded to the SBA for performance by eligible 8(a) participants on either a sole source or competitive basis.

(c) Acting under the authority of the program, the SBA certifies to an agency that SBA is competent and responsible to perform a specific contract. The contracting officer has the discretion to award the contract to the SBA based upon mutually agreeable terms and conditions.

(d) The contracting officer shall comply with 19.203 before deciding to offer an acquisition to a small business concern under the 8(a) program. For acquisitions above the simplified acquisition threshold, the contracting officer shall consider 8(a) set-asides or sole source awards before considering small business set-asides.

(e) When SBA has delegated its 8(a) program contract execution authority to an agency, the contracting officer must refer to its agency supplement or other policy directives for appropriate guidance.

■ 7. Revise section 19.802 to read as follows:

19.802 Determining eligibility for the 8(a) program.

Determining the eligibility of a small business to be a participant in the 8(a) program is the responsibility of the SBA. SBA's regulations on eligibility requirements for participation in the 8(a) program are found at 13 CFR 124.101 through 124.112.

■ 8. Revise section 19.803 to read as follows:

19.803 Selecting acquisitions for the 8(a) program.

Through their cooperative efforts, the SBA and an agency match the agency's requirements with the capabilities of 8(a) participants to establish a basis for the agency to contract with the SBA under the program. Selection is initiated in one of three ways:

(a) The SBA advises the contracting activity of an 8(a) participant's capabilities through a search letter and requests the contracting activity to identify acquisitions to support the participant's business plans. In these instances, the SBA will provide at a minimum the following information in order to enable the contracting activity to match an acquisition to the participant's capabilities:

(1) Identification of the participant and its owners.

(2) Background information on the participant, including any and all information pertaining to the participant's technical ability and capacity to perform.

(3) The participant's present production capacity and related facilities.

(4) The extent to which contracting assistance is needed in the present and the future, described in terms that will enable the agency to relate the participant's plans to present and future agency requirements.

(5) If construction is involved, the request shall also include the following:

(i) A participant's capabilities in and qualifications for accomplishing various categories of construction work typically found in North American Industrial Category System subsector 236 (construction of buildings), subsector 237 (heavy and civil engineering construction), or subsector 238 (specialty trade contractors).

(ii) The participant's capacity in each construction category in terms of estimated dollar value (*e.g.,* electrical, up to $100,000).

(b) The SBA identifies a specific requirement for one or more 8(a) participant(s) and sends a requirements letter to the agency's Office of Small and Disadvantaged Business Utilization, or for the Department of Defense, Office of Small Business Programs, requesting the contracting office offer the acquisition to the 8(a) program. In these instances, in addition to the information in paragraph (a) of this section, the SBA will provide—

(1) A clear identification of the acquisition sought; *e.g.,* project name or number;

(2) A statement as to how the required equipment and real property will be provided in order to ensure that the participant will be fully capable of satisfying the agency's requirements;

(3) If construction, information as to the bonding capability of the participant(s); and

(4) Either—

(i) If a sole source request—

(A) The reasons why the participant is considered suitable for this particular acquisition; *e.g.,* previous contracts for the same or similar supply or service; and

(B) A statement that the participant is eligible in terms of its small business size status relative to the assigned NAICS code, business support levels, and business activity targets; or

(ii) If competitive, a statement that at least two 8(a) participants are considered capable of satisfying the agency's requirements and a statement that the participants are also eligible in terms of their small business size status relative to the assigned NAICS code, business support levels, and business activity targets. If requested by the contracting office, SBA will identify at least two such participants and provide information concerning the participants' capabilities.

(c) Agencies may also review other proposed acquisitions for the purpose of identifying requirements which may be offered to the SBA. Where agencies independently, or through the self marketing efforts of an 8(a) participant, identify a requirement for the 8(a) program, they may offer on behalf of a specific 8(a) participant, for the 8(a) program in general, or for 8(a) competition.

■ 9. Revise section 19.804–1 to read as follows:

19.804–1 Agency evaluation.

In determining the extent to which a requirement should be offered in support of the 8(a) program, the agency should evaluate—

(a) Current and future plans to acquire the specific items or work that 8(a) participants are seeking to provide, identified in terms of—

(1) Estimated quantities of the supplies or services required or the estimated number of construction projects planned; and

(2) Performance or delivery requirements, including—

(i) Required monthly production rates, when applicable; and

(ii) For construction, the geographical location where work is to be performed;

(b) The impact of any delay in delivery;

(c) Whether the items or work have previously been acquired using small business set-asides, and the date the items or work were acquired;

(d) Problems encountered in previous acquisitions of the items or work from the 8(a) participants or other contractors; and

(e) Any other pertinent information about known 8(a) participants, the items, or the work. This includes any information concerning the participants' products or capabilities. When necessary, the contracting agency shall make an independent review of the factors in 19.803(a) and other aspects of the participants' capabilities which would ensure the satisfactory performance of the requirement being considered for commitment to the 8(a) program.

■ 10. Amend section 19.804–2 by—

■ a. Revising paragraphs (a) introductory text and (a)(10);

■ b. Redesignating paragraphs (a)(12) through (15) as paragraphs (a)(13) through (16), respectively;

■ c. Adding a new paragraph (a)(12);

■ d. Removing from the newly redesignated paragraph (a)(13)

''Program'' and adding ''program'' in its place;

■ e. Removing from paragraph (b)(3) ''firm'' and adding ''8(a) participant'' in its place (twice).

The revisions and addition read as follows:

19.804–2 Agency offering.

(a) After completing its evaluation, the contracting office shall notify the SBA of the extent of its plans to place 8(a) contracts with the SBA for specific quantities of items or work. The notification, referred to as an offering letter, shall identify the time frames within which resulting 8(a) awards must be completed in order for the agency to meet its responsibilities. The offering letter shall also contain the following information applicable to each prospective contract:

* * * * *

(10) Identification of any particular 8(a) participant designated for consideration, including a brief justification, such as—

(i) The 8(a) participant, through its own efforts, marketed the requirement and caused it to be reserved for the 8(a) program; or

(ii) The acquisition is a follow-on or renewal contract and the nominated 8(a) participant is the incumbent.

* * * * *

(12) Identification of all 8(a) participants which have expressed an interest in being considered for the acquisition.

* * * * *

■ 11. Revise section 19.804–3 to read as follows:

19.804–3 SBA acceptance.

(a) Upon receipt of the contracting office's offering letter, SBA will determine whether to accept the requirement for the 8(a) program. SBA's decision whether to accept the requirement will be transmitted to the contracting office in writing within 10 working days of receipt of the offer if the contract is likely to exceed the simplified acquisition threshold and within two working days of receipt if the contract is at or below the simplified acquisition threshold. The contracting office may grant an extension of these time periods, if requested by SBA.

(1) For acquisitions exceeding the simplified acquisition threshold, if SBA does not respond to an offering letter within ten working days, the contracting office may seek SBA's acceptance through the Associate Administrator for Business Development. The contracting office may assume that SBA has accepted the requirement into the 8(a) program if it does not receive a reply from the Associate Administrator for Business Development within five calendar days of receipt of the contracting office's request.

(2) For acquisitions not exceeding the simplified acquisition threshold, when the contracting office makes an offer to the 8(a) program on behalf of a specific 8(a) participant and does not receive a reply to its offering letter within two working days, the contracting office may assume the offer is accepted and proceed with award of an 8(a) contract.

(b) As part of the acceptance process, SBA will review the appropriateness of the NAICS code designation assigned to the requirement by the contracting officer.

(1) SBA will not challenge the NAICS code assigned to the requirement by the contracting officer if it is reasonable, even though other NAICS codes may also be reasonable.

(2) If SBA and the contracting officer are unable to agree on a NAICS code designation for the requirement, SBA may refuse to accept the requirement for the 8(a) program, appeal the contracting officer's determination to the head of the agency pursuant to 19.810, or appeal the NAICS code designation to the SBA Office of Hearings and Appeals under subpart C of 13 CFR part 134.

(c) *Sole source 8(a) awards.* If an appropriate match exists, SBA will advise the contracting officer whether it will participate in contract negotiations or whether SBA will authorize the contracting officer to negotiate directly with the identified 8(a) participant. Where SBA has delegated its contract execution functions to a contracting agency, SBA will also identify that delegation in its acceptance letter.

(1) *Sole source award where the contracting officer nominates a specific 8(a) participant.* SBA will determine whether an appropriate match exists where the contracting officer identifies a particular participant for a sole source award.

(i) Once SBA determines that a procurement is suitable to be accepted as an 8(a) sole source contract, SBA will normally accept it on behalf of the 8(a) participant recommended by the contracting officer, provided that the 8(a) participant complies with the requirements of 13 CFR 124.503(c)(1).

(ii) If an appropriate match does not exist, SBA will notify the 8(a) participant and the contracting officer, and may then nominate an alternate 8(a) participant.

(2) *Sole source award where the contracting officer does not nominate a specific 8(a) participant.* When a contracting officer does not nominate an 8(a) participant for performance of a sole source 8(a) contract, SBA will select an 8(a) participant for possible award from among two or more eligible and qualified 8(a) participants. The selection will be based upon relevant factors, including business development needs, compliance with competitive business mix requirements (if applicable), financial condition, management ability, technical capability, and whether award will promote the equitable distribution of 8(a) contracts. (For construction requirements see 13 CFR 124.503(d)(1)).

■ 12. Amend section 19.804–4—

■ a. Removing from the introductory text ''Program'' and adding ''program'' in its place;

■ b. Revising paragraph (b); and

■ c. Removing from paragraph (d) ''Program'' and adding ''program'' in its place.

The revision reads as follows:

19.804–4 Repetitive acquisitions.

* * * * *

(b) A nominated 8(a) participant's eligibility, and whether or not it is the same 8(a) participant that performed the previous contract;

* * * * *

■ 13. Amend section 19.804–5 by revising paragraphs (a) and (c) to read as follows:

19.804–5 Basic ordering agreements.

(a) The contracting office shall submit an offering letter for, and SBA must accept, each order under a basic ordering agreement (BOA) in addition to the agency offering and SBA accepting the BOA itself.

* * * * *

(c) Once an 8(a) participant's program term expires, the participant otherwise exits the 8(a) program, or becomes other than small for the NAICS code assigned under the BOA, SBA will not accept new orders for the participant.

■ 14. Revise section 19.804–6 to read as follows:

19.804–6 Indefinite-delivery contracts.

(a) Separate offers and acceptances are not required for individual orders under multiple-award contracts (including the Federal Supply Schedules managed by GSA, multi-agency contracts or Governmentwide acquisition contracts, or indefinite-delivery, indefinite-quantity (IDIQ) contracts) that have been set aside for exclusive competition among 8(a) contractors. SBA's acceptance of the original contract is valid for the term of the contract. Offers and acceptances are required for individual orders under multiple-award

contracts that have not been set aside for exclusive competition among 8(a) contractors.

(b) An 8(a) contractor may continue to accept new orders under the contract, even if it exits the 8(a) program, or becomes other than small for the NAICS code assigned to the contract.

(c) Agencies may continue to take credit toward their prime contracting small disadvantaged business or small business goals for orders awarded to 8(a) participants, even after the contractor's 8(a) program term expires, the contractor otherwise exits the 8(a) program, or the contractor becomes other than small for the NAICS code assigned under the 8(a) contract. However, if an 8(a) contractor rerepresents that it is other than small for the NAICS code assigned under the contract in accordance with 19.301–2 or, where ownership or control of the 8(a) contractor has changed and SBA has granted a waiver to allow the contractor to continue performance (see 13 CFR 124.515), the agency may not credit any subsequent orders awarded to the contractor towards its small disadvantaged business or small business goals.

■ 15. Amend section 19.805–1 by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing from paragraph (a)(1) ''firms'' and adding ''participants'' in its place;

■ c. Revising paragraph (b) introductory text;

■ d. Removing from paragraph (b)(1) ''firms'' and adding ''participants'' in its place; and

■ e. Revising paragraph (d).

The revisions read as follows:

19.805–1 General.

(a) Except as provided in paragraph (b) of this section, an acquisition offered to the SBA under the 8(a) program shall be awarded on the basis of competition limited to eligible 8(a) participants when—

* * * * *

(b) Where an acquisition exceeds the competitive threshold (see paragraph (a)(2) of this section), the SBA may accept the requirement for a sole source 8(a) award if—

* * * * *

(d) The SBA Associate Administrator for Business Development may approve a contracting office's request for a competitive 8(a) award below the competitive thresholds. Such requests will be approved only on a limited basis and will be primarily granted where technical competitions are appropriate or where a large number of responsible 8(a) participants are available for competition. In determining whether a request to compete below the threshold will be approved, the SBA Associate Administrator for Business Development will, in part, consider the extent to which the contracting activity is supporting the 8(a) program on a noncompetitive basis. The agency may include recommendations for competition below the threshold in the offering letter or by separate correspondence to the SBA Associate Administrator for Business Development.

■ 16. Revise section 19.805–2 to read as follows:

19.805–2 Procedures.

(a) Offers shall be solicited from those sources identified in accordance with 19.804–3.

(b) The SBA will determine the eligibility of the participants for award of the contract. Eligibility will be determined by the SBA as of the time of submission of initial offers which include price. Eligibility is based on Section 8(a) program criteria. An 8(a) participant must represent that it is a small business in accordance with the size standard corresponding to the NAICS code assigned to the contract.

(1) In either negotiated or sealed bid competitive 8(a) acquisitions SBA will determine the eligibility of the apparent successful offeror and advise the contracting office within 5 working days after receipt of the contracting office's request for an eligibility determination.

(i) If SBA determines that the apparent successful offeror is ineligible, the contracting office will then send to SBA the identity of the next highest evaluated offeror for an eligibility determination. The process is repeated until SBA determines that an identified offeror is eligible for award.

(ii) If the contracting officer believes that the apparent successful offeror (or the offeror SBA has determined eligible for award) is not responsible to perform the contract, the contracting officer must refer the matter to SBA for Certificate of Competency consideration under subpart 19.6.

(2) In any case in which an 8(a) participant is determined to be ineligible, SBA will notify the 8(a) participant of that determination.

(c) Any party with information questioning the eligibility of an 8(a) participant to continue participation in the 8(a) program or for the purposes of a specific 8(a) award may submit such information to the SBA in accordance with 13 CFR 124.112(c).

■ 17. Amend section 19.808–1 by removing from paragraph (c) ''activity'' and ''contractor'' and adding ''officer'' and ''participant'' in their places, respectively, and adding paragraphs (d) and (e) to read as follows:

19.808–1 Sole source.

* * * * *

(d) An 8(a) participant must represent that it is a small business in accordance with the size standard corresponding to the NAICS code assigned to the contract.

(e) An 8(a) participant owned by an Alaska Native Corporation, Indian Tribe, Native Hawaiian Organization, or Community Development Corporation may not receive an 8(a) sole source award that is a follow-on contract to an 8(a) contract, if the predecessor contract was performed by another 8(a) participant (or former 8(a) participant) owned by the same Alaska Native Corporation, Indian Tribe, Native Hawaiian Organization, or Community Development Corporation (See 13 CFR 124.109 through 124.111).

■ 18. Revise section 19.808–2 to read as follows.

19.808–2 Competitive.

In competitive 8(a) acquisitions subject to part 15, the contracting officer conducts negotiations directly with the competing 8(a) participants. Conducting competitive negotiations among 8(a) participants prior to SBA's formal acceptance of the acquisition for the 8(a) program may be grounds for SBA's not accepting the acquisition for the 8(a) program.

■ 19. Revise section 19.809 to read as follows.

19.809 Preaward considerations.

The contracting officer should request a preaward survey of the 8(a) participant whenever considered useful. If the results of the preaward survey or other information available to the contracting officer raise substantial doubt as to the participant's ability to perform, the contracting officer must refer the matter to SBA for Certificate of Competency consideration under subpart 19.6.

■ 20. Amend section 19.810 by—

■ a. Removing from paragraph (a)(2) ''firm'' and ''Program'' and adding ''participant'' and ''program'' in their places, respectively;

■ b. Removing from paragraph (a)(3) ''activity's'' and adding ''officer's'' in its place;

■ c. Revising paragraph (b); and

■ d. Removing from paragraph (c) ''firm'' and adding ''participant'' in its place.

The revision reads as follows:

19.810 SBA appeals.

* * * * *

(b)(1) Notification by SBA of an intent to appeal to the agency head—

(i) Must be received by the contracting officer within 5 working days after SBA is formally notified of the contracting officer's decision; and

(ii) Must be provided to the contracting agency Director for Small and Disadvantaged Business Utilization or, for the Department of Defense, the Director of Small Business Programs.

(2) SBA must send the written appeal to the agency head within 15 working days of SBA's notification of intent to appeal or the appeal may be considered withdrawn. Pending issuance of a decision by the agency head, the contracting officer shall suspend action on the acquisition. The contracting officer need not suspend action on the acquisition if the contracting officer makes a written determination that urgent and compelling circumstances that significantly affect the interests of the United States will not permit waiting for a decision.

* * * * *

■ 21. Amend section 19.811–1 by revising paragraph (b) introductory text to read as follows:

19.811–1 Sole source.

* * * * *

(b) The contracting officer shall prepare the contract that the SBA will award to the 8(a) participant in accordance with agency procedures, as if awarding the contract directly to the 8(a) participant, except for the following:

* * * * *

19.811–3 [Amended]

■ 22. Amend section 19.811–3 by—

■ a. Removing from paragraph (d) introductory text ''Concerns'' and adding ''Participants'' in its place; and

■ b. Removing from paragraphs (d)(1) and (e) ''concerns'' and adding ''participants'' in its place, respectively.

■ 23. Amend section 19.812 by removing from paragraph (b) ''firm'' and adding ''8(a) contractor'' in its place and revising paragraph (d) to read as follows:

19.812 Contract administration.

* * * * *

(d) An 8(a) contract, whether in the base or an option year, must be terminated for convenience if the 8(a) contractor to which it was awarded transfers ownership or control of the firm or if the contract is transferred or novated for any reason to another firm, unless the Administrator of the SBA waives the requirement for contract termination (13 CFR 124.515). The Administrator may waive the termination requirement only if certain conditions exist. Moreover, a waiver of the requirement for termination is permitted only if the 8(a) contractor's request for waiver is made to the SBA prior to the actual relinquishment of ownership or control, except in the case of death or incapacity where the waiver must be submitted within 60 calendar days after such an occurrence. The clauses in the contract entitled ''Special 8(a) Contract Conditions'' and ''Special 8(a) Subcontract Conditions'' require the SBA and the 8(a) subcontractor to notify the contracting officer when ownership of the firm is being transferred. When the contracting officer receives information that an 8(a) contractor is planning to transfer ownership or control to another firm, the contracting officer shall take action immediately to preserve the option of waiving the termination requirement. The contracting officer shall determine the timing of the proposed transfer and its effect on contract performance and mission support. If the contracting officer determines that the SBA does not intend to waive the termination requirement, and termination of the contract would severely impair attainment of the agency's program objectives or mission, the contracting officer shall immediately notify the SBA in writing that the agency is requesting a waiver. Within 15 business days thereafter, or such longer period as agreed to by the agency and the SBA, the agency head must either confirm or withdraw the request for waiver. Unless a waiver is approved by the SBA, the contracting officer must terminate the contract for convenience upon receipt of a written request by the SBA. This requirement for a convenience termination does not affect the Government's right to terminate for default if the cause for termination of an 8(a) contract is other than the transfer of ownership or control.

■ 24. Add sections 19.813 through 19.816 to read as follows:

Sec.

19.813 Protesting an 8(a) participant's eligibility or size status.
19.814 Requesting a formal size determination (8(a) sole source requirements).
19.815 Release for non-8(a) procurement.
19.816 Exiting the 8(a) program.
19.813 Protesting an 8(a) participant's eligibility or size status.

(a) The eligibility of an 8(a) participant for a sole source or competitive 8(a) requirement may not be challenged by another 8(a) participant or any other party, either to SBA or any administrative forum as part of a bid or other contract protest (see 13 CFR 124.517).

(b) The size status of an 8(a) participant nominated for an 8(a) sole source contract may not be protested by another 8(a) participant or any other party.

(c) The size status of the apparent successful offeror for competitive 8(a) awards may be protested. The filing of a size status protest is limited to—

(1) Any offeror whom the contracting officer has not eliminated for reasons unrelated to size;

(2) The contracting officer; or

(3) The SBA District Director in either the district office serving the geographical area in which the contracting activity is located or the district office that services the apparent successful offeror, or the Associate Administrator for Business Development.

(d) Protests of competitive 8(a) awards shall follow the procedures at 19.302. For additional information, refer to 13 CFR 121.1001.

19.814 Requesting a formal size determination (8(a) sole source requirements).

(a) If the size status of an 8(a) participant nominated for award of an 8(a) sole source contract is called into question, a request for a formal size determination may be submitted to SBA pursuant to 13 CFR 121.1001(b)(2)(ii) by—

(1) The 8(a) participant nominated for award of the particular sole source contract;

(2) The contracting officer who has been delegated SBA's 8(a) contract execution functions, where applicable, or the SBA program official with authority to execute the 8(a) contract;

(3) The SBA District Director in the district office that services the 8(a) participant or the Associate Administrator for Business Development; or

(4) The SBA Inspector General.

(b) SBA's Government Contracting Area Director will issue a formal size determination within 15 business days, if possible, after SBA receives the request for a formal size determination.

(c) An appeal of an SBA size determination shall follow the procedures at 19.302.

19.815 Release for non-8(a) procurement.

(a) Once a requirement has been accepted by SBA into the 8(a) program, any follow-on requirements shall remain in the 8(a) program unless there is a mandatory source (see 8.002 or

8.003) or SBA agrees to release the requirement from the 8(a) program in accordance with 13 CFR 124.504(d).

(b) To obtain release of a requirement for a non-8(a) procurement (other than a mandatory source listed at 8.002 or 8.003), the contracting officer shall make a written request to, and receive concurrence from, the SBA Associate Administrator for Business Development.

(c)(1) The written request to the SBA Associate Administrator for Business Development shall indicate—

(i) Whether the agency has achieved its small disadvantaged business goal;

(ii) Whether the agency has achieved its HUBZone, SDVOSB, WOSB, or small business goal(s); and

(iii) Whether the requirement is critical to the business development of the 8(a) contractor that is currently performing the requirement.

(2) Generally, a requirement that was previously accepted into the 8(a) program will only be released for procurements outside the 8(a) program when the contracting activity agency agrees to set aside the requirement under the small business, HUBZone, SDVOSB, or WOSB programs.

(3) The requirement that a follow-on procurement must be released from the 8(a) program in order for it to be fulfilled outside the 8(a) program does not apply to task or delivery orders offered to and accepted into the 8(a) program, where the basic contract was not accepted into the 8(a) program.

19.816 Exiting the 8(a) program.

(a) Except as provided in paragraph (c) of this section, when a contractor exits the 8(a) program, it is no longer eligible to receive new 8(a) contracts. However, the contractor remains under contractual obligation to complete existing contracts, and any priced options that may be exercised.

(b) If an 8(a) contractor is suspended from the program (see 13 CFR 124.305), it may not receive any new 8(a) contracts unless the head of the contracting agency makes a determination that it is in the best interest of the Government to issue the award and SBA adopts that determination.

(c) A contractor that has completed its term of participation in the 8(a) program may be awarded a competitive 8(a) contract if it was an 8(a) participant eligible for award of the contract on the initial date specified for receipt of offers contained in the solicitation, and if the contractor continues to meet all other applicable eligibility criteria.

(d) SBA's regulations on exiting the 8(a) program are found at 13 CFR 124.301 through 124.305, and 13 CFR 124.507(d).

19.1304 [Amended]

■ 25. Amend section 19.1304 by removing from paragraph (d) ''Program'' and adding ''program'' in its place (twice).

19.1404 [Amended]

■ 26. Amend section 19.1404 by removing from paragraph (d) ''Program'' and adding ''program'' in its place (twice).

■ 27. Amend section 19.1504 by revising paragraph (a) to read as follows:

19.1504 Exclusions.

* * * * *

(a) Requirements that an 8(a) contractor is currently performing under the 8(a) program or that SBA has accepted for performance under the authority of the 8(a) program, unless SBA has consented to release the requirements from the 8(a) program;

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 28. Amend section 52.212–5 by revising the date of the clause and paragraph (b)(19) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (JAN 2017)

* * * * *

(b) * * *

(19) 52.219–14, Limitations on Subcontracting (JAN 2017) (15 U.S.C. 637(a)(14)).

* * * * *

■ 29. Amend section 52.219–11 by revising the date of the clause and removing from paragraph (c) ''and advance payments'' to read as follows:

52.219–11 Special 8(a) Contract Conditions.

* * * * *

Special 8(a) Contract Conditions (JAN 2017)

* * * * *

■ 30. Amend section 52.219–12 by revising the date of the clause and paragraph (b)(2) to read as follows:

52.219–12 Special 8(a) Subcontract Conditions.

* * * * *

Special 8(a) Subcontract Conditions (JAN 2017)

* * * * *

(b) * * *

(2) That the SBA has delegated responsibility, except for novation agreements, for the administration of this subcontract to the _____[[*insert name of contracting agency*] with complete authority to take any action on behalf of the Government und_d conditions of this subcontract.

* * * * *

■ 31. Amend section 52.219–14 by revising the date of the clause and removing from paragraphs (b)(1), (2), and (3) ''8(a) concerns'' and adding ''8(a) participants'' in its place to read as follows:

52.219–14 Limitations on Subcontracting.

* * * * *

Limitations on Subcontracting (JAN 2017)

* * * * *

■ 32. Amend section 52.219–17 by revising the date of the clause and removing from paragraph (a)(2) ''and advance payments'' to read as follows:

52.219–17 Section 8(a) Award.

* * * * *

Section 8(a) Award (JAN 2017)

* * * * *

■ 33. Amend section 52.219–18 by—

■ a. Revising the section and clause headings; and

■ b. In Alternate I, revising the date of the alternate and removing ''concerns'' and adding ''participants'' in its place.

The revisions read as follows:

52.219–18 Notification of Competition Limited to Eligible 8(a) Participants.

* * * * *

Notification of Competition Limited to Eligible 8(a) Participants (JAN 2017)

* * * * *

Alternate I (JAN 2017) * * *

* * * * *

[FR Doc. 2016–31498 Filed 1–12–17; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 31

[FAC 2005–95; FAR Case 2015–016; Item V; Docket No. 2015–0016; Sequence No. 1]

RIN 9000–AM97

Federal Acquisition Regulation; Prohibition on Reimbursement for Congressional Investigations and Inquiries

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule to amend the Federal Acquisition Regulation (FAR) to implement section 857 of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015. This section provides additional requirements relative to the allowability of costs incurred by a contractor in connection with a Congressional investigation or inquiry.

DATES: *Effective:* January 13, 2017.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Zenaida Delgado, Procurement Analyst, at 202–969–7207. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAC 2005–95, FAR Case 2015–016.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 81 FR 8031 on February 17, 2016, soliciting public comments on implementing section 857 of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2015 (Pub. L. 113–291).

This statute amended 10 U.S.C. 2324(e)(1) to disallow costs incurred by a contractor in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition as described in 10 U.S.C. 2324(k)(2).

While section 857 only applies to contracts with DoD, NASA, and the Coast Guard, for the purpose of promoting consistency in the accounting systems of Federal contractors, it was decided to apply the section's requirements to all agencies subject to the FAR.

Additionally, conforming language on unallowable costs is added to FAR 31.603–16 and 31.603–15 (to update language associated with whistleblower complaints).

Two respondents submitted public comments.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule:

A. Summary of Significant Changes

Several editorial changes are made to the rule as a result of the comments received; these were aimed at simplifying sentence structure for clarification purposes. There were no comments on the Initial Regulatory Flexibility Analysis.

B. Analysis of Public Comments

1. Unfair Withholding of Costs

Comment: One respondent stressed that contractors should not be penalized until guilt is determined by a court of law. Contractors should be reimbursed for their costs, as incurred, at the time of their participation in a Congressional investigation or inquiry. While affirming that it only makes sense that a contractor found guilty of defrauding or cheating the Government in association with their work should forfeit their reimbursement, the respondent maintained that, until guilt is determined by a court of law, the contractor should be reimbursed for its costs. Then, if the contractor is found guilty of defrauding or cheating the Government, it should pay those costs back to the Government.

Response: The disallowance of costs in accordance with 10 U.S.C. 2324(e)(1)(Q) (*i.e.,* any costs incurred by a contractor in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition that meets conditions at FAR 31.205–47(b)(1) through (5)) does not constitute a penalty. The regulation clearly states that costs are unallowable if incurred in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding that results in a specified disposition. Absent a specified disposition, no disallowance of costs would exist.

Comment: The same respondent stated that the ''guilty verdict'' must come from an impartial court, and must be associated with the inquiry.

Response: The Councils appreciate this concern, but note that it extends beyond the scope of this case.

2. Use of Congressional Investigations

Comment: One respondent suggested fixing ''the real problem'' by writing regulations to penalize politicians who use Congressional investigations to promote their personal or their affiliated party's agenda. The respondent noted that, in many cases, small businesses incur hundreds of thousands of dollars in costs associated with the inquiry, despite the fact that the only thing they did wrong was work for a Government entity that was targeted by a political party.

Response: The Councils appreciate this concern, but note that it extends beyond the scope of this case.

3. Clarify Relationship Among the FAR 31.205–47 Paragraphs

Comment: One respondent questioned whether FAR 31.205–47(c) or (d) would impact the allowability of the cost of a Congressional investigation or inquiry. Specifically, the respondent asked if the cost of a Congressional investigation or inquiry related to an issue that is the subject matter of a FAR 31.205–47(b) proceeding, whose result is described in FAR 31.205–47(b)(1) through (5), would be unallowable if one of the circumstances described in FAR 31.205–47(c) or (d) existed.

Response: The cost of a Congressional investigation or inquiry cannot be treated the same as the cost of a proceeding under FAR 31.205–47(c) or (d). Although the section 857 language ties the cost of the Congressional investigation or inquiry to an issue that is the subject matter of a proceeding resulting in a disposition as described in 10 U.S.C. 2324(k)(2), Congress did not enact parallel treatment. 10 U.S.C. 2324(e)(1)(O) disallows ''Costs incurred by a contractor in connection with any criminal, civil, or administrative proceeding commenced by the United States or a State, to the extent provided in subsection (k),'' which includes the exceptions in paragraphs (k)(3) and (k)(4), covered in the FAR at 31.205–47(c) and (d). Section 857, as implemented in 10 U.S.C. 2324(e)(1)(Q), references only paragraph (k)(2) and does not reference paragraph (k) in its entirety; nor does it reference paragraphs (k)(3) or (k)(4) specifically. Therefore, the statute requires that the costs incurred in connection with a Congressional investigation or inquiry be treated differently than the costs incurred in connection with other

criminal, civil, or administrative proceedings in which costs may be allowable under certain circumstances.

Comment: The same respondent questioned whether the limitations at FAR 31.205–47(e) would be applicable to the costs incurred in connection with a Congressional investigation or inquiry. Specifically, the respondent asked if the costs of a Congressional investigation or inquiry into a subject matter of a FAR 31.205–47(b) proceeding, whose result is *not* one described in FAR 31.205–47(b)(1) through (5), would be subject to the limitations in FAR 31.205–47(e).

Response: FAR 31.205–47(e) relates to costs *not* made unallowable by paragraph (b), while the new paragraph (f)(9) relates to costs made unallowable by paragraphs (b)(1) through (5), which describe the outcomes that would deem the costs unallowable. Because there is no overlap between the two concepts, there is no need to clarify that relationship in the FAR text.

Comment: The same respondent questioned whether requirements in FAR 31.205–47(g), regarding costs that may be unallowable under FAR 31.205–47(b), would be applicable to costs that may be unallowable under FAR 31.205–47(f)(9).

Response: FAR 31.205–47(g) pertains to *all* unallowable costs under 31.205–47.

4. Clarify the Relationship Between FAR 31.205–47(g) and FAR 31.603(b)(15) and FAR 31.603(b)(16)

Comment: One respondent questioned whether the FAR 31.205–47(g) segregation of cost requirements are to be imposed regarding costs that may be made unallowable based on FAR 31.603(b)(15) or (16). Since the proposed rule does not address this issue, there was a question as to whether FAR 31.205–47(g) is applicable to costs that may be made unallowable based on FAR 31.603(b)(15) or (16). For costs that may be made unallowable under FAR 31.205–47, the respondent argued that it would be in the Government's best interest for: (1) State, local, and federally recognized Indian tribal governments to segregate and account separately for costs that may be made unallowable under FAR 31.603(b)(15) and FAR 31.603(b)(16) during the pendency of a related proceeding, and (2) the contracting officer to normally withhold payment of such costs. Accordingly, the respondent recommended that FAR 31.603(b)(15) and (16) be revised to incorporate requirements similar to those in FAR 31.205–47(g).

Response: The Councils appreciate this concern, but note that adding this as a requirement would require a separate FAR case. Although segregation of potentially unallowable costs (as described at FAR 31.205–47(g)) is a prudent business practice for State, local, and federally recognized Indian tribal governments, section 857 of the NDAA for FY 2016 did not extend this requirement to such entities.

5. Clarification of Regulatory Intent of FAR 31.205–47(f)(9)

Comment: One respondent focused a question upon Congressional inquiry or investigation activities that predate the existence of the proceeding, noting that the proposed version of FAR 31.205–47(f)(9) makes unallowable costs incurred in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition as described in FAR 31.205–47(b)(1) through (5). The respondent interpreted this to mean that, in order for the costs of the Congressional investigation or inquiry to be unallowable, a proceeding would have to be in process. Therefore, it would follow that costs incurred in connection with a Congressional investigation or inquiry that predate the existence of a proceeding are allowable. Specifically, even if the issue becomes the subject matter of a FAR 31.205–47 proceeding at a later date, there is no intention under the proposed rule to retroactively make costs incurred in connection with a Congressional investigation or inquiry that is the subject matter of the proceeding unallowable. If that understanding is incorrect and the rule's intent is to make the costs incurred in connection with a Congressional investigation or inquiry that pre-date the existence of a proceeding unallowable, then the proposed rule should be revised to state that requirement in the cost principle.

Response: The statutory language states: ''. . . congressional investigation or inquiry into an issue that *is* [emphasis added] the subject matter of a proceeding.'' Therefore, the proceeding must be a known event, whether it has already commenced or is known to be commencing on a future date. Preparation (*i.e.,* segregation of costs) for a potential disallowance begins when it is known that a proceeding will ensue.

Comment: The same respondent asked about Government Accountability Office (GAO) investigations, noting that the proposed version of FAR 31.205–47(f)(9) makes unallowable the costs incurred in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition described in FAR paragraphs 31.205–47(b)(1) through (5). The respondent stated that no specifics are provided in the proposed rule concerning what is considered a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding, cautioning that this could lead to different interpretations concerning costs incurred to facilitate or respond to a GAO audit or request, in the event that the project was suggested or specifically required by a Congressional committee or subcommittee. The respondent posited that some might conclude that the proposed rule makes such costs unallowable, and requested confirmation that there is, in fact, no intent to make such costs unallowable.

Response: The Councils believe that Congress intended 10 U.S.C. 2324(e)(1)(Q) to apply only to investigations and inquiries conducted by Congress, *per se.* Therefore, under FAR 31.205–47(f)(9), the potential disallowance and requisite segregation of costs would not be triggered by the GAO's efforts, but rather by an actual investigation or inquiry conducted by Congress. Further, the language is clear in its applicability to a Congressional investigation or inquiry into an issue—one that is the subject matter of a proceeding, a known event.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This has been deemed a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act,

5 U.S.C. 601, *et seq.,* because the rule will be manifested as a cost principle to which only select small businesses are subject. Pursuant to FAR 31.000, the cost principles are applicable to contracts, subcontracts, and modifications whenever cost analysis is performed, or when a contract clause requires the determination or negotiation of costs. An analysis of contracts awarded during Fiscal Year 2014, the most recent full year for which information was available, revealed that fewer than 200 small businesses were performing contracts subject to FAR 31.

Again, the rule merely disallows costs incurred in the extremely rare instances when a contractor incurs costs in connection with a Congressional investigation or inquiry into an issue resulting in a disposition (*e.g.,* conviction, liability, corrective action, etc.), as described in 10 U.S.C. 2324(k)(2). Accordingly, given the miniscule segment of the small business population that could potentially be impacted by the rule, and the low likelihood of the conditions being met, the impact on small businesses is insignificant.

There were no significant issues raised by the public in response to the Initial Regulatory Flexibility Analysis provided in the proposed rule. The final rule applies to all entities, both small and other than small, performing as contractors or subcontractors on U.S. Government contracts, and who are required to abide by the Cost Principles at FAR part 31. However, the rule is not expected to have a significant impact.

There are no reporting, recordkeeping, or other information collection requirements of the rule.

DoD, GSA, and NASA did not identify any significant alternatives that would reduce the impact on small entities and still meet the objectives of the statute.

Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat. The Regulatory Secretariat has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

V. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 31

Government procurement.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 31 as set forth below:

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

■ 1. The authority citation for 48 CFR part 31 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

■ 2. Amend section 31.205–47 by—

■ a. In paragraph (a):

■ i. In the definition of ''Fraud'', removing ''*Fraud*means'' and adding ''*Fraud* means'' in its place;

■ ii. In the definition of ''Penalty'', removing the comma after the word ''Penalty'';

■ iii. In the definition of ''Proceeding'', removing the comma after the word ''Proceeding'';

■ b. Revising paragraph (b) introductory text; and

■ c. Adding paragraph (f)(9).

The addition reads as follows:

31.205–47 Costs related to legal and other proceedings.

* * * * *

(b) Costs incurred in connection with any proceeding brought by: A Federal, State, local, or foreign government for a violation of, or failure to comply with, law or regulation by the contractor (including its agents or employees) (41 U.S.C. 4310 and 10 U.S.C. 2324(k)); a contractor or subcontractor employee submitting a whistleblower complaint of reprisal in accordance with 41 U.S.C. 4712 or 10 U.S.C. 2409; or a third party in the name of the United States under the False Claims Act, 31 U.S.C. 3730, are unallowable if the result is—

* * * * *

(f) * * *

(9) A Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition as described in paragraphs (b)(1) through (5) of this section (see 10 U.S.C. 2324(e)(1)(Q)).

* * * * *

■ 3. Amend section 31.603 by—

■ a. Revising paragraphs (b) introductory text and (b)(15); and

■ b. Adding paragraph (b)(16).

The revisions and addition reads as follows:

31.603 Requirements.

* * * * *

(b) Agencies are not expected to place additional restrictions on individual items of cost. However, under 10 U.S.C. 2324, 41 U.S.C. 4304, 31 U.S.C. 3730, and 41 U.S.C. 4310, the following costs are unallowable:

* * * * *

(15) Unless any of the exceptions at 31.205–47(c) or (d) apply, costs incurred by a contractor in connection with any criminal, civil, or administrative proceedings that result in dispositions described at 31.205–47(b)(1) through (5) commenced by: A Federal, State, local, or foreign government, for a violation of, or failure to comply with, law or regulation by the contractor (including its agents or employees); a contractor or subcontractor employee submitting a whistleblower complaint of reprisal in accordance with 41 U.S.C. 4712 or 10 U.S.C. 2409; or a third party in the name of the United States under the False Claims Act, 31 U.S.C. 3730. For any such proceeding that does not result in a disposition described at 31.205–47(b)(1) through (5), or to which 31.205–47(c) exceptions apply, the cost of that proceeding shall be subject to the limitations in 31.205–47(e).

(16) Costs incurred in connection with a Congressional investigation or inquiry into an issue that is the subject matter of a proceeding resulting in a disposition as described at 31.205–47(b)(1) through (5).

[FR Doc. 2016–31499 Filed 1–12–17; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2016–0051, Sequence No. 9]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–95; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rules appearing in Federal Acquisition Circular (FAC) 2005–95, which amends the Federal Acquisition Regulation (FAR). An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared. Interested parties may obtain further information regarding these rules by referring to FAC 2005–95, which precedes this document. These

documents are also available via the Internet at *http://www.regulations.gov.*

DATES: January 13, 2017.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2005–95 and the FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

RULES LISTED IN FAC 2005–95

Item	Subject	FAR Case	Analyst
*I	Uniform Use of Line Items	2013–014	Francis.
*II	Acquisition Threshold for Special Emergency Procurement Authority	2016–004	Francis.
*III	Contractor Employee Internal Confidentiality Agreements or Statements	2015–012	Davis.
*IV	Contracts Under the Small Business Administration 8(a) Program	2012–022	Uddowla.
*V	Prohibition on Reimbursement for Congressional Investigations and Inquiries	2015–016	Delgado.

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–95 amends the FAR as follows:

Item I—Uniform Use of Line Items (FAR Case 2013–014)

This final rule amends the FAR to establish standards for the uniform use of line items in Federal procurement. These standards are designed to improve the accuracy, traceability, and usability of procurement data. The implementation of these standards will facilitate the identification and traceability of spending from appropriation through expenditure, supporting automated collection of information using key identifiers. The implementation date for FAR 4.1002 through 4.1008 will be October 1, 2019.

The requirements in the rule have the potential to impact any entity, small or large, that does business with the Federal Government because the proposed rule would apply to purchases of items, including commercial items and commercially available off-the-shelf items, and purchases under the simplified acquisition threshold. Any small business that contracts with a Federal agency could be impacted to at least some extent.

Item II—Acquisition Threshold for Special Emergency Procurement Authority (FAR Case 2016–004)

This final rule amends the FAR by increasing the simplified acquisition threshold (SAT) for special emergency procurement authority from $300,000 to $750,000 (within the United States) and from $1 million to $1.5 million (outside the United States) for acquisitions of supplies or services that, as determined by the head of the agency, are to be used to support a contingency operation or to facilitate defense against or recovery from nuclear, biological, chemical, or radiological attack. This change implements Section 816 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92). This rule provides contracting officers with more flexibility when contracting in support of contingency operations.

The rule is not anticipated to have a significant economic impact on small business entities, because the rule raises the SAT for special emergency procurements, an arena in which a smaller percentage of small businesses participate, as compared to larger businesses. This final rule does not place any new requirements on small entities.

Item III—Contractor Employee Internal Confidentiality Agreements or Statements (FAR Case 2015–012)

This final rule revises the FAR to implement section 743 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) and successor provisions in subsequent appropriations acts. Section 743 prohibits the use of funds appropriated or otherwise made available by Division E or any other act, for a contract with an entity that requires employees and subcontractors of such entity to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse, to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (*e.g.,* agency office of the Inspector General). This rule is not expected to have a significant impact on small entities contracting with the Government.

Item IV—Contracts Under the Small Business Administration 8(a) Program (FAR Case 2012–022)

This final rule amends the Federal Acquisition Regulation (FAR) to implement clarifications made by the Small Business Administration in its final rule, which published in the **Federal Register** at 76 FR 8222 on February 11, 2011. This final rule clarifies in the FAR the procedures and requirements used when contracting under the 8(a) program. Clarifications include the evaluation, offering, and acceptance process, procedures for acquiring SBA's consent to procure an 8(a) requirement outside the 8(a) program, and the impact of exiting the 8(a) program in terms of the firm's ability to receive future 8(a) requirements and its current contractual commitments.

This final rule does not place any new requirements, financial or otherwise, on small entities, and serves mainly to provide more explicit guidance to Federal contracting officials.

Item V—Prohibition on Reimbursement for Congressional Investigations and Inquiries (FAR Case 2015–016)

This rule amends the FAR to implement section 857 of the Carl Levin and Howard P. 'Buck' McKeon National Defense Authorization Act for Fiscal Year 2015. Section 857 imposes additional requirements relative to the allowability of costs incurred by a contractor in connection with a congressional investigation or inquiry. Contracting officers need to be aware of these new restrictions on certain costs, which cannot be charged under contracts. Although small businesses subject to FAR part 31 will need to maintain accounting records, this rule does not place any new requirements on small entities.

Dated: December 21, 2016.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2016–31500 Filed 1–12–17; 8:45 am]

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Part VI

Department of Homeland Security

8 CFR Parts 204 and 216

EB–5 Immigrant Investor Program Modernization; Proposed Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 204 and 216

[CIS No. 2555–14; DHS Docket No. USCIS–2016–0006]

RIN 1615–AC07

EB–5 Immigrant Investor Program Modernization

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security (DHS) proposes to amend its regulations governing the employment-based, fifth preference (EB–5) immigrant investor classification and associated regional centers to reflect statutory changes and modernize the EB–5 program. In general, under the EB–5 program, individuals are eligible to apply for lawful permanent residence in the United States if they make the necessary investment in a commercial enterprise in the United States and create or, in certain circumstances, preserve 10 permanent full-time jobs for qualified U.S. workers. This proposed rule would change the EB–5 program regulations to reflect statutory changes and codify existing policies. It would also change certain aspects of the EB–5 program in need of reform.

DATES: Written comments must be received on or before April 11, 2017.

ADDRESSES: You may submit comments, identified by DHS Docket No. USCIS–2016–0006, by any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *Mail:* You may submit comments directly to U.S. Citizenship and Immigration Services (USCIS) by mail by sending correspondence to Samantha Deshommes, Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529. To ensure proper handling, please reference DHS Docket No. USCIS–2016–0006 in your correspondence. This mailing address may be used for paper or CD–ROM submissions.
- *Hand Delivery/Courier:* You may submit comments directly to USCIS through hand delivery to Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529; Telephone 202–272–8377. To ensure proper handling, please reference DHS Docket No. USCIS–2016–0006 in your correspondence.

FOR FURTHER INFORMATION CONTACT: Lori MacKenzie, Division Chief, Operations Policy and Performance, Immigrant Investor Program Office, U.S. Citizenship and Immigration Services, Department of Homeland Security, 131 M Street NE., 3rd Floor, Washington, DC 20529; Telephone 202–357–9214.

SUPPLEMENTARY INFORMATION:

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List of Acronyms and Abbreviations Used

CFR Code of Federal Regulations
CPI Consumer Price Index
CPI–U Consumer Price Index for all Urban Consumers
DHS Department of Homeland Security
DOL Department of Labor
DOS Department of State
EB–5 Employment-Based Fifth Preference
GDP Gross Domestic Product
HSA Homeland Security Act
IEFA Immigration Examinations Fee Account
INA Immigration and Nationality Act
INS Immigration and Naturalization Service
IRFA Initial Regulatory Flexibility Analysis
JCE Job-Creating Entity
MSA Metropolitan Statistical Area
NCE New Commercial Enterprise
NOID—Notice of Intent to Deny
NOIT—Notice of Intent to Terminate
PRA—Paperwork Reduction Act
RFE—Request for Evidence
TEA—Targeted Employment Area
U.S.C.—United States Code
USCIS—United States Citizenship and Immigration Services
UR—Unemployment Rates
VPC—Volume Projections Committee

I. Public Participation

DHS invites comments, data, and information from all interested parties, including regional centers, investors, advocacy groups, nongovernmental organizations, community-based organizations, and legal representatives who specialize in immigration law on any and all aspects of the proposed amendments. Comments must be submitted in English, or an English translation must be provided. Comments that will provide the most assistance to DHS will reference a specific portion of the proposed amendments; explain the reason for any recommended change; and include data, information, or authority that support such recommended change.

In addition to its general call for comments, DHS is specifically seeking comments on the following proposals:

A. Priority date retention for EB–5 petitioners;

B. Increases to the minimum investment amount for targeted employment areas (TEAs) and non-TEAs;

C. Revisions to the TEA designation process, including the elimination of state designation of high unemployment areas as a method of TEA designation;

D. Revisions to the filing and interview process for removal of conditions on lawful permanent residence.

DHS also invites comments on the economic analysis supporting this rule and the proposed form revisions.

Instructions: All submissions must include the DHS Docket No. USCIS–2016–0006 for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal

information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

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

II. Executive Summary

A. Purpose of the Regulatory Action

DHS proposes to update its regulations governing EB–5 immigrant investors and regional centers to reflect statutory changes and codify existing policies. DHS also proposes changes to areas of the EB–5 program in need of reform.

B. Summary of Major Provisions

DHS proposes the following major revisions to the EB–5 program regulations.

(1) Priority Date Retention

DHS proposes to authorize certain EB–5 petitioners to retain the priority date [1] of an approved EB–5 immigrant petition for use in connection with any subsequent EB–5 immigrant petition.[2] Petitioners with approved immigrant petitions might need to file new petitions due to circumstances beyond their control (for instance, DHS might have terminated a regional center associated with the original petition), or might choose to do so for other reasons (for instance, a petitioner may seek to materially change aspects of his or her qualifying investment). DHS is proposing to generally allow EB–5 petitioners to retain the priority dates of previously approved petitions so as to avoid further delays on immigrant visa processing associated with the loss of priority dates. DHS believes that priority date retention may become increasingly important due to the strong possibility that the EB–5 visa category will remain oversubscribed for the foreseeable future.

(2) Increases to the Investment Amounts

DHS is proposing to increase the minimum investment amounts for all new EB–5 petitioners. The increase would ensure that program requirements reflect the present-day dollar value of the investment amounts established by Congress in 1990. Specifically, DHS proposes to initially increase the standard minimum investment amount, which also applies to high employment areas, from $1 million to $1.8 million. This change would represent an adjustment for inflation from 1990 to 2015 as measured by the unadjusted Consumer Price Index for All Urban Consumers (CPI–U),[3] an economic indicator that tracks the prices of goods and services in the United States. For those investors seeking to invest in a new commercial enterprise that will be principally doing business in a targeted employment area (TEA), DHS proposes to increase the minimum investment amount from $500,000 to $1.35 million, which is 75 percent of the proposed standard minimum investment amount. In addition, DHS is proposing to make regular CPI–U-based adjustments in the standard minimum investment amount, and conforming adjustments to the TEA minimum investment amount, every 5 years, beginning 5 years from the effective date of these regulations.

(3) TEA Designations

DHS proposes to reform the TEA designation process to ensure consistency in TEA adjudications and ensure that designations more closely adhere to Congressional intent. First, DHS proposes to allow any city or town with high unemployment [4] and a population of 20,000 or more to qualify as a TEA. Currently, TEA designations are not available at the city or town level, unless a state designates the city or town as a TEA and provides evidence of such designation to a prospective EB–5 investor for submission with the Form I–526. *See* 8 CFR 204.6(i). Second, DHS proposes to eliminate the ability of a state to designate certain geographic and political subdivisions as high-unemployment areas; instead, DHS would make such designations directly, using standards described in more detail elsewhere in this proposed rule. DHS believes these changes would help address inconsistencies between and within states in designating high unemployment areas, and better ensure that the reduced investment threshold is reserved for areas experiencing significantly high levels of unemployment.

(4) Removal of Conditions

DHS proposes to revise the regulations to clarify that derivative family members must file their own petitions to remove conditions on their permanent residence when they are not included in a petition to remove conditions filed by the principal investor. In addition, DHS is proposing to improve the adjudication process for removing conditions by providing flexibility in interview locations and to update the regulation to conform to the current process for issuing permanent resident cards.

(5) Miscellaneous Changes

Lastly, DHS proposes to update the regulations to reflect miscellaneous statutory changes made since the regulation was first published in 1991, as well as to clarify definitions of key terms for the program. By aligning DHS regulations with statutory changes and defining key terms, this proposed rule will provide greater certainty regarding the eligibility criteria for investors and their family members.

C. Legal Authority

The Secretary of Homeland Security's authority for the proposed regulatory amendments is found in various provisions of the Immigration and Nationality Act (INA), 8 U.S.C. 1101 *et seq.,* as well as the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993, Public Law 102–395, 106 Stat. 1828; the 21st Century Department of Justice Appropriations Authorization Act, Public Law 107–273, 116 Stat. 1758; and the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 101 *et seq.* General authority for issuing the proposed rule is found in section 103(a) of the INA, 8 U.S.C. 1103(a), which authorizes the Secretary to administer and enforce the immigration and nationality laws, including establishing such regulations as the Secretary deems necessary to carry out his authority; section 101(b)(1)(F) of the HSA, 6 U.S.C. 111(b)(1)(F), which establishes that a primary mission of DHS is to ensure that the economic security of the United States is not diminished by the Department's efforts, activities, and programs; and section 102 of the HSA, 6 U.S.C. 112, which vests all of the

[1] An EB–5 immigrant petition's priority date is normally the date on which the petition was properly filed. In general, when demand exceeds supply for a particular visa category, an earlier priority date is more advantageous than a later one.

[2] The priority date retention proposal, like other proposals described in this Executive Summary, is subject to important conditions and limitations described in more detail elsewhere in this proposed rule.

[3] *See* Bureau of Labor Statistics, CPI–U Inflation Calculator, *http://data.bls.gov/cgi-bin/cpicalc.pl.*

[4] An area has ''high unemployment'' if it has an average unemployment rate of at least 150 percent of the national average rate.

functions of DHS in the Secretary and authorizes the Secretary to issue regulations.

The aforementioned authorities for the proposed regulatory amendments include:

- Section 203(b)(5) of the INA, 8 U.S.C. 1153(b)(5), which makes visas available to immigrants investing in new commercial enterprises in the United States that will benefit the U.S. economy and create full-time employment for not fewer than 10 U.S. workers.
- Section 204(a)(1)(H) of the INA, 8 U.S.C. 1154(a)(1)(H), which requires individuals to file petitions with DHS when seeking classification under section 203(b)(5);
- Section 216A of the INA, 8 U.S.C. 1186b, which places conditions on permanent residence obtained under section 203(b)(5) and authorizes the Secretary to remove such conditions for immigrant investors who have met the applicable investment requirements, sustained such investment, and otherwise conformed to the requirements of sections 203(b)(5) and 216A.
- Section 610 of Public Law 102–395, 8 U.S.C. 1153 note, as amended, which created the Immigrant Investor Pilot Program (the ''Regional Center Program''), authorizing the designation of regional centers for the promotion of economic growth, and which authorizes the Secretary to set aside visas authorized under section 203(b)(5) of the INA for individuals who invest in regional centers.

D. Costs and Benefits

This rule proposes changes to certain aspects of the EB–5 program that are in need of reform, and would also update the regulations to reflect statutory changes and codify existing policies. There are three major provisions proposed with several minor provisions and some miscellaneous technical changes. DHS has analyzed these provisions carefully and has determined that due to data limitations and the complexity of EB–5 investment structures, which typically involve multiple layers of investment, finance, development, and legal business entities, it is difficult to quantify and monetize the costs and benefits of the proposed provisions, with the exception of total estimated costs of approximately $91,000 [5] annually for dependents who would file the Petition by Entrepreneur to Remove Conditions on Permanent Resident Status (Form I–829) separately from principal investors, and familiarization costs to review the rule, estimated at $501,154 annually.

However, DHS does provide qualitative discussions on the potential costs and benefits of these proposed provisions. One of the main proposed provisions increases the standard minimum investment amount to $1.8 million and the minimum investment amount for TEAs to $1.35 million in order to account for inflation since the inception of the program. DHS has no way to assess the potential reduction in investments either in terms of past activity or forecasted activity, and cannot therefore estimate any impacts concerning job creation, losses or other downstream economic impacts driven by the proposed investment amount increases. DHS provides a full qualitative analysis and discussion on the increase in investment amounts in the executive orders 12866 and 13563 section of this proposed rule. DHS believes these provisions would increase the integrity, effectiveness, and economic impact of the program positively, stimulating investment in areas where it is needed most and generating jobs.

The costs and benefits summary of the proposed provisions is provided in Table 1, below. In addition, DHS has prepared an Initial Regulatory Flexibility Analysis (IRFA) under the Regulatory Flexibility Act (RFA) to discuss any potential impacts to small entities. As discussed further in the IRFA, DHS cannot estimate the exact impact to small entities. DHS, however, does expect some impact to regional centers and non-regional center projects, although it does not anticipate that this impact will be substantial or significant.

TABLE 1—SUMMARY OF CHANGES AND IMPACT OF THE PROPOSED PROVISIONS

Current policy	Proposed change	Impact
Current DHS regulations do not permit investors to use the priority date of an approved EB–5 immigrant petition for a subsequently filed EB–5 immigrant petition.	DHS proposes to allow an EB–5 immigrant petitioner to use the priority date of an approved EB–5 immigrant petition for a subsequently filed EB–5 immigrant petition for which the petitioner qualifies.	Benefits: • Makes visa allocation more predictable for investors with less possibility for large fluctuations in visa availability dates due to regional center termination. • Provides greater certainty and stability regarding the timing of eligibility for investors pursuing permanent residence in the U.S. and thus lessens the burden of unexpected changes in the underlying investment. • Provides more flexibility to investors to contribute into more viable investments, potentially reducing fraud and improving potential for job creation. Costs: • Not identified.
The standard minimum investment amount has been $1 million since 1990 and has not kept pace with inflation. Further, the statute authorizes a reduction in the minimum investment amount when such investment is made in a TEA by up to 50 percent of the standard minimum investment amount. Since 1991, DHS regulations have set the TEA investment threshold at 50 percent of the minimum investment amount. Similarly, DHS has not proposed to increase the minimum investment amount for investments made in a high employment area beyond the standard amount.	DHS proposes to account for inflation in the investment amount since the inception of the program. DHS proposes to raise the minimum investment amount to $1.8 million. DHS also proposes to include a mechanism to automatically adjust the minimum investment amount based on the unadjusted CPI–U every 5 years. DHS proposes to decrease the reduction for TEA investment thresholds, and set the TEA minimum investment at 75 percent of the standard amount. Assuming the standard investment amount is $1.8 million, investment in a TEA would initially increase to $1.35 million. DHS is not proposing to change the equivalency between the standard minimum investment amount and those made in high employment areas. As such, DHS proposes that the minimum investment amounts in high employment areas would be $1.8 million, and follow the same mechanism for future inflationary adjustments.	Benefits: • Increases in investment amounts are necessary to keep pace with inflation and real value of investments; • Raising the investment amounts increases the amount invested by each investor and potentially increases the total amount invested under this program. • For regional centers, the higher investment amounts per investor would mean that fewer investors would have to be recruited to pool the requisite amount of capital for the project, so that searching and matching of investors to projects could be less costly. Costs: • Some investors may be unable or unwilling to invest at the higher proposed levels of investment. • There may be fewer jobs created if fewer investors invest at the proposed higher investment amounts. • For regional centers, the higher amounts could reduce the number of investors in the global pool and result in fewer investors and thus make search and matching of investors to projects more costly. • Potential reduced numbers of EB–5 investors could prevent projects from moving forward due to lack of requisite capital.

[5] The cost estimate is rounded from $90,762.

TABLE 1—SUMMARY OF CHANGES AND IMPACT OF THE PROPOSED PROVISIONS—Continued

Current policy	Proposed change	Impact
A TEA is defined by statute as a rural area or an area which has experienced high unemployment (of at least 150 percent of the national average rate). Currently, investors demonstrate that their investments are in a high unemployment area in two ways: (1) Providing evidence that the Metropolitan Statistical Area (MSA), the specific county within the MSA, or the county in which a city or town with a population of 20,000 or more is located, in which the new commercial enterprise is principally doing business, has experienced an average unemployment rate of at least 150 percent of the national average rate or (2) Submitting a letter from an authorized body of the government of the state in which the new commercial enterprise is located, which certifies that the geographic or political subdivision of the metropolitan statistical area or of the city or town with a population of 20,000 or more in which the enterprise is principally doing business has been designated a high unemployment area.	DHS proposes to eliminate state designation of high unemployment areas. DHS also proposes to amend the manner in which investors can demonstrate that their investments are in a high unemployment area. (1) In addition to MSAs, specific counties within MSAs, and counties in which a city or town with a population of 20,000 or more is located, DHS proposes to add cities and towns with a population of 20,000 or more to the types of areas that can be designated as a high unemployment area. (2) DHS is proposing that a TEA may consist of a census tract or contiguous census tracts in which the new commercial enterprise is principally doing business if the weighted average of the unemployment rate for the tract or tracts is at least 150 percent of the national average. (3) DHS is also proposing that a TEA may consist of an area comprised of the census tract(s) in which the new commercial enterprise is principally doing business, including any and all adjacent tracts, if the weighted average of the unemployment rate for all included tracts is at least 150 percent of the national average.	• An increase in the investment amount could make foreign investor visa programs offered by other countries more attractive. Benefits: • Rules out TEA configurations that rely on a large number of census tracts indirectly linked to the actual project tract by numerous degrees of separation. • Potential to better stimulate job growth in areas where unemployment rates are the highest. Costs: • The proposed TEA provision could cause some projects and investments to not qualify. DHS presents the potential number of projects and investments that could be affected in Table 5.
Current technical issues: • The current regulation does not clearly define the process by which derivatives may file a Form I–829 petition when they are not included on the principal's petition. • Interviews for Form I–829 petitions are generally scheduled at the location of the new commercial enterprise. • The current regulations require an immigrant investor and his or her derivatives to report to a district office for processing of their permanent resident cards.	DHS is proposing the following technical changes: • Clarify the filing process for derivatives who are filing a Form I–829 petition separately from the immigrant investor. • Provide flexibility in determining the interview location related to the Form I–829 petition. • Amend the regulation by which the immigrant investor obtains the new permanent resident card after the approval of his or her Form I–829 petition because DHS captures biometric data at the time the immigrant investor and derivatives appear at an ASC for fingerprinting.	Conditions of Filing: Benefits: • Adds clarity and eliminates confusion for the process of derivatives who file separately from the principal immigrant investor. Costs: • Total cost to applicants filing separately would be $90,762 annually. Conditions of Interview: Benefits: • Interviews may be scheduled at the USCIS office having jurisdiction over either the immigrant investor's commercial enterprise, the immigrant investor's residence, or the location where the Form I–829 petition is being adjudicated, thus making the interview program more effective and reducing burdens on the immigrant investor. • Some applicants may have cost savings from lower travel costs. Costs: • Not estimated. Investors obtaining a permanent resident card: Benefits: • Cost and time savings for applicants for biometrics data. Costs: • Not estimated.
Current miscellaneous items: • 8 CFR 204.6(j)(2)(iii) refers to the former U.S. Customs Service. • Public Law 107–273 eliminated the requirement that alien entrepreneurs establish a new commercial enterprise from both INA § 203(b)(5) and INA § 216A. • 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii) reference "management"; • Current regulation at 8 CFR 204.6(j)(5) has the phrase "as opposed to maintain a purely passive role in regard to the investment"; • Public Law 107–273 allows limited partnerships to serve as new commercial enterprises; • Current regulation references the former Associate Commissioner for Examinations. • 8 CFR 204.6(k) requires USCIS to specify in its Form I–526 decision whether the new commercial enterprise is principally doing business in a targeted employment area. • Sections 204.6 and 216.6 use the term "entrepreneur" and "deportation." These sections also refer to Forms I–526 and I–829.	DHS is proposing the following miscellaneous changes: • DHS is updating references at 8 CFR 204.6(j)(2)(iii) from U.S. Customs Service to U.S. Customs and Border Protection. • Removing references to requirements that alien entrepreneurs establish a new commercial enterprise in 8 CFR 204.6 and 216.6. • Removing references to "management" at 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii); • Removing the phrase "as opposed to maintain a purely passive role in regard to the investment" from 8 CFR 204.6(j)(5); • Clarifies that any type of entity can serve as a new commercial enterprise; • Replacing the reference to the former Associate Commission for Examinations with a reference to the USCIS AAO. • Amending 8 CFR 204.6(k) to specify how USCIS will issue a decision. • Revising sections 204.6 and 216.6 to use the term "investor" instead of "entrepreneur" and to use the term "removal" instead of "deportation."	These provisions are technical changes and will have no impact on investors or the government. Therefore, the benefits and costs for these changes were not estimated.
Miscellaneous Cost: • Familiarization cost of the rule.	Applicants would need to read and review the rule to become familiar with the proposed provisions.	Familiarization costs to read and review the rule are estimated at $501,154 annually.

III. Background

A. The EB–5 Program

As part of the Immigration Act of 1990, Public Law 101–649, 104 Stat. 4978, Congress established the EB–5 immigrant visa classification to incentivize employment creation in the United States. Under the EB–5 program, lawful permanent resident (LPR) status is available to foreign nationals who invest at least $1 million in a new commercial enterprise (NCE) that will create at least 10 full-time jobs in the United States. *See* INA section 203(b)(5), 8 U.S.C. 1153(b)(5). A foreign

national may also invest $1 million if the investment is in a high employment area or $500,000 if the investment is in a TEA, defined to include certain rural areas and areas of high unemployment. *Id.;* 8 CFR 204.6(f). The INA allots 9,940 immigrant visas each fiscal year for foreign nationals seeking to enter the United States under the EB–5 classification.[6] *See* INA section 201(d), 8 U.S.C. 1151(d); INA section 203(b)(5), 8 U.S.C. 1153(b)(5). Not less than 3,000 of these visas must be reserved for foreign nationals investing in TEAs. *See* INA section 203(b)(5)(B), 8 U.S.C. 1153(b)(5)(B).

B. The Regional Center Program

Enacted in 1992, section 610 of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993, Public Law 102–395, 106 Stat. 1828, established a pilot program that requires the allocation of a limited number of EB–5 immigrant visas to individuals who invest through DHS-designated regional centers.[7] The Regional Center Program was initially designed as a pilot program set to expire after 5 years, but Congress has continued to extend the program to the present day.[8] The Regional Center Program was last extended in December 2016.[9]

Under the Regional Center Program, foreign nationals base their EB–5 petitions on investments in new commercial enterprises located within ''regional centers.'' DHS regulations define a regional center as an economic unit, public or private, that promotes economic growth, regional productivity, job creation, and increased domestic capital investment. *See* 8 CFR 204.6(e). While all EB–5 petitioners go through the same petition process, those petitioners participating in the Regional Center Program may meet statutory job creation requirements based on economic projections of either *direct* or *indirect* job creation, rather than only on jobs directly created by the new commercial enterprise. *See* 8 CFR 204.6(m)(3). In addition, Congress authorized the Secretary to give priority to EB–5 petitions filed through the Regional Center Program. *See* section 601(d) of Public Law 102–395, 106 Stat. 1828, as amended by Public Law 112–176, Sec. 1, 126 Stat. 1326 (Sept. 28, 2012).

Requests for regional center designation must be filed with USCIS on the Application for Regional Center Under the Immigrant Investor Program (Form I–924). *See* 8 CFR 204.6(m)(3)–(4). Once designated, regional centers must provide USCIS with updated information to demonstrate continued eligibility for the designation by submitting an Annual Certification of Regional Center (Form I–924A) on an annual basis or as otherwise requested by USCIS. *See* 8 CFR 204.6(m)(6)(i)(B). USCIS may seek to terminate a regional center's participation in the program if the regional center no longer qualifies for the designation, the regional center fails to submit the required information or pay the associated fee, or USCIS determines that the regional center is no longer promoting economic growth. *See* 8 CFR 204.6(m)(6)(i). As of November 1, 2016, there were 864 designated regional centers.[10]

C. EB–5 Immigrant Visa Process

A foreign national seeking LPR status under the EB–5 immigrant visa classification must go through a multi-step process. The individual must first file an Immigrant Petition by Alien Entrepreneur (Form I–526, or ''EB–5 petition'') with USCIS. The petition must be supported by evidence that the foreign national's lawfully obtained investment capital is invested (*i.e.,* placed at risk), or is actively in the process of being invested, in a new commercial enterprise in the United States that will create full-time positions for not fewer than 10 qualifying employees. *See* 8 CFR 204.6(j).

If USCIS approves the EB–5 petition, the petitioner must take additional steps to obtain LPR status. In general, the petitioner may either apply for an immigrant visa through a Department of State consular post abroad [11] or, if the petitioner is already in the United States and is otherwise eligible to adjust status, the petitioner may seek adjustment of status by filing an Application to Register Permanent Residence or Adjust Status (Form I–485) with USCIS.[12] Congress has imposed limits on the availability of such immigrant visas, including by capping the annual number of visas available in the EB–5 category and by separately limiting the percentage of immigrant visas that may be issued on an annual basis to individuals born in any one country.[13]

To request an immigrant visa while abroad, an EB–5 petitioner must apply at a U.S. consular post. *See* INA sections 203(e) and (g), 221 and 222, 8 U.S.C. 1153(e) and (g), 1201 and 1202; *see also* 22 CFR part 42, subparts F and G. The petitioner must generally wait to receive a visa application packet from the DOS National Visa Center to commence the visa application process. After receiving this packet, the petitioner must collect required information and file the immigrant visa application with DOS. As noted above, the wait for a visa depends on the demand for immigrant visas in the EB–5 category and the petitioner's country of birth.[14] Generally, DOS authorizes the issuance of a visa and schedules the petitioner for an immigrant visa interview for the month in which the priority date will be current. If the petitioner's immigrant visa application is ultimately approved, he or she is issued an immigrant visa and, on the date of admission to the United States, obtains LPR status on a conditional basis. *See* INA sections 211, 216A and 221; 8 U.S.C. 1181, 1186b and 1201.

Alternatively, an EB–5 petitioner who is in the United States in lawful nonimmigrant status generally may seek LPR status by filing with USCIS an Application to Register Permanent Residence or Adjust Status (Form I–485, or ''application for adjustment of status''). *See* INA section 245, 8 U.S.C. 1255; 8 CFR part 245. Before filing such an application, however, the EB–5 petitioner must wait until an immigrant visa is ''immediately available.'' *See* INA section 245(a), 8 U.S.C. 1255(a); 8 CFR 245.2(a)(2)(i)(A). Generally, an immigrant visa is considered

[6] An immigrant investor, his or her spouse, and children (if any) will each use a separate visa number.

[7] Current law requires that DHS annually set aside 3,000 EB–5 immigrant visas for regional center investors. Section 116 of Public Law 105–119, 111 Stat. 2440 (Nov. 26, 1997). If this full annual allocation is not used, remaining visas may be allocated to foreign nationals who do not invest in regional centers.

[8] *See* Section 116 of Public Law 105–119, 111 Stat. 2440, 2467 (Nov. 26, 1997); Section 1 of Public Law 112–176, 126 Stat. 1325, 1325 (Sept. 28, 2012); Section 575 of Public Law 114–113, 129 Stat. 2242, 2526 (Dec. 18, 2015).

[9] *See* Public Law 114–254 (Dec. 10, 2016).

[10] USCIS, Immigrant Investor Regional Centers, *https://www.uscis.gov/working-united-states/permanent-workers/employment-based-immigration-fifth-preference-eb-5/immigrant-investor-regional-centers.*

[11] *See* INA sections 203, 221 and 222; 8 U.S.C. 1153, 1201, and 1202.

[12] *See* INA section 245, 8 U.S.C. 1255.

[13] *See* INA sections 201, 202 and 203; 8 U.S.C. 1151, 1152 and 1153.

[14] When demand for a visa exceeds the number of visas available for that category and country, the demand for that particular preference category and country of birth is deemed oversubscribed. The Department of State (DOS) publishes a Visa Bulletin that determines when a visa may be authorized for issuance. *See* U.S. Dep't of State, Bureau of Consular Aff., Visa Bulletin, *available at https://travel.state.gov/content/visas/en/law-and-policy/bulletin.html.* Specifically, an individual cannot be issued an immigrant visa unless the individual's ''priority date,'' *i.e.,* the date USCIS received the properly filed Form I–526, is earlier than the ''final action date'' indicated in the ''date for filing application'' chart in the current Visa Bulletin for the relevant category and country of birth. *See* 8 CFR 204.6(d) (defining the ''priority date'' for EB–5 petitioners).

''immediately available'' if the petitioner's priority date under the EB–5 category is earlier than the relevant date indicated in the monthly DOS Visa Bulletin.[15] *See* 8 CFR 245.1(g)(1).

Whether obtained pursuant to issuance of an immigrant visa or adjustment of status, LPR status based on an EB–5 petition is granted on a conditional basis. *See* INA section 216A(a)(1), 8 U.S.C. 1186b(a)(1). Within the 90-day period preceding the second anniversary of the date the immigrant investor obtains conditional permanent resident status, the immigrant investor is required to file with USCIS a Petition by Entrepreneur to Remove Conditions on Permanent Resident Status (Form I–829). *See* INA section 216A(c) and (d), 8 U.S.C. 1186b(c) and (d); 8 CFR 216.6(a)(1). Failure to timely file Form I–829 results in automatic termination of the immigrant investor's conditional permanent resident status and the initiation of removal proceedings. *See* INA section 216A(c), 8 U.S.C. 1186b(c); 8 CFR 216.6(a)(5). In support of the petition to remove conditions, the investor must show, among other things, that he or she established the commercial enterprise, that he or she invested or was actively involved in the process of investing the requisite capital, that he or she sustained those actions for the period of residence in the United States, and that job creation requirements were met or will be met within a reasonable time. *See* 8 CFR 216.6(a)(4). If approved, the conditions on the investor's permanent residence are removed as of the second anniversary of the date the investor obtained conditional permanent resident status. *See* 8 CFR 216.6(d)(1).

IV. The Proposed Rule

DHS has not comprehensively revised the EB–5 program regulations since they were published in 1993, *see* 58 FR 44606 (1993), but has issued policy guidance to conform agency practice to intervening changes in the governing statutes. In addition to proposing changes to portions of the EB–5 program that are in need of reform, this proposed rule would codify and clarify certain policies. For example, the current regulation requires that the interview for the petition to remove conditions take place at the USCIS office located in the same location as the new commercial enterprise, although there is no requirement that the EB–5 immigrant petitioner reside in that vicinity. *See* 8 CFR 216.6(b)(2). In some instances, DHS has been allowing the interview to take place at a variety of different locations, including the USCIS office closest to the immigrant petitioner's residence, as DHS recognizes the burden of conducting an interview in a location that is a considerable distance from an immigrant petitioner's residence. DHS is proposing conforming revisions to the regulations in order to reflect this practice. *See* proposed 8 CFR 216.6(b)(2).

A. Priority Date Retention

DHS proposes to allow an EB–5 immigrant petitioner to use the priority date of an approved EB–5 immigrant petition for any subsequently filed EB–5 immigrant petition for which the petitioner qualifies. *See* proposed 8 CFR 204.6(d). This provision would not apply where DHS revoked the original petition's approval based on fraud, willful misrepresentation of a material fact, or a determination that DHS approved the petition based on a material error. *Id.* Similarly, priority date retention would not be available once the investor uses the priority date to obtain conditional LPR status based upon the approved petition (*e.g.,* when such an investor fails to remove the conditional basis of that status and thus loses his or her LPR status). Should DHS seek to revoke the approval of an immigrant petition, DHS would provide notice of the revocation detailing the reasons for revocation.[16] If the revocation is not based on fraud, a willful misrepresentation of a material fact, or material DHS error, the investor would be able to utilize the priority date of that petition should he or she seek to file another immigrant petition under the EB–5 program. *See* proposed 8 CFR 204.6(d). An investor seeking to use a retained priority date should provide a copy of the original immigrant petition's approval notice indicating the earlier priority date when filing the new EB–5 immigrant petition. Under this proposal, denied petitions would not establish a priority date, and a priority date would not be transferable to another investor. *See* proposed 8 CFR 204.6(d).

The current regulation does not permit investors to use the priority date of an approved EB–5 immigrant petition for a subsequently filed EB–5 immigrant petition. *See* 8 CFR 204.6(d). DHS has generally allowed beneficiaries in the employment-based first, second, and third preference categories to retain the priority date of their previously approved immigrant petitions unless DHS revokes petition approval. *See* 8 CFR 204.5(e). DHS recently issued a final rule that will expand the ability of beneficiaries in these preference categories to retain their priority dates even when their petitions have been revoked, so long as the approval was not revoked based on fraud, willful misrepresentation of a material fact, material error, or the revocation or invalidation of the labor certification associated with the petition.[17] *See* 8 CFR 204.5(e)(2). DHS's proposal in this regulation to allow priority date retention for those in the EB–5 category would bring the EB–5 priority date retention policy into harmony with those other employment-based preference categories. *See* proposed 8 CFR 204.6(d).

DHS is proposing to allow priority date retention in order to: (1) Address situations in which petitioners may become ineligible through circumstances beyond their control (*e.g.,* the termination of a regional center) as they wait for their EB–5 visa priority date to become current; and (2) provide investors with greater flexibility to deal with changes to business conditions. For example, investors involved with an underperforming or failing investment project would be able to move their investment funds to a new, more promising investment project without losing their place in the visa queue.

Providing EB–5 investors with the opportunity to retain their priority dates is increasingly important as the demand for EB–5 visas outpaces the statutorily limited supply of such visas, which lengthens wait times for visa numbers. Since the severe economic recession between 2007 and 2009,[18] the EB–5 program has experienced a dramatic increase in participation. Prior to 2008, the EB–5 program received an average of fewer than 600 EB–5 immigrant petitions per year. In the following years, the EB–5 program has received an

[15] More specifically, an individual generally may file an application for adjustment of status with USCIS only if his or her priority date is earlier than the cut-off date for the relevant category and country of birth in the ''final action dates'' chart in the relevant Visa Bulletin. However, when USCIS determines that there are more immigrant visas available for the fiscal year than there are known applicants for such visas, USCIS will state on its Web site that, during that month, applicants may instead use the ''dates for filing visa applications'' chart in the Visa Bulletin for purposes of determining whether they may file applications for adjustment of status with USCIS. DOS, moreover, may not issue a visa and USCIS may not grant adjustment of status unless the individual's priority date is earlier than the corresponding cut-off date in the ''final action date'' chart listed in the Visa Bulletin.

[16] *See* 8 CFR 205.2.

[17] *See* Retention of EB–1, EB–2, and EB–3 Immigrant Workers and Program Improvements Affecting High-Skilled Nonimmigrant Workers, 81 FR 82398, 82485 (Nov. 18, 2016).

[18] The Nat'l Bureau of Econ. Research, U.S. Business Cycle Expansions and Contractions, *available at http://www.nber.org/cycles.html.*

average of over 5,500 petitions per year. And between FY 2014 and FY 2015 alone, the program received over 25,000 petitions.[19] As a result, demand for EB–5 visas by investors has now outpaced the annual supply, resulting in visa backlogs for certain petitioners and their family members. Individuals affected by those backlogs frequently wait for one year or more before they can obtain conditional permanent residence.

The EB–5 program began to experience oversubscription (*i.e.,* demand that outpaced the supply in visa numbers) for the first time during FY 2014. At that time, DOS announced that EB–5 visas were no longer available for the remainder of the fiscal year for individuals born in China.[20] Since then, the program has continued to experience annual demand from individuals born in China that has outpaced the supply in visas, resulting in increasingly long backlogs every year for those individuals.[21] This trend is anticipated to continue and likely worsen for the foreseeable future, especially considering that individuals born in China currently file about 80 percent of the EB–5 immigrant visas granted on an annual basis.[22] Indeed, given the 20,000 EB–5 petitions currently pending with USCIS, DHS estimates that there are currently 16,000 EB–5 petitions pending for individuals born in China.[23]

Although Congress sets visa numbers, DHS recognizes that having to wait for a visa can create difficulties for individuals seeking to invest in the United States. There are also consequences for investors who invest through a regional center that is subsequently terminated through no fault of the investor. When a regional center is terminated, EB–5 immigrant petitions filed through that regional center are generally also denied or revoked depending on the procedural status of the petition. The filers of such petitions may have met all requirements to participate in the EB–5 program, but absent priority date retention they will lose their place in the immigrant visa queue. Currently, an investor in this situation who wants to continue with the EB–5 immigrant visa process must start the process all over again by investing in a new commercial enterprise and going to the end of the EB–5 visa queue. Allowing priority date retention would allow such an investor to retain his or her place in the queue, thereby alleviating the harsh consequences of regional center terminations and other material changes that occur unexpectedly and through no fault of the investor.

Finally, priority date retention would also benefit other investors with approved EB–5 immigrant petitions who, while waiting for their priority dates to become current, learn that they have invested in severely delayed projects that are likely not to succeed. Under current regulations, such investors cannot reinvest their investment funds without losing their place in the immigrant visa queue. Under the proposed rule, such investors would be able to reinvest in new projects while retaining their previously established priority dates. By allowing priority date retention, DHS is thus eliminating an external incentive that currently distorts market forces and increases financial risk for investors.

DHS welcomes public comment on the proposal to allow investors in certain circumstances to retain their priority dates. DHS also welcomes comment on the proposed standards that may be considered when determining whether or not to allow for priority date retention, including alternative suggestions to those standards.

B. Increasing the Minimum Investment Amount

In 1990, Congress set the minimum investment amount for the program at $1 million and authorized the Attorney General (now the Secretary of Homeland Security) to increase the minimum investment amount, in consultation with the Secretaries of State and Labor. INA section 203(b)(5)(C)(i), 8 U.S.C. 1153(b)(5)(C)(i). Neither the former INS nor DHS has exercised its authority to increase the minimum investment amount. As a result, over the past 25 years inflation has eroded the present-day value of the minimum investment required to participate in the EB–5 program.[24] After consulting with the Departments of State and Labor, DHS proposes to account for inflation by increasing the minimum investment amount consistent with increases in the CPI–U during the intervening period, for a new minimum investment amount of $1.8 million.[25] As discussed below, DHS also proposes to include a mechanism for future adjustments every 5 years, based on the CPI–U.

DHS believes that it is appropriate to adjust the minimum investment amount upward based on inflation, without regard for the amount of capital that would likely be required to fulfill the statutory requirement to create 10 jobs. As a preliminary matter, DHS notes that Congress did not provide for adjustments in the investment threshold to be related in any way to the EB–5 job creation requirements. Indeed, based on the controlling statutory authorities, Congress itself does not appear to have tied the statutory investment thresholds to the job creation requirement. For example, when Congress first created the EB–5 category, Congress established a single job creation standard (*i.e.,* the direct creation of at least 10 jobs) but authorized three different levels of qualifying investments:

(1) The standard minimum investment amount of $1 million;

(2) The reduced minimum investment amount of no less than 50 percent of the standard for investments in targeted employment areas; and

(3) A higher minimum investment amount of up to three times the standard amount for investments in high employment areas.

[19] Statistics provided by USCIS Immigrant Investor Program Office.

[20] DOS issued a statement in August 2014 indicating the EB–5 preference category was unavailable for Chinese nationals through the end of FY2014. *See* Nataliya Rymer, *U.S. Department of State Announces EB–5 Visas for China Unavailable Until October 1, 2014,* Nat'l L. Rev., Aug. 23, 2014, *http://www.natlawreview.com/article/us-department-state-announces-eb-5-visas-china-unavailable-until-october-1-2014.*

[21] While the demand has exceeded supply for investors from China, the demand has not exceeded supply for investors from any other countries as of December 2016.

[22] Dep't of State, Visa Statistics, Report of the Visa Office, *available at https://travel.state.gov/content/visas/en/law-and-policy/statistics.html.*

[23] USCIS, Number of I–526 Immigrant Petitions by Alien Entrepreneurs by Fiscal Year, Quarter, and Case Status 2008–2016, (May 25, 2016) *available at https://www.uscis.gov/sites/default/files/USCIS/Resources/Reports%20and%20Studies/Immigration%20Forms%20Data/Employment-based/I526_performancedata_fy2016_qtr2.pdf.*

[24] DHS also notes that prior to the passage of IMMACT, the former INS provided a written response to Senator Simon regarding the ''creation of a subcategory for immigrant investors'' and stated that the ''minimum investment amount would be set in terms of the value of the dollar at the time of enactment and would be adjusted periodically based on some criteria such as the Consumer Price Index.'' *A Bill to Amend the Immigration and Nationality Act to Effect Changes in the Numerical Limitation and Preference System for the Admission of Immigrants: Hearing on S. 1611 Before the S. Subcomm. on Immigr. & Refugee Aff. of the S. Comm. on the Judiciary,* 100th Cong. 90 (1987) (statement of Mark W. Everson, Deputy Comm'r of the Immigr. and Naturalization Serv.).

[25] DHS may conduct further consultations following receipt of public comment and prior to issuing a final rule. The $1.8 million figure is rounded down to the nearest hundred thousand from approximately $1,813,443, based on an inflation factor of 1.813443 between 1990 and 2015. The actual increase in prices is obtained as $((CPI\text{–}U_{2015}/CPI\text{–}U_{1990})\text{–}1)$. Using a base period of 1982–84, the CPI–U increased from 130.7 in 1990 to 237.017 in 2015, for an actual increase in price of approximately 81.34 percent. DHS rounded the figure down for ease of agency administration and the convenience of all stakeholders. The CPI–U data is publicly available at *http://www.bls.gov/data/#prices.*

As noted, Congress originally provided for up to three different qualifying investment amounts but did not vary the job creation requirements to correspond to the level of investment. Congress also did not tie investment levels to job creation criteria when it established the regional center program. For regional center investments, Congress used the same three investment levels as the original program but varied the job creation requirement by including both direct and *indirect* job creation. Based on the plain language of INA section 203(b)(5)(C)(i) and the regional center legislation, Congress does not appear to have intended to tie the minimum investment amounts to the number of jobs to be created.

DHS considered a number of different measures upon which to base the proposed adjustment and future adjustments. Among these, DHS is proposing to rely on the Consumer Price Index (CPI), which ''is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services.'' [26] According to the Bureau of Labor Statistics at the Department of Labor (DOL), the CPI is—

> the most widely used measure of inflation . . . . It provides information about price changes in the Nation's economy to government, business, labor, and private citizens and is used by them as a guide to making economic decisions. . . . The CPI and its components are used to adjust other economic series for price changes and to translate these series into inflation-free dollars.[27]

The specific CPI index that DHS proposes to rely on is the unadjusted All Items CPI–U. The CPI–U is the ''broadest and most comprehensive CPI,'' and using unadjusted data is more appropriate for this purpose, because seasonally adjusted CPI data is subject to revision for up to five years after their original release, making such data difficult to use for escalation purposes.[28]

DHS also considered other indices used by the Bureau of Labor Statistics to measure different aspects of inflation.[29] One of these is the Producer Price Indexes, which ''measure changes in the selling prices received by domestic producers of goods and services.'' [30] Although the Producer Price Indexes could also provide an appropriate measure for adjusting the standard minimum investment amount, DHS believes the CPI–U is a better measure because it is more widely relied upon.[31] The BLS also produces a number of other business cost statistics that measure labor costs or the costs of goods and services,[32] but DHS chose not to propose these as measures as they are more narrowly focused on different and discrete aspects of economic activity.

Because the EB–5 program is focused on investment, DHS also considered adjusting the standard minimum investment amount based on changes in the overall value of a specific stock index, such as the Dow Jones Industrial Average or the Standard and Poor's 500 Stock Index. But these indexes are based on trades in the secondary market that are tied to the value of existing companies strictly for investment purposes. By comparison, investment in the EB–5 program is related to job creation, which in turn results from an adequately capitalized enterprise (as determined by the costs of goods or services required to do business). DHS believes the CPI–U is a more appropriate indicator of the costs of goods and services necessary for an EB–5 enterprise to be adequately capitalized for the purpose of job creation.

DHS believes that increasing the standard minimum investment amount to account for inflation since creation of the EB–5 program would both modernize the program and ensure a level of capital investment in the United States that more closely adheres to congressional intent. DHS also believes that this change will benefit the U.S. economy by increasing the amount of foreign investment in the United States. This conclusion is supported by the fact that the EB–5 program has recently suffered from oversubscription at current investment levels; that investors' economic resources have likely increased since the program's creation by at least the rate of inflation; and that even with the proposed increases, the EB–5 program would remain extremely competitive with other countries' investor visa programs, which typically require higher investment thresholds.[33]

In addition to raising the standard minimum investment amount effective as of the date specified in the final rule, DHS proposes that the minimum investment amount be adjusted every 5 years based on the CPI–U. *See* proposed 8 CFR 204.6(f)(1). DHS proposes that each such future adjustment will be in effect for a 5-year period beginning on October 1 of the year of the adjustment. *Id.* DHS believes it is important to include a periodic inflation-adjustment mechanism in the regulations to avoid a recurrence of the current situation, where the minimum investment amount remains unchanged for a lengthy period and is eroded by inflation. DHS also proposes to adjust the investment threshold every 5 years, rather than on an annual basis, as a way of balancing the need to counteract inflation with the need to provide predictability and reliability to stakeholders. Such predictability is especially helpful for investors and project developers who need to prepare for the infusion of pooled EB–5 capital into new commercial enterprises. DHS estimates that more than 96 percent of all EB–5 immigrant petitions filed are based on pooled investments involving more than one EB–5 investor in the same new commercial enterprise. In addition, a 5-year adjustment period would be straightforward for the agency to administer in adjudicating multiple petitions based on investments in the

[26] Bureau of Labor Statistics, Consumer Price Index: Frequently Asked Questions, *available at http://www.bls.gov/cpi/cpifaq.htm;* Bureau of Labor Statistics, Consumer Price Index: Addendum to Frequently Asked Questions, *available at http://www.bls.gov/cpi/cpiadd.htm#2_1.*

[27] *Id.*

[28] *See id.*

[29] Bureau of Labor Statistics, Overview of BLS Statistics on Inflation and Prices, *available at http://www.bls.gov/bls/inflation.htm.*

[30] Bureau of Labor Statistics, Producer Price Indexes: Frequently Asked Questions, *available at http://www.bls.gov/ppi/ppifaq.htm.*

[31] Bureau of Labor Statistics, Consumer Price Index: Addendum to Frequently Asked Questions, *available at http://www.bls.gov/cpi/cpiadd.htm.* For additional comparison of CPI and PPI, see Bureau of Labor Statistics, Comparing the Producer Price Index for Personal Consumption with the U.S. All Items CPI for All Urban Consumers, *available at https://www.bls.gov/cpi/cpiadd.htm.*

[32] Bureau of Labor Statistics, Overview of BLS Statistics on Business Costs, *available at http://www.bls.gov/bls/business.htm.*

[33] The United Kingdom's Tier 1 Investor visa requires a minimum investment of £2,000,000 (approximately $2.5 million USD), and offers permanent residence to those who have invested at least £5 million (approximately $6.3 million USD). *Tier 1 (Investor) Visa,* Gov.UK, *https://www.gov.uk/tier-1-investor/overview.* Australia's Significant and Premium Investment Visa Programs require AU $5 million (approximately $3.7 million USD) and AU $15 million (approximately $11.2 million USD), respectively; its ''investor stream'' visa program requires an AU $1.5 million (approximately $1.1 million USD) investment and a host of other requirements. *Business Innovation and Investment Visa,* Australian Government, *http://www.border.gov.au/Trav/Visa-1/188-.* Canada's Immigrant Investor Venture Capital Pilot Program requires a minimum investment of CDN $2 million (approximately $1.5 million USD) and a net worth of CDN $10 million (approximately $7.6 million USD) or more. *Immigrant Investor Venture Capital Pilot Program,* Government of Canada, *http://www.cic.gc.ca/english/immigrate/business/iivc/eligibility.asp.* New Zealand's Investor 1 Resident Visa requires a NZ $10 million (approximately $7.2 million USD) investment, and its Investor 2 Resident Visa requires a NZ $2.5 million (approximately $1.8 million USD) investment. *Investor Visas,* New Zealand Now, *https://www.newzealandnow.govt.nz/move-to-nz/new-zealand-visa/visas-to-invest/investor-visa.* Currency exchange calculations are as of December 2016.

same new commercial enterprise and business plan, filed over a period of several years.

Finally, DHS proposes that each investor will be required to contribute the minimum investment amount that is designated at the time the initial petition is filed. *See* proposed 8 CFR 204.6(f)(1). EB–5 investors may qualify for the program based either on having made their investment prior to petition filing or by being in the process of investing at the time of filing. However, all EB–5 investors must demonstrate a present commitment of the full minimum amount of required investment at the time the petition is filed. DHS believes that tying the required minimum investment amount to the amount designated at the time of filing provides clarity for stakeholders and simplifies the adjudication process for the agency.

DHS seeks public comment on all aspects of this proposal, including the proposed increase of the standard minimum investment amount to $1.8 million, the proposed 5-year inflation-adjustment periods, the proposed use of the CPI–U as the basis for the initial increase and the periodic adjustments, the proposal to round future adjustments down to the nearest 100,000, and the proposed requirement that the minimum investment amount be set at the time of filing the EB–5 immigrant petition. DHS recognizes that under this proposal, the required minimum investment amount would increase significantly, in relative and absolute terms, to account for a quarter century of inflation. DHS is seeking comment on whether it should increase the standard minimum investment amount as proposed under this rule, or whether a different methodology or different investment amount would be more appropriate. DHS also seeks comment on whether it should implement any such increase incrementally or by another method that reduces impacts on stakeholders. DHS notes, however, that incremental increases may result in a lack of clarity for stakeholders and may pose operational burdens on adjudicators.

C. Increasing the Minimum Investment Amount for High Employment Areas

Congress also provided DHS with the authority to set the qualifying investment amount for high employment areas to an amount greater than—but not three times greater than—the standard minimum investment amount. *See* INA section 203(b)(5)(C)(iii), 8 U.S.C. 1153(b)(5)(C)(iii). At the outset of the program, the former INS did not wish to increase the investment for these areas beyond $1 million. *See* 56 FR 60897, 60903. Because the standard minimum investment amount has applied to such areas since the program's inception, DHS has not tracked which projects have been set in high employment areas. DHS thus does not have sufficient information at this time to determine whether to increase the investment threshold for such areas. DHS recently adjusted its forms to capture this information, which, once collected and analyzed, may help the Department determine whether to adjust the minimum investment amount for high employment areas. For now, however, DHS is not proposing an increase beyond the standard minimum investment amount, and therefore proposes applying the standard investment threshold in high employment areas. *See* proposed 8 CFR 204.6(f)(3). DHS also proposes that the minimum investment amount for high employment areas be adjusted consistent with adjustments to the standard investment threshold—*i.e.,* every five years based on increases in the CPI–U and rounded down to the nearest 100,000.

DHS seeks public comment on all aspects of this proposal, including the continuing application of the standard investment threshold to high employment areas, which would increase the threshold to $1.8 million, the proposed 5-year inflation-adjustment periods, the proposed use of the CPI–U as the basis for the periodic adjustments, and the proposal to round future adjustments down to the nearest 100,000.

D. Increasing the Minimum Investment Amount for TEAs

In 1990, Congress set the minimum investment amount for the program at $1 million and authorized DHS to set a different amount for investments made in TEAs (*i.e.,* rural areas and areas of high unemployment). *See* INA section 203(b)(5)(C)(ii), 8 U.S.C. 1153(b)(5)(C)(ii). Specifically, Congress authorized DHS to reduce the minimum investment amount in a TEA by up to 50 percent of the standard minimum investment amount. *Id.* The former INS subsequently issued regulations in 1991 setting the TEA investment threshold at 50 percent of the minimum investment amount, or $500,000.[34] *See* 8 CFR 204.6(f)(2).

In establishing two tiers of investment, and setting aside 3,000 visas for those investing in rural areas and areas subject to high unemployment, Congress sought to incentivize investment in such areas.[35] But although some in Congress expected that most investors would invest at the higher amount,[36] experience shows that such investments have become relatively rare. An agency analysis of petitions filed in 2015 indicates that approximately 97 percent of all investments by EB–5 petitioners are made in TEAs and thus at the reduced amount of $500,000. In other words, while Congress expressed concern about investments in TEAs and thus set aside approximately 30 percent of visas at a reduced investment amount for such purpose, investments in TEAs have effectively become the settled norm. As investments in TEAs have dominated the program in recent years, the de facto standard threshold has become $500,000, thus undermining congressional aims to also encourage investments at the standard minimum investment amount of $1 million.

Accordingly, DHS has determined that the large differential between the standard and reduced investment amounts has failed to strike the balance that Congress appears to have intended by creating a multi-leveled investment framework in the EB–5 program. Moreover, based on its 25-year history implementing the program, DHS believes that the differential—and the sizable monetary incentive it presents—has the potential of distorting general market forces and the business decisions that follow from such forces to an unintended degree. To strike a better balance between investments at the standard and reduced thresholds, and to reduce the degree to which the differential between the thresholds affects investment decisions, DHS is proposing to reduce the difference between the two investment thresholds. Specifically, DHS is proposing to set the

[34] In the final rule published in 1991, the former INS noted that 82 commenters called for the maximum percentage reduction because they believed that ''lowering the investment capital requirement would promote the purpose of the Act to stimulate investment in rural and high unemployment areas.'' 56 FR 60897 (Nov. 29, 1991). ''They further felt that viable businesses could be maintained with the lower investment amount.'' *Id.*

[35] *See* 135 Cong. Rec. S7858–02 (July 13, 1989) (statement of Sen. Boschwitz) (stating that the amendment's purpose was to ''attract significant investments to rural America.''); 136 Cong. Rec. S17106–01 (Oct. 26, 1990) (statement of Sen. Simon) (''We are mindful of the need to target investments to rural America and areas with particularly high unemployment—areas that can use the job creation the most . . . America's urban core and rural areas have special job creation needs.'').

[36] *See* 136 Cong. Rec. S17106–01 (Oct. 26, 1990) (statement of Sen. Simon) (''The general rule-and the vast majority of the investor immigrants will fit in this category-is that the investor must invest $1 million and create 10 U.S. jobs.'').

minimum amount for investments in TEAs at 75 percent of the standard amount (*i.e.,* change the percentage reduction for investments in TEAs from 50 percent of the standard amount to 25 percent of the standard amount). *See* proposed 8 CFR 204.6(f)(2). Because DHS has proposed to set the standard investment amount at $1.8 million, the effect of this change is to set the TEA investment amount at $1.35 million (*i.e.,* 75% of $1.8 million).

DHS considered changing the percentage reduction for TEA investments to various degrees but settled on a 25 percent reduction for several reasons. First, DHS believes that reducing the TEA investment discount by half will significantly reduce the potential for unintended distortions in investment decisions. Second, DHS notes that a 25 percent reduction represents a midway point between the two extremes allowed by Congress—applying the maximum 50 percent reduction and applying no reduction at all. Because DHS is seeking to reduce the investment imbalance caused by the 50 percent differential on the one hand, while continuing to effectuate the congressional intent of incentivizing investments in rural and high unemployment areas on the other, DHS believes that proposing the midway point between the two possible extremes for public comment is appropriate. Third, DHS determined that due to other proposed changes to the standard minimum investment amount in this rulemaking, the impact of a 25 percent reduction for TEA investments would initially be softened by the fact that the difference between the standard amount and the TEA investment amount, in terms of dollars, would remain roughly the same (changing from $500,000 to $450,000). Thus, at least for the first 5 years after the change proposed in this section, investors who choose to invest in TEAs will be able to invest at approximately the same savings in terms of real dollars as they do under the current regulations.

Finally, in addition to proposing to raise the minimum investment amount for TEAs, DHS proposes to adjust this amount every five years consistent with other parts of this proposed rule. *See* proposed 8 CFR 204.6(f)(2). Specifically, DHS proposes to keep the investment threshold for TEAs at 75 percent of the standard investment threshold. *Id.* As with the standard investment threshold, adjustments to the TEA investment threshold would be in effect for a 5-year period beginning on October 1 of the year of the adjustment. *Id.*

DHS welcomes public comment on all aspects of this proposal, including the proposed minimum investment amount for TEAs as well as the proposal for adjusting the amount every five years. DHS also welcomes comment on the specific percentage reduction for TEA investments relative to the standard investment threshold, including alternative suggestions on the percentage to be considered.

E. TEA Designation Process

As discussed in the previous section, Congress created the two-tier investment system in order to incentivize investments in targeted employment areas, defined in the statute as ''a rural area or an area which has experienced high unemployment (of at least 150 percent of the national average rate).'' 8 U.S.C. 1153(b)(5)(B)(ii). In subsequent regulations published in 1991, the former INS allowed investors to demonstrate that their investment was in a high unemployment area in one of two ways: (1) By providing evidence that the metropolitan statistical area, the specific county within a metropolitan statistical area, or the county in which a city or town with a population of 20,000 or more is located, in which the new commercial enterprise is principally doing business has experienced an average unemployment rate of at least 150 percent of the national average rate; or (2) by submitting a letter from an authorized body of the government of the state in which the new commercial enterprise is located which certifies that the geographic or political subdivision of the metropolitan statistical area or of the city or town with a population of 20,000 or more in which the enterprise is principally doing business has been designated a high unemployment area. 8 CFR 204.6(j)(6)(ii). When the INS promulgated this provision, it permitted states to designate smaller TEAs—areas within an MSA or within a city or town with a population of 20,000 or more—because the agency believed that due to the nature of the data involved, states should have an opportunity to participate in TEA determinations.[37]

Reliance on states' TEA designations has resulted in the application of inconsistent rules by different states. Some of these rules understandably may be motivated primarily by the desire to promote economic development in the relevant state, rather than by the desire to fulfill congressional intent with respect to the EB–5 program.[38] As mentioned previously, at least 97 percent of all EB–5 petitions filed in 2015 involved investments at the lower investment threshold for projects in TEAs. In addition, the deference to state determinations provided by current regulations has resulted in the acceptance of some TEAs that consist of areas of relative economic prosperity linked to areas with lower employment, and some TEAs that have been criticized as ''gerrymandered.''[39]

For these reasons, DHS proposes to eliminate state designation of high unemployment areas. This change would help ensure consistency across TEA designations. DHS would itself determine which areas qualify as TEAs, by applying standards proposed in this rule to the evidence presented by investors and regional centers. DHS alternatively considered continuing to allow states to make TEA designations while providing a clearer basis for DHS to scrutinize and overturn such designations. DHS, however, currently prefers to avoid such an approach because of the administrative burden it presents. DHS believes it would be more difficult to evaluate the individualized determinations of the various states than to implement and administer a nationwide standard on its own.

The proposed new standards for designating TEAs are as follows. First, the term ''targeted employment area'' would be defined, consistent with statutory authority, to mean an area which, at the time of investment, is a rural area or is designated as an area

[37] 56 FR 60897 (Oct. 26, 1990) (''With respect to geographic and political subdivisions of this size, however, the Service believes that the enterprise of assembling and evaluating the data necessary to select targeted areas, and particularly the enterprise of defining the boundaries of such areas, should not be conducted exclusively at the Federal level without providing some opportunity for participation from state or local government.'').

[38] *Is the Investor Visa Program an Underperforming Asset?: Hearing Before the H. Comm. on the Judiciary,* 114th Cong. 62 (2016) (statement of Matt Gordon, Chief Exec. Officer, E3 Inv. Group) ((''Generally, States quickly learned to be as permissive as possible in an attempt to attract ever greater amounts of EB–5 capital.''); *see also The Distortion of EB–5 Targeted Employment Areas: Time to End the Abuse: Hearing Before the S. Comm. on the Judiciary,* 114th Cong. 12 (2016) (statement of Gary Friedland, Scholar-in-Residence, N.Y. Univ., Stern School of Bus.) (''USCIS' continued delegation to the states of the TEA authority without guidelines results in the application of inconsistent rules by the various states. More important, each state has the obvious self-interest to promote economic development within its own borders. Delegation presents an opportunity for the states to establish lenient rules to enable project locations to qualify as a TEA. Compounding the problem, often the state agency that is charged with making the TEA determination is the same agency that promotes local economic development. As a consequence, virtually every EB–5 project location qualifies as a TEA.'').

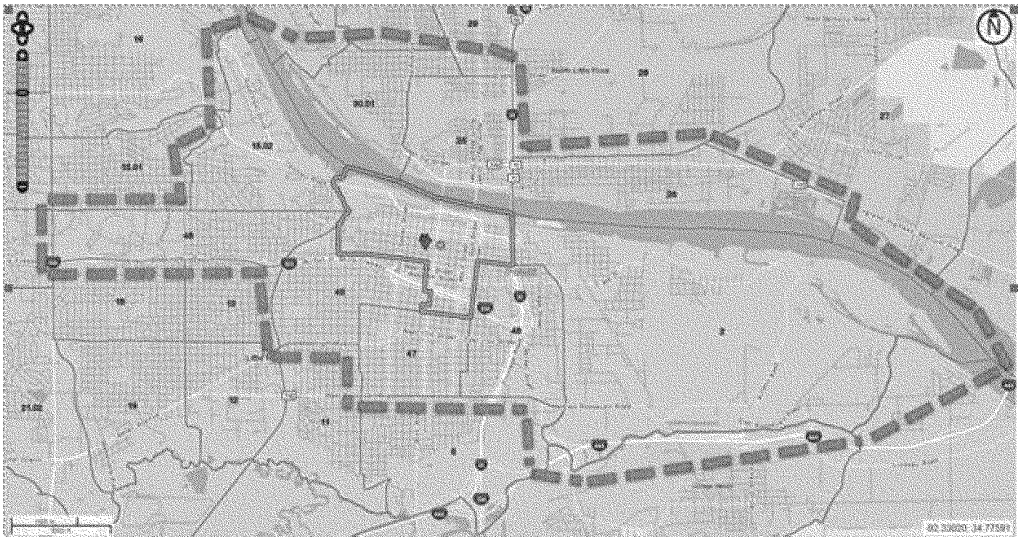
[39] *See, e.g.,* Eliot Brown, *Swanky New York Condo Project Exploits Aid Program,* Wall St. Journal, Oct. 13, 2015, *http://www.wsj.com/articles/posh-tower-proposed-for-struggling-new-york-neighborhood-central-park-south-1444728781.*

which has experienced unemployment of at least 150 percent of the national average rate. *See* proposed 8 CFR 204.6(e). DHS is also proposing to amend the definition of a ''rural area'' to mean any area other than an area within a metropolitan statistical area (as designated by the Office of Management and Budget (OMB)) or within the outer boundary of any city or town having a population of 20,000 or more based on the most recent decennial census of the United States. *See* proposed 8 CFR 204.6(e). This definition clarifies, consistent with statute, that qualification as a rural area is based on data from the most recent decennial census of the United States.

DHS is also proposing new guidelines for the designation of a TEA. As in the current system, investors may continue to provide evidence that the new commercial enterprise is principally doing business in (1) an MSA, (2) a specific county within an MSA, or (3) a county with a city or town with a population of 20,000 or more, that has experienced an average unemployment rate of at least 150 percent of the national average rate. *See* proposed 8 CFR 204.6(j)(6)(ii)(A). To this list, DHS proposes to add cities and towns with a population of 20,000 or more. *Id.* Because cities and towns fall between counties and MSAs on the one hand, and geographic or political subdivisions *within* counties and MSAs on the other, DHS believes it is appropriate to include them as an area that could independently qualify as a TEA if the average unemployment rate for the city or town is at least 150 percent of the national average.

In addition to including cities and towns, DHS proposes new rules for determining when a geographic or political subdivision could qualify as a TEA—determinations that states currently make on a case-by-case basis. DHS proposes that a TEA may consist of a census tract or contiguous census tracts in which the new commercial enterprise is principally doing business [40] (the ''project tract(s)'') if the weighted average of the unemployment rate [41] for the tract or tracts is at least 150 percent above the national average. *See* proposed 8 CFR 204.6(i). Moreover, if the project tract(s) do not independently qualify under this analysis, a TEA may also be designated if the project tract(s) and any or all additional tracts that are directly adjacent to the project tract(s) comprise an area in which the weighted average of the unemployment rate for all of the included tracts is at least 150 percent of the national average. *Id.* DHS proposes that petitioners submit a description of the boundaries of the geographic or political subdivision and the unemployment statistics in the area for which designation is sought as set forth in proposed 8 CFR 204.6(i), and the method or methods by which the unemployment statistics were obtained. *See* proposed 8 CFR 204.6(j)(6)(ii)(B).

The figure below illustrates how to apply the proposed limitations.[42] The areas on the map outlined with a thin solid line represent census tracts. The tract outlined in a solid bold line near the center, just south of the waterway, represents the project tract in which the new commercial enterprise (represented by the pointer) is principally doing business. The broader area outlined in a dashed bold line contains all of the tracts that are adjacent to the project tract. Under the proposed limits, the tract outlined in a solid bold line may independently qualify as a TEA. If it does not, an area consisting of that tract and any or all of the additional tracts outlined in the dashed bold line could qualify as a TEA. Qualification is determined by looking to the weighted average unemployment rate of the entire area proposed.



[40] According to USCIS policy in effect at the time of issuance of this proposed rulemaking:

A new commercial enterprise is principally doing business in the location where it regularly, systematically, and continuously provides goods or services that support job creation. If the new commercial enterprise provides such goods or services in more than one location, it will be principally doing business in the location most significantly related to the job creation.

Factors considered in determining where a new commercial enterprise is principally doing business include, but are not limited to, the location of:

- Any jobs directly created by the new commercial enterprise;
- Any expenditure of capital related to the creation of jobs;
- The new commercial enterprise's day-to-day operation; and
- The new commercial enterprise's assets used in the creation of jobs.

USCIS Policy Manual, 6 USCIS–PM G (Nov. 30, 2016).

[41] In order to determine if a project qualifies for TEA designation USCIS would first determine the weighted unemployment rate for each census tract in the TEA area. To determine the weighted unemployment rate of a census tract, USCIS would divide the labor force (civilians ages 16 and older who are employed or employed, plus active duty military) of each census tract by the labor force of the entire TEA area. USCIS would then multiply this figure by the unemployment rate of that specific census tract. The resulting figure is the weighted unemployment rate for each individual census tract. The total weighted unemployment rate is the sum of the weighted unemployment rates for each census tract in the TEA area. If the total weighted unemployment rate is 150% above the national unemployment rate then the project would qualify for TEA designation.

[42] For ease of reference, a color-coded version of this figure is available in the docket for this rulemaking.

The proposed new TEA designation rules would rely on the census tract as the building block for the geographic or political subdivision for multiple reasons. First, census tracts offer uniformity. Although census tracts vary in size, they are generally drawn to define a residential population of between 1,200 and 8,000 people, with an optimum size of 4,000 people per census tract according to the U.S. Census Bureau.[43] No census tract can extend beyond county lines, meaning the largest census tract would, at most, cover a single county.[44] Second, data at the census tract level is more readily publicly available, and is updated annually based on data collected through the Census Bureau's ''American Community Survey'' (ACS).[45] Third, census tract numbering is generally stable and would only change at the time of the next available census (generally every 10 years). Fourth, as local planning agencies can request changes to census tract configurations, the use of census tracts still provides localities with some input into the overall process. However, DHS believes this input is sufficiently limited to avoid concerns regarding political influence on TEA designations, because census tracts typically only change when populations change to the point that a tract is split or two tracts are merged.[46] DHS also surveyed agencies in several locations to obtain information regarding how they have approached the TEA designation process, namely: the states of Illinois, New York, and California, and the city of Dallas, Texas. Every state or local agency consulted by DHS relied on census tract level unemployment data in the TEA designation process.[47]

In addition to utilizing the census tract as the most appropriate and reliable building block for EB–5 program purposes, DHS believes it is appropriate for a TEA to consist of both the project tract(s) and the census tracts adjacent to the project tracts as such an area—including the tracts immediately surrounding the project tract(s)—is likely to experience the employment-creation impact of the investment. DHS considered extending the cluster to census tracts beyond those directly adjacent to the project tract(s), but determined that doing so in some cases would include areas that are too far from the site of the proposed project.[48]

DHS considered other options presented by stakeholders[49] and during congressional hearings[50] to determine the parameters for a TEA. One option DHS considered was limiting the geographic or political subdivision to the project tract(s). This option would be easy to put in practice for both stakeholders and the agency, but was considered too restrictive in that it would exclude immediately adjacent areas that would be impacted by the investment. Another option DHS considered was limiting the geographic or political subdivision to an area containing up to, but no more than, 12 contiguous census tracts, an option currently used by the state of California in its TEA designation process.[51] However, DHS is not confident that this option is necessarily appropriate for nationwide application, as the limitation to 12 census tracts may be justifiable for reasons specific to California but may not be apt on a national scale.

DHS also considered options based on a ''commuter pattern'' analysis, which focuses on defining a TEA as encompassing the area in which workers may live and be commuting from, rather than just where the investment is made and where the new commercial enterprise is principally doing business. The ''commuter pattern'' proposal was deemed too operationally burdensome to implement as it posed challenges in establishing standards to determine the relevant commuting area that would fairly account for variances across the country.[52] In addition, DHS could not identify a commuting-pattern standard that would appropriately limit the geographic scope of a TEA designation

[43] U.S. Census Bureau, Census Tracts, *available at https://www.census.gov/geo/reference/webatlas/tracts.html.*

[44] U.S. Census Bureau, Geographic Terms and Concepts—Census Tract, *available at https://www.census.gov/geo/reference/gtc/gtc_ct.html* (Note: Tribal census tracts are unique and can cross state and county boundaries).

[45] U.S. Census Bureau, Am. Cmty. Survey, *available at http://factfinder.census.gov/faces/nav/jsf/pages/programs.xhtml?program=acs.*

[46] U.S. Census Bureau, Geography: Census Tracts, *available at https://www.census.gov/geo/reference/webatlas/tracts.html.*

[47] We note that only one state, California, set parameters on the use of census tracts, limiting the tracts to 12 contiguous tracts encompassing the investment project location.

[48] *See* Stuart S. Rosenthal and William C. Strange, *Evidence on the Nature and Sources of Agglomeration Economies,* Aug. 24, 2003, *available at http://siteresources.worldbank.org/INTLED/Resources/339650-1105473440091/WillAndStuart.pdf* (''More recently still, Rosenthal and Strange (2003) provide a micro-level analysis of the geographic scope of agglomeration economies. The environment of an establishment is measured by constructing rings around the centroid of the establishment's zip code. Rings of 1 mile, 5 miles, 10 miles, and 15 miles are included. For each of the six industries studied . . . new arrivals are more likely to be attracted to zip codes as employment in the own industry within one mile increases. Employment in the own industry just five miles away, however, has a much smaller effect, as does employment further out in the ten and fifteen mile rings.''); *see also* John C. Ham, Charles Swenson, Ayşe İmrohoroğlu, and Heonjae Song, *Government Programs Can Improve Local Labor Markets: Evidence from State Enterprise Zones, Federal Empowerment Zones and Federal Enterprise Communities,* 95 J. Pub. Econ. 779, 779–97 (2011) (''Federal and state governments spend well over a billion dollars a year on programs that encourage employment development in disadvantaged labor markets through the use of subsidies and tax credits . . . . We find that all three programs have positive, statistically significant, impacts on local labor markets in terms of the unemployment rate, the poverty rate, the fraction with wage and salary income, and employment.'').

[49] On April 25, 2016, DHS held an EB–5 Listening Session, in which it solicited and received feedback from stakeholders on several issues, including the TEA process. Stakeholders expressed concerns about a lack of consistency in state TEA designations (''I think we all know that every single state in this union has a different way of doing targeted employment areas''), the inefficiency of state TEA designation (''I think that the current process is very inefficient . . . the states are reviewing . . . federal data and the states don't provide any benefit.''), and the natural incentive for states to approve TEAs (''The other thing is that . . . there's an incentive to lower the hurdle for their state.''). DHS further solicited feedback on the same issues through its Idea Community Web site, an online portal available to the general public. *See* USCIS Idea Community, *https://www.uscis.gov/outreach/uscis-idea-community;* Remarks, EB–5 Immigrant Investor Program Stakeholder Engagement (July 28, 2016), *available at https://www.uscis.gov/sites/default/files/USCIS/Outreach/Notes%20from%20Previous%20Engagements/PED_EB5NatStakeholderEng072816_MackenzieRemarks.pdf.* DHS received various suggestions for changing the TEA process, including the consideration of commuting patterns and greater scrutiny of the state designation process by DHS.

[50] *See The Distortion of EB–5 Targeted Employment Areas: Time to End the Abuse: Hearing Before the S. Comm. on the Judiciary,* 114th Cong. (2016) (statement of Gary Friedland, Scholar-in-Residence, N.Y. Univ., Stern School of Bus.).

[51] *See* Cal. Governor's Office of Bus. and Econ. Dev., EB–5 Investor Visa Program, *available at http://business.ca.gov/International/EB5Program.aspx.*

[52] DHS reviewed a proposed commuter pattern analysis incorporating the data table, Federal Highway Administration, CTPP 2006–2010 Census Tract Flows, *available at* (*http://www.fhwa.dot.gov/planning/census_issues/ctpp/data_products/2006-2010_tract_flows/*) (last updated Mar. 25, 2014). DHS found the required steps to properly manipulate the Census Transportation Planning Product (CTPP) database might prove overly burdensome for petitioners with insufficient economic and statistical analysis backgrounds. Further, upon contacting the agency responsible to manage the CTPP data table, DHS was informed that the 2006–2010 CTPP data is unlikely to be updated prior to FY2018 to incorporate proposed changes to the data table. U.S. Census is currently reviewing the CTPP proposed changes. As an alternate methodology for TEA commuter pattern analysis, DHS reviewed data from the U.S. Census tool, On the Map, *http://onthemap.ces.census.gov/*, which is tied to the U.S. Census Bureau's American Community Survey. Although the interface appeared to be more user-friendly overall, using this data would be operationally burdensome, potentially requiring hours of review to obtain the appropriate unemployment rates for the commuting area.

consistent with the statute and the policy goals of this proposed regulation.

DHS believes the proposed guidelines limiting TEAs to MSAs, counties, cities, or project tracts (including any and all adjacent tracts) would remove the possibility of gerrymandering and better ensure that the reduced investment threshold is reserved for areas experiencing significantly higher levels of unemployment. DHS seeks public comment on all aspects of this proposal, including on the feasibility and appropriateness of each of the potential alternatives to the census tract model discussed above, as well as any other alternatives that commenters wish to propose. With respect to all such alternatives, DHS would particularly benefit from comments that set forth a clear and easily administrable methodology.

F. Technical Changes

DHS is also proposing a number of other technical changes. These changes would variously: (1) Clarify the filing process for derivatives who are filing the Petition by Entrepreneur to Remove Conditions on Permanent Resident Status (Form I–829) separately from the immigrant investor; (2) enhance flexibility in determining the interview location related to the Form I–829 adjudication; and (3) update the regulation to conform to the current process for issuing permanent resident cards after the removal of conditions on status. DHS is also proposing miscellaneous other changes. The proposed changes are described in more detail below.

(1) Separate Filings for Derivatives

The proposed rule would clarify the process by which an immigrant investor's spouse and children file separate Form I–829 petitions when they are not included in the Form I–829 filed by the immigrant investor. Generally, an immigrant investor's derivatives should be included in the principal immigrant investor's Form I–829 petition. *See* 8 CFR 216.6(a)(1). However, there are situations in which derivatives may not be included on the principal immigrant investor's Form I–829 petition, such as when the immigrant investor dies during the conditional residence period, or when the immigrant investor decides not to continue his or her conditional permanent resident status. In such circumstances, if the immigrant investor would have otherwise been eligible to have his or her conditions on status removed, then the derivatives would remain eligible to remove the conditions on their status even if the immigrant investor cannot or will not file a Form I–829 petition.[53]

The current regulation does not clearly define the process by which derivatives may file a Form I–829 petition when they are not included on the principal's petition, including whether each derivative in such cases should file his or her own separate Form I–829 petition or whether the derivatives should jointly file on the same petition. The proposed regulations specify that where the dependent family members cannot be included in the Form I–829 petition filed by the principal investor because that principal is deceased, all dependents of the deceased investor may be included on a single Form I–829 petition. *See* proposed 8 CFR 216.6(a)(1)(ii). DHS also clarifies, however, that consistent with current practice, each derivative must file a separate Form I–829 petition in all other situations in which the investor's spouse and children are not included in the investor's Form I–829 petition. *See id.*

(2) Interviews

Section 216A(c)(1)(B) of the INA, 8 U.S.C. 1186b(c)(1)(B), generally requires Form I–829 petitioners to be interviewed prior to final adjudication of the petition, although DHS may waive the interview requirement in its discretion, *see* INA section 216A(d)(3), 8 U.S.C. 1186b(d)(3). The statute also provides that the interview may be held at a location that ''is convenient to the parties involved.'' *See* INA section 216A(d)(3), 8 U.S.C. 1186b(d)(3). Under current regulations, however, interviews are generally scheduled in the location of the new commercial enterprise, even though there is no statutory or regulatory requirement that the immigrant investor reside in the same location as the new commercial enterprise. Specifically, the current regulation requires the interview to be conducted by an immigration examiner or other officer so designated by the director of the USCIS District Office ''that has jurisdiction over the location of the alien entrepreneur's commercial enterprise.'' 8 CFR 216.6(b)(2).

Under this rule, DHS is proposing to give stakeholders greater flexibility in the interview location by clarifying the agency's discretion under the INA to determine the appropriate location for Form I–829 petition interviews. Specifically, the proposed amendment would allow USCIS to schedule an interview at the USCIS office holding jurisdiction over either the immigrant investor's commercial enterprise, the immigrant investor's residence in the United States, or the location where the Form I–829 petition is adjudicated. *See* proposed 8 CFR 216.6(b)(2). DHS believes this change will both benefit the agency by making the interview process more effective and benefit immigrant investors by reducing the need to travel long distances to participate in Form I–829 petition interviews.

(3) Process for Issuing Permanent Resident Cards

DHS also proposes to amend regulations governing the process by which immigrant investors obtain their new permanent resident cards after the approval of their Form I–829 petitions. After an immigrant investor's Form I–829 petition is approved, the immigrant investor and each included derivative is entitled to a Permanent Resident Card (Form I–551). The provision of this card documents that the conditions on the immigrant investor's LPR status have been removed. Current regulations include an outdated description of the process for obtaining such permanent resident cards. Specifically, the current regulation requires the immigrant investor and his or her derivatives to report to a district office for processing of their permanent resident cards after approval of the Form I–829 petition. 8 CFR 216.6(d)(1). This process is no longer necessary in light of intervening improvements in DHS's biometric data collection program.[54] DHS now captures the required biometric data during the pendency of the Form I–829 petition, at the time the immigrant investor and his or her derivatives appear at an Application Support Center for fingerprinting, as required for the Form I–829 background and security checks. DHS then mails the permanent resident card directly to the immigrant investor by U.S. Postal Service registered mail after the Form I–829 petition is approved. There is therefore no need for each immigrant investor or any derivatives to report to a district office for processing of their permanent resident cards after petition approval.

DHS is thus proposing to remove the mandatory reporting requirement from the regulatory text, and to replace that requirement with the discretionary authority to require an immigrant investor to report to a district office to provide biometric data when needed to

[53] *See* INA section 204(l), 8 U.S.C. 1154(l) (providing that upon the death of the principal beneficiary, surviving relative petitions and ''related applications'' must be adjudicated notwithstanding the death of the principal beneficiary).

[54] DHS already has authority to collect this information under 8 CFR part 103.

complete card production. *See* proposed 8 CFR 216.6(d)(1). This discretionary authority is intended to address circumstances in which an in-person meeting is necessary, such as when the biometrics captured during the Form I–829 background process may not be suitable for issuing a permanent resident card.

(4) Miscellaneous Other Changes

DHS is also proposing a number of other technical changes to the EB–5 regulations. First, DHS is proposing to update a reference to the former United States Customs Service, so that it will now refer to U.S. Customs and Border Protection. *See* proposed 8 CFR 204.6(j)(2)(iii). On March 1, 2003, the Homeland Security Act of 2002 created U.S. Customs and Border Protection, which is now responsible for activities previously handled by the U.S. Customs Service, including the issuance of commercial entry documents. *See* 6 U.S.C. 211.

Second, DHS is proposing to conform DHS regulations to the 21st Century Department of Justice Appropriations Authorization Act, Public Law 107–273, which eliminated the requirement that immigrant entrepreneurs establish a new commercial enterprise from both section 203(b)(5) and section 216A of the INA. Accordingly, USCIS proposes to remove references to this requirement in 8 CFR 204.6 and 216.6.

Third, DHS is proposing to further conform DHS regulations to Public Law 107–273 by removing the references to ''management'' at 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii). Section 203(b)(5)(A) of the INA requires that EB–5 petitioners be seeking ''to enter the United States for the purpose of engaging in a new commercial enterprise.'' INA section 203(b)(5)(A), 8 U.S.C. 1153(b)(5)(A). To give effect to this provision, existing regulations require investors to be ''engaged in the management of the new commercial enterprise,'' which can be accomplished in one of two ways: ''through the exercise of day-to-day managerial control'' or ''through policy formulation.'' 8 CFR 204.6(j)(5). DHS has determined that the reference to ''management'' should be removed, as actual management of the new commercial enterprise is not strictly required by section 203(b)(5)(A) of the INA. The statutory text does not use the term, and strictly requiring the exercise of managerial control may be inconsistent with Public Law 107–273, which amended section 203(b)(5) to expressly permit new commercial enterprises to take the form of limited partnerships (as had been previously permitted by existing regulation). Removal of the reference to ''management'' from 8 CFR 204.6(j)(5) would have no practical effect, as the provision already allows and would continue to allow investors to demonstrate eligibility either through management or through policy formulation. The reference to ''management'' would also be removed from 8 CFR 204.6(j)(5)(iii) because that provision pertains to evidence that is largely unrelated to management.

Fourth, DHS is proposing to remove the phrase ''as opposed to maintaining a purely passive role in regard to the investment'' from 8 CFR 204.6(j)(5). DHS deems this phrase unnecessary as both the existing regulations at 8 CFR 204.6(j)(5)(iii) and the proposed version of that subsection specify the circumstances in which investments may be essentially passive in nature.

Fifth, DHS is proposing to allow investors in any type of entity to demonstrate that they are sufficiently engaged in a new commercial enterprise through policymaking activities by virtue of being an equity holder in the new commercial enterprise with rights, powers and duties normally granted to such equity holders. *See* proposed 8 CFR 204.6(j)(5)(iii). DHS recognizes that the amendment made by Public Law 107–273 to allow limited partnerships to serve as new commercial enterprises was intended to require flexibility in the administration of the EB–5 program with respect to the use of different entity types. Accordingly, to provide clarity and flexibility for all currently existing entity types, including limited liability companies, as well as to accommodate future entity types without creating an unnecessary distortion in the choice of entities used within the EB–5 program, DHS is proposing to revise the regulations to cover all types of entities and to consider equity holders in any type of entity to be considered sufficiently engaged if they are provided with the rights, duties, and powers normally provided to those types of equity holders. *See id.*

Sixth, DHS is proposing to amend 8 CFR 204.6(k) to remove the requirement on USCIS to specify in the decision on the EB–5 immigrant petition whether the new commercial enterprise is principally doing business in a TEA. *See* proposed 8 CFR 204.6(k). This requirement provides no operational benefit to USCIS, as the agency relies on other means to track which approved petitions were based on investments in TEAs. The requirement also provides no benefit to investors; an approved petition based on an investment in a TEA necessarily means that the petitioner has met the burden of satisfying that eligibility requirement, and if a petition is denied due to failure to satisfy the requirement, the decision and analysis will be explicitly stated in the denial. This revision would also replace a reference to the Associate Commissioner for Examinations with a reference to the Administrative Appeals Office, which is now the appropriate appellate authority in denied cases. *See id.*

Finally, DHS is proposing revisions to otherwise unaffected portions of section 204.6 and 216.6 to replace the term ''entrepreneur'' with the term ''investor.'' This will provide clarity and consistency in the program's terminology, including by mirroring terminology in USCIS policy. DHS also proposes to remove the ''Form I–526'' and ''Form I–829'' references in 8 CFR 204.6(a), and 8 CFR 216.6(a) and (b), respectively. Throughout the proposed regulations, DHS has removed references to specific form names and numbers to ensure the regulations remain relevant and informative, regardless of potential future form name or number changes. Additionally, the proposed revision to 8 CFR 216.6(a)(5) would replace the word ''deportation'' with ''removal'' proceedings to conform to terminology used in the INA.

V. Statutory and Regulatory Requirements

A. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. The value equivalent of $100 million in 1995 adjusted for inflation to 2015 levels by the Consumer Price Index for All Urban Consumers is $155 million.

This proposed rule does not include any unfunded Federal mandates. The requirements of Title II of the Act, therefore, do not apply, and DHS has not prepared a statement under the Act.

B. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small

Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States companies to compete with foreign-based companies in domestic and export markets. However, as some small businesses may be impacted under this regulation, DHS has prepared an IRFA under the Regulatory Flexibility Act.

C. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 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 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by OMB.

(1) Summary

This rule proposes changes to certain aspects of the EB–5 program that are in need of reform, and would also update the regulations to reflect statutory changes and codify existing policies. This proposed rule would make three major changes along with other technical and miscellaneous changes to the current regulations. First, DHS proposes to allow EB–5 immigrant petitioners, with limited exception, to use the priority date of an approved EB–5 immigrant petition for any subsequently filed EB–5 immigrant petition for which the petitioner qualifies. Second, DHS proposes to increase the standard minimum investment amount to $1.8 million to account for inflation since the program's inception, and builds in a mechanism to adjust the investment amount based on the unadjusted CPI–U every 5 years. Similarly, DHS proposes to increase the TEA minimum investment amount to $1.35 million, or 75 percent of the standard amount, and to periodically adjust the TEA minimum investment amount so that it remains 75 percent of the standard amount. Third, DHS proposes to eliminate state designation of high unemployment areas and proposes new standards for the designation of TEAs.

DHS is also proposing several technical changes. These changes include clarifying the filing process for derivatives who are filing Form I–829 petitions separately from the principal immigrant investor, providing flexibility in determining the location of interviews for Form I–829 petitions, and updating outdated regulations on how an immigrant investor obtains a new permanent resident card after approval of the Form I–829 petition. Additionally, this proposed rule would make miscellaneous changes including updating references to the U.S. Customs and Border Protection, removing references to requirements that foreign entrepreneurs establish a new commercial enterprise (NCE) in 8 CFR 204.6 and 216.6, removing references to ''management'' at 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii), removing the phrase ''as opposed to maintain a purely passive role in regard to the investment'' from 8 CFR 204.6(j)(5), allowing any type of entity to serve as a new commercial enterprise, amending 8 CFR 204.6(k) to specify how USCIS will issue decisions, and revising 8 CFR 204.6 and 216.6 to use the term ''investor'' instead of ''entrepreneur'' and ''removal'' instead of ''deportation.''

Several of the provisions are expected to generate costs and benefits, although DHS does not have the necessary data to monetize these costs and benefits, with the exception of total costs of approximately $91,000 [55] expected for dependents who would file Form I–829 petitions separately from principal investors. The proposed rule would likely result in long term expected benefits in the form of job stimulation due to increased EB–5 investment overall. The Table below is the same as Table 1 found in the ''Costs and Benefits'' portion of the Executive Summary above and provides a synopsis of each of the provisions in this proposed rule and its estimated impacts. In addition to the impacts outlined in the table, DHS believes that there would be some familiarization costs associated with reading and assessing the proposed rule. Based on several assumptions, DHS estimates these costs to be about $501,154 annually.

TABLE 2—SUMMARY OF CHANGES AND IMPACT OF THE PROPOSED PROVISIONS

Current policy	Proposed change	Impact
Current DHS regulations do not permit investors to use the priority date of an approved EB–5 immigrant petition for a subsequently filed EB–5 immigrant petition.	DHS proposes to allow an EB–5 immigrant petitioner to use the priority date of an approved EB–5 immigrant petition for a subsequently filed EB–5 immigrant petition for which the petitioner qualifies.	Benefits: • Makes visa allocation more predictable for investors with less possibility for large fluctuations in visa availability dates due to regional center termination. • Provides greater certainty and stability regarding the timing of eligibility for investors pursuing permanent residence in the U.S. and thus lessens the burden of unexpected changes in the underlying investment. • Provides more flexibility to investors to contribute into more viable investments, potentially reducing fraud and improving potential for job creation. Costs: • Not estimated.

[55] The cost estimate is rounded from $90,762.

TABLE 2—SUMMARY OF CHANGES AND IMPACT OF THE PROPOSED PROVISIONS—Continued

Current policy	Proposed change	Impact
The standard minimum investment amount has been $1 million since 1990 and has not kept pace with inflation. Further, the statute authorizes a reduction in the minimum investment amount when such investment is made in a TEA by up to 50 percent of the standard minimum investment amount. Since 1991, DHS regulations have set the TEA investment threshold at 50 percent the minimum investment amount. Similarly, DHS has not proposed to increase the minimum investment amount for investments made in a high employment area beyond the standard amount.	DHS proposes to account for inflation in the investment amount since the inception of the program. DHS proposes to raise the minimum investment amount to $1.8 million. DHS also proposes to include a mechanism to automatically adjust the minimum investment amount based on the unadjusted CPI–U every 5 years. DHS proposes to decrease the reduction for TEA investment thresholds, and set the TEA minimum investment at 75 percent of the standard amount. Assuming the standard investment amount is $1.8 million, investment in a TEA would initially increase to $1.35 million. DHS is not proposing to change the equivalency between the standard minimum investment amount and those made in high employment areas. As such, DHS proposes that the minimum investment amounts in high employment areas would be $1.8 million, and follow the same mechanism for future inflationary adjustments.	Benefits: • Increases in investment amounts are necessary to keep pace with inflation and real value of investments; • Raising the investment amounts increases the amount invested by each investor and potentially increases the total amount invested under this program. • For regional centers, the higher investment amounts per investor would mean that fewer investors would have to be recruited to pool the requisite amount of capital for the project, so that searching and matching of investors to projects could be less costly. Costs: • Some investors may be unable or unwilling to invest at the higher proposed levels of investment. • There may be fewer jobs created if fewer investors invest at the proposed higher investment amounts. • For regional centers, the higher amounts could reduce the number of investors in the global pool and result in fewer investors and thus make search and matching of investors to projects more costly. • Potential reduced numbers of EB–5 investors could prevent projects from moving forward due to lack of requisite capital. • An increase in the investment amount could make foreign investor visa programs offered by other countries more attractive.
A TEA is defined by statute as a rural area or an area which has experienced high unemployment (of at least 150 percent of the national average rate). Currently, investors demonstrate that their investments are in a high unemployment area in two ways: (1) providing evidence that the MSA, the specific county within the MSA, or the county in which a city or town with a population of 20,000 or more is located, in which the new commercial enterprise is principally doing business, has experienced an average unemployment rate of at least 150 percent of the national average rate or (2) submitting a letter from an authorized body of the government of the state in which the new commercial enterprise is located, which certifies that the geographic or political subdivision of the metropolitan statistical area or of the city or town with a population of 20,000 or more in which the enterprise is principally doing business has been designated a high unemployment area.	DHS proposes to eliminate state designation of high unemployment areas. DHS also proposes to amend the manner in which investors can demonstrate that their investments are in a high unemployment area. (1) In addition to MSAs, specific counties within MSAs, and counties in which a city or town with a population of 20,000 or more is located, DHS proposes to add cities and towns with a population of 20,000 or more to the types of areas that can be designated as a high unemployment area. (2) DHS is proposing that a TEA may consist of a census tract or contiguous census tracts in which the new commercial enterprise is principally doing business if the weighted average of the unemployment rate for the tract or tracts is at least 150 percent of the national average. (3) DHS is also proposing that a TEA may consist of an area comprised of the census tract(s) in which the new commercial enterprise is principally doing business, including any and all adjacent tracts, if the weighted average of the unemployment rate for all included tracts is at least 150 percent of the national average.	Benefits: • Rules out TEA configurations that rely on a large number of census tracts indirectly linked to the actual project tract by numerous degrees of separation. • Potential to better stimulate job growth in areas where unemployment rates are the highest. Costs: • The proposed TEA provision could cause some projects and investments to not qualify. DHS presents the potential number of projects and investments that could be affected in Table 5.

TABLE 2—SUMMARY OF CHANGES AND IMPACT OF THE PROPOSED PROVISIONS—Continued

Current policy	Proposed change	Impact
Current technical issues: • The current regulation does not clearly define the process by which derivatives may file a Form I–829 petition when they are not included on the principal's petition. • Interviews for Form I–829 petitions are generally scheduled at the location of the new commercial enterprise. • The current regulations require an immigrant investor and his or her derivatives to report to a district office for processing of their permanent resident cards.	DHS is proposing the following technical changes: • Clarify the filing process for derivatives who are filing a Form I–829 petition separately from the immigrant investor. • Provide flexibility in determining the interview location related to the Form I–829 petition. • Amend the regulation by which the immigrant investor obtains the new permanent resident card after the approval of his or her Form I–829 petition because DHS captures biometric data at the time the immigrant investor and derivatives appear at an ASC for fingerprinting.	Conditions of Filing: Benefits: • Adds clarity and eliminates confusion for the process of derivatives who file separately from the principal immigrant investor. Costs: • Total cost to applicants filing separately would be $90,762 annually. Conditions of Interview: Benefits: • Interviews may be scheduled at the USCIS office having jurisdiction over either the immigrant investor's commercial enterprise, the immigrant investor's residence, or the location where the Form I–829 petition is being adjudicated, thus making the interview program more effective and reducing burdens on the immigrant investor; • Some applicants may have cost savings from lower travel costs. Costs: • Not estimated. Investors obtaining a permanent resident card: Benefits: • Cost and time savings for applicants for biometrics data. Costs: • Not estimated.
Current miscellaneous items: • 8 CFR 204.6(j)(2)(iii) refers to the former U.S. Customs Service. • Public Law 107–273 eliminated the requirement that alien entrepreneurs establish a new commercial enterprise from both INA § 203(b)(5) and INA § 216A. • 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii) reference "management"; • Current regulation at 8 CFR 204.6(j)(5) has the phrase "as opposed to maintain a purely passive role in regard to the investment"; • Public Law 107–273 allows limited partnerships to serve as new commercial enterprises; • Current regulation references the former Associate Commissioner for Examinations • 8 CFR 204.6(k) requires USCIS to specify in its Form I–526 decision whether the new commercial enterprise is principally doing business in a targeted employment area • Sections 204.6 and 216.6 use the term "entrepreneur" and "deportation." These sections also refer to Forms I–526 and I–829	DHS is proposing the following miscellaneous changes: • DHS is updating references at 8 CFR 204.6(j)(2)(iii) from U.S. Customs Service to U.S. Customs and Border Protection. • Removing references to requirements that alien entrepreneurs establish a new commercial enterprise in 8 CFR 204.6 and 216.6. • Removing references to "management" at 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii); • Removing the phrase "as opposed to maintain a purely passive role in regard to the investment" from 8 CFR 204.6(j)(5); • Clarifies that any type of entity can serve as a new commercial enterprise; • Replacing the reference to the former Associate Commission for Examinations with a reference to the USCIS AAO. • Amending 8 CFR 204.6(k) to specify how USCIS will issue a decision. • Revising sections 204.6 and 216.6 to use the term "investor" instead of "entrepreneur" and to use the term "removal" instead of "deportation."	These provisions are technical changes and will have no impact on investors or the government. Therefore, the benefits and costs for these changes were not estimated.
Miscellaneous Cost: • Familiarization cost of the rule	Applicants would need to read and review the rule to become familiar with the proposed provisions.	Familiarization costs to review the rule are estimated at $501,154 annually.

(2) Background and Purpose of the Proposed Rule

The preceding sections of the preamble review key historical aspects and goals of the program, and specific justifications for the particular provisions proposed in the rule. This section supplements and provides additional points of analysis that are pertinent to this regulatory impact assessment.

A person wishing to immigrate to the United States under the EB–5 program must file an Immigrant Petition by Alien Entrepreneur (Form I–526). Each individual immigrant investor files a Form I–526 petition containing information about their investment.[56] The investment must be made into either an NCE within a designated regional center in accordance with the Regional Center Program or a standalone NCE outside of the Regional Center

[56] To be eligible at the time of the Form I–526 petition's filing, investors must demonstrate either that they have already invested their funds into the NCE or that they are actively in the process of investing. Some investors choose to demonstrate commitment of funds by placing their capital contribution in an escrow account in a U.S. financial intermediary, to be released irrevocably to the NCE upon a certain trigger date or event, such as approval of the Form I–526 petition.

Program (''non-regional center'' investment). The NCE may create jobs directly (required for non-regional center investments), or serve as a source of funding for separate job creating entities (JCEs) (allowable for regional center investments).

With respect to regional center investors, once a regional center has been designated, affiliated investors can submit Form I–526 petitions in the concurrent year and in future years, provided the regional center maintains its designation. Each year, the stock of approved regional centers represents the previous year's approved total, plus new regional centers approved during the current year, minus a relatively small number of regional centers that are terminated in the concurrent year.[57]

DHS analysis of Form I–526 filing data for FY 2013–2015 indicates that on average, 10,547 Form I–526 petitions were filed annually. Regional centers accounted for 9,623 such petitions annually, or 91 percent of all submitted Form I–526 petitions, while non-regional centers accounted for an average of 924 Form I–526 petitions annually, or 9 percent.

EB–5 filings grew rapidly starting in 2008, when the U.S. financial crisis reduced available U.S.-based commercial lending funds and alternative funding sources, such as the EB–5 program, were sought. Based on the type of projects that Form I–526 petitions describe, it appears that EB–5 capital has been used as a source of financing for a variety of projects, including a large number of commercial real estate development projects to develop hotels, assisted living facilities, and office buildings.

In general, DHS databases do not track the total number of investment projects associated with each individual EB–5 investment, but rather track the NCE associated with each individual investment. Any given NCE could fund multiple projects. DHS analysis of filing data reveals that for FY 2013–2015, on average per year, 1,246 unique NCEs were referenced in the Form I–526 petitions submitted. On average, 726 of these NCEs (58 percent of the overall number of unique NCEs) were found in petitions associated with regional centers. And on average, 520 of these NCEs, or 42 percent of the overall number of NCEs, were found in non-regional center-associated petitions. This suggests that on average, unique NCEs are more common in non-regional center filings, as 91 percent of filings are associated with regional centers.[58]

DHS obtained and analyzed a random sample of Form I–526 petitions that were submitted in FY 2016. The files in the sample were pending adjudicative review at the EB–5 program office in May 2016.[59] As the results obtained from analysis of this random sample are utilized in forthcoming sections of this regulatory analysis, it will be referred to as the ''2016 NCE sample'' for brevity. A key takeaway from the review of the sample is that a majority of all NCEs (80 percent) blended program capital with other sources. For regional center NCEs sourced with blended capital, the EB–5 portion comprised 40 percent of the total capital outlay, while for non-regional center NCEs sourced with blended capital, the EB–5 portion comprised 50 percent of the total capital outlay.

(3) Baseline Program Forecasts

DHS produced a baseline forecast of the total number of Form I–526 receipts, beginning in the first year the rule would take effect and extending for 10 years for the period FY 2017–2026.[60] This Form I–526 forecast includes the historical trend of Form I–526 receipts from FY 2005 to FY 2015, the filing projections from the USCIS Volume Projections Committee (VPC), and input from the EB–5 program office. The VPC projects that the high rate of growth in EB–5 investment filings, which averaged 39 percent annually since FY 2008, will slow to about 3.3 percent over the next 3 years and will subsequently level off.[61] The program grew exponentially starting in 2008 with the economic downturn. At that time, commercial lending was extremely difficult to obtain. Over time as the U.S. economy has improved, commercial lending is now more viable, resulting in fewer overall petitions. In addition, over the past two fiscal years, USCIS has experienced significant spikes in filings in anticipation of Congress either allowing the regional center program to sunset or implementing new legislative reforms that would make it difficult for some regional centers to immediately comply. These spikes have occurred around the program's anticipated sunset (September 2015, December 2015, and September 2016). USCIS believes that the filings will level off once the program is extended for longer than one year at a time. DHS used this information to inform a forecasting model based on a logistic function that captures the past increase in receipts from a low baseline, the exponential growth that the program experienced from FY 2008–2015, the anticipated growth rate for the next 3 years, and then the projected levelling off of future growth. The technical details are provided in the accompanying footnote, and as can be seen in the graph, the DHS estimation technique closely fits past filings and captures the expected trends alluded to above.[62]

Figure 1 graphs the volume of past Form I–526 filings from 2005 to 2015, compared with DHS's estimation of the filings for that period, and the forecasts thereafter.

[57] Between May 2008 and May 2016, 51 regional centers have been terminated, averaging about 6 per year. USCIS, Immigrant Investor Regional Centers, *http://www.uscis.gov/working-united-states/permanent-workers/employment-based-immigration-fifth-preference-eb-5/immigrant-investor-regional-centers.*

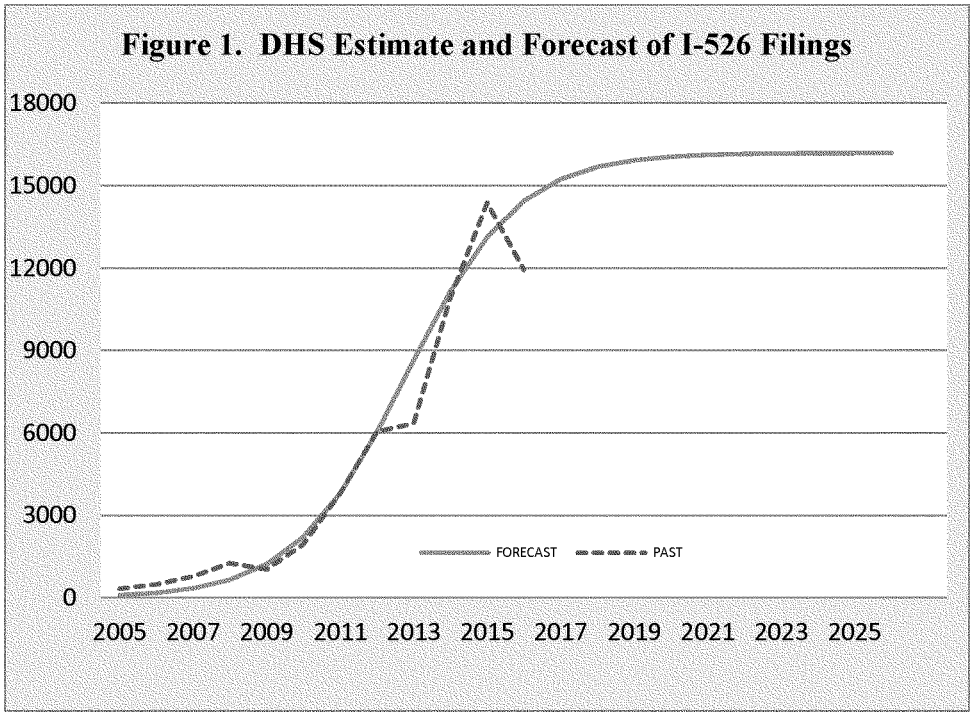
[58] EB–5 program office NCE data records indicate that the disparity in the regional center share of investments compared to NCEs—91 percent compared to 58 percent, respectively—exists because regional center projects include 15 investors on average, while non-regional center investments include only 2 investors on average.

[59] The figures for yearly volumes of Form I–526 filings are publicly available under DHS performance data: USCIS, Number of I–526 Immigrant Petitions by Alien Entrepreneurs by Fiscal Year, Quarter, and Case Status 2008–2016, *available at https://www.uscis.gov/sites/default/files/USCIS/Resources/Reports%20and%20Studies/Immigration%20Forms%20Data/Employment-based/I526_performancedata_fy2016_qtr3.pdf.* The NCE data were obtained from file tracking data supplied by the EB–5 program office. Because the NCE file submissions contain detailed business plan and investor information, the NCE data are not captured in formal DHS databases that are provided publicly, but rather in internal program office and adjudication records.

[60] DHS did not attempt a similar forecast for Form I–924 receipts, because DHS does not have a sound basis for predicting how the proposed rule would affect such receipts.

[61] The VPC estimates that the final total number of Form I–526 filings for FY 2016 will be about 12,000. While this projection is below the FY 2015 total filings, the VPC expects growth to increase again in FY 2017 by 3.3 percent. FY 2015 was an anomaly for Form I–526 petitions and experienced an influx of petitions that DHS does not expect in the future.

[62] DHS utilized a logistic function of the format, $(C/(\lambda + \beta e^{-\rho t}))$ where input t is the time year code (starting with zero), e is the base of the natural logarithm, and C, λ, β, and ρ are parameters such that C/λ asymptotically approaches the maximum level of the predicted variable, the Form I–526 receipts. The parameters β and ρ jointly impact the inflection and elongation of the sigmoidal curve. Because the data includes non-sample information, DHS did not attempt an estimation procedure focused on minimizing the sum of squared errors (such as least squares regression) or other fitting technique, and instead utilized a direct trial-and-error approach for calibration. For the final forecast run, the specific calibration was $C = 17{,}000$, $\lambda = 1.05$, $\beta = 180$, and $\rho = .66$. The maximum expected level of receipts (equal to 17,000/1.05 which is approximately 16,200) was determined via input from EB–5 program management.



The forecast values are listed in Table 3, below:

TABLE 3—DHS FORECASTS FOR INVESTOR FORM I–526 RECEIPTS AND NCEs

FY	Investors	NCEs
2017	15,241	1,314
2018	15,685	1,353
2019	15,925	1,373
2020	16,052	1,384
2021	16,119	1,390
2022	16,153	1,393
2023	16,171	1,395
2024	16,181	1,395
2025	16,185	1,396
2026	16,188	1,396
10-year total	159,900	13,789
Annual Average	15,990	1,379

The last column of Table 3 provides estimates of the total number of NCEs. An assumption of the NCE forecasts is that there is no change in the relationship between the number of NCEs and the number of Form I–526 filings over time.[63] The impact of the proposed provisions on the forecasts will be described in the relevant sections of this analysis.

(4) Economic Impacts of the Major Rule Provisions

a. Retention of Priority Date

This rule proposes to generally allow an EB–5 immigrant petitioner to use the priority date of an approved EB–5 immigrant petition for any subsequently filed EB–5 immigrant petition for which the petitioner qualifies. Provided that petitioners have not yet obtained lawful permanent residence pursuant to their approved petition and that such petition has not been revoked on certain grounds, petitioners would be able to retain their priority date and therefore retain their place in the visa queue. DHS is proposing to allow priority date retention to: (1) Address situations in which petitioners may become ineligible through circumstances beyond their control (*e.g.,* the termination of a regional center) as they wait for their EB–5 visa priority date to become current; and (2) provide investors with greater flexibility to deal with changes to business conditions. For example, investors involved with an underperforming or failing investment project would be able to move their investment funds to a new, more promising investment project without losing their place in the visa queue.

There would be an operational benefit to the investor cohort because priority date retention would make visa allocation more predictable with less possibility for massive fluctuations due to regional center termination that could, in the case of some large regional

[63] In other words, the assumption is that the current number of investors per NCE holds in the future. For the NCE projections, the 2016 value is set at the 2013–2015 average of 1,246. For each year thereafter, the figure is based on the growth rate of predicted Form I–526 receipts.

centers, negatively affect investors who are in the line at a given time. This change would provide greater certainty and stability for investors in their pursuit of permanent residence in the United States, helping lessen the burden of situations unforeseen by the investor related to their investment. In addition, by allowing priority date retention, investors obtain more ability to move their investment funds out of potentially risky projects, thereby potentially reducing fraud and improving the potential for job creation in the United States. DHS cannot quantify or monetize the net benefits of the priority date retention provision or assess how many past or future investors might be impacted. DHS welcomes public comment on the costs and benefits of the priority date retention provision.

b. Investment Amount Increase

DHS proposes to raise the standard minimum investment amount from the current $1 million to $1.8 million to account for the rate of inflation since the program's inception in 1990. DHS also proposes to raise the reduced investment amount, for TEA projects, to $1.35 million, which is 75 percent of the general investment amount.[64] DHS further proposes to adjust the minimum investment amounts every 5 years so that the standard minimum investment amount keeps pace with the rate of inflation and the TEA minimum investment amount remains 75 percent of the standard minimum investment amount. These increases are necessary because the investment amounts have not kept pace with inflation, thereby eroding the real value of the investments.

Because the proposed discounted amount for investments in TEAs is higher than the current minimum amount for investments in non-TEAs, DHS believes it is reasonable to assume that some investors may be unable or unwilling to invest at either of the higher proposed levels of investment. However, DHS has no way to assess the potential reduction in investments either in terms of past activity or forecasted activity, and cannot therefore estimate any impacts concerning job creation, losses or other downstream economic impacts driven by the proposed investment amount increases. DHS evaluates the source of investor funds for legitimacy but not for information on investor income, wealth, or investment preferences. DHS cannot therefore estimate how many past investors would have been unable or unwilling to have invested at the proposed amounts, and hence cannot make extrapolations to potential future investors and projects. DHS requests public input on the impact of the newly proposed amount on potential investors' willingness to participate in the program. DHS also welcomes any input, including identification of relevant data sources, that might provide insight on the number of total jobs that these potential investors may create.[65]

In addition to the effect on investors, it is reasonable to assume that the proposed changes to the investment amounts would also affect regional centers. If the higher amounts reduce the number of investors in the global pool, competition for fewer investors may make it more costly for regional centers to identify and match with investors. The net effect on regional centers would depend on the elasticities associated with these activities and is not something DHS can forecast with accuracy. DHS requests information from the public on how the proposed changes may impact regional center costs.

DHS also believes that for both regional center and non-regional center investments, the projects and the businesses involved could be impacted. A reduced number of EB–5 investors could preclude some projects from going forward due to outright lack of requisite capital. Other projects would likely see an increase in the share of non-EB–5 capital, such as capital sourced to domestic or other foreign sources. As alluded to above in Section Two of the analysis, analysis of the 2016 NCE sample reveals the 80 percent of NCEs involving EB–5 capital blend this type of capital with other sources of capital. DHS believes that the costs of capital and return to capital could be different depending on the source of the capital. As a result, a change in the composition of capital could change the overall profitability for one or more of the parties involved; however, if the project on the whole promises net profitability, it is likely to proceed. The specific impact on each party for each project would vary on a case by case basis, and would be dependent on, among other things, the particular financial structures and agreements between the regional center, investors, NCE, and project developer. It would also be determined by local and regional investment supply and demand, lending conditions, and general business and economic factors. DHS welcomes any comments the public may provide on how the proposed rules may impact regional center and non-regional center investments, projects and businesses.

DHS also considers that an increase in the investment amount could make other countries' foreign investor visa programs more attractive and therefore there could be some substitution into such programs. The decision to invest in another country's program would depend in part on the investment and country-specific risk preferences of each investor. While DHS has no means of ascertaining such preferences, it is possible that some substitution into non-U.S. investor visa programs could occur as a result of the higher required investment amounts. However, according to DHS research, substitution into another countries' immigrant investor program would likely be more costly for investors than investing in the EB–5 program even with increases in the EB–5 investment amounts. As stated earlier in this preamble, the United Kingdom's immigrant investor programs range in minimum investment amounts of approximately $2.5 million to $6.3 million, Australia's immigrant investor programs range in minimum investments amounts from approximately $1.1 million to $11.2 million, Canada's immigrant investor programs range from approximately $1.5 million and require a net worth of $7.6 million, and New Zealand's immigrant investor programs range from minimum investment amounts of approximately $1.8 million to $7.2 million. All of these values are approximations, in U.S. dollars, and are not an exhaustive list. DHS notes that most of these minimum investment amounts are considerably higher than the proposed increased investment amounts in the EB–5 program. DHS requests comments from the public regarding foreign investor visa programs from other countries and how they may compare to the U.S. EB–5 program, and the likelihood that investors will shift their investments to other countries' programs as a result of the changes proposed here.

There are numerous ancillary services and activities linked to both regional center and direct investments, such as, but not limited to, business consulting

[64] The adjustment to the standard minimum investment amount is based on the CPI–U, which, as compared to a base date of 1982–1984, was 130.7 in 1990 and 237.017 in 2015. The actual increase in prices for the period was approximately 81.34 percent, obtained as $((CPI–U_{2015}/CPI–U_{1990}) - 1))$. The $1.8 million proposed investment amount is rounded. *See generally* Bureau of Labor Statistics, Inflation & Prices, *available at http://www.bls.gov/data/#prices.*

[65] DHS has arranged with the Department of Commerce to assess the EB–5 program to determine the number of jobs created, but the report has not yet been released. Remarks, EB–5 Immigrant Investor Program Stakeholder Engagement (July 28, 2016), available at *https://www.uscis.gov/sites/default/files/USCIS/Outreach/Notes%20from%20Previous%20Engagements/PED_EB5NatStakeholderEng072816_ColucciRemarks.pdf.*

and advising, finance, legal services, and immigration services. However, DHS is not certain how these services would be affected by the proposed rule. Similarly, DHS does not have information on how the revenues collected from these types of activities contribute to the overall revenue of the regional centers or direct investments. DHS requests information from the public on the several layers of business and financial activities that focus on matching foreign investor funds to development projects, and on the potential effects of this proposed rule on such activities.

In summary, DHS believes that the proposed increase in the minimum investment amount would bring the nominal investment amounts in line with real values and increase the investment amounts in areas where it is needed most. However, DHS recognizes that some of the investment increase benefits could be offset if some investors are deterred from investing at the higher amounts. DHS does not have the data or information necessary to attempt to estimate such mitigating effects. It is reasonable to conclude that the higher investment amounts could deter some investors from EB–5 activity and therefore negatively impact regional center revenue in some cases, although the magnitudes and net effects of these impacts cannot be estimated. However, it is also possible that the higher investment amounts could attract additional capital overall and stimulate projects to get off the ground that otherwise might not. Due to the complexity of EB–5 financial arrangements and unpredictability of market conditions, DHS cannot forecast with confidence how many projects could be affected by the increased investment amounts through a change in the number of individuals investing through the EB–5 program. However, it is possible that some projects could be forgone and that others would proceed with a higher composition of non-EB–5 capital, with resultant changes in profitability and rates of return to the parties involved. An overall decrease in investments and projects would potentially reduce some job creation and result in other downstream effects.

c. Periodic Adjustments to the Investment Amounts

In addition to initially raising the investment thresholds to account for inflation, DHS proposes to adjust the standard investment threshold every 5 years to account for future inflation, and to adjust the reduced investment threshold for TEAs to keep pace with the standard amount. DHS projected the effects of this methodology using a relatively low, recent, inflation index (1.4 percent) and a more moderate inflation index (3.2 percent). DHS made two separate projections based on two different indexes because DHS cannot predict with certainty what the future inflation index will be. The 1.4 percent estimate is based on the average rate of inflation for the period 2009–2015, which economists generally consider to be relatively low compared to earlier periods. The 3.2 percent estimate used for the higher-end projection is based on the 3.2 percent inflation rate in 2011, which was the highest annual inflation rate observed from the 2009 to 2015 period. DHS believes it is appropriate to characterize the 3.2 percent rate as a ''moderate'' inflation baseline, because although it is higher than the average annual rate since 2008, it is not considered by economists to be high as compared to other historical periods.[66]

Table 4 lists the general minimum investment amounts and reduced investment amounts after 5 and 10 years if the amounts are raised initially as proposed in this rule. The figures are in millions of U.S. dollars and are rounded to the nearest fifty-thousandth.

TABLE 4—PROJECTED INVESTMENT AMOUNTS AT 5-YEAR REVISIONS

[Figures are in millions of $]

Proposed provision: initial increase	Revision (year)	Projected investment amount based on average inflation scenario, 1.4 percent	Projected investment amount based on moderate inflation scenario, 3.2 percent
Standard Investment Amount = $1.8 Million in 2017	5 year	1.90	2.04
	10 Year	2.04	2.40
Minimum Investment Amount = $1.35 Million in 2017	5 year	1.43	1.53
	10 Year	1.53	1.80

DHS attempted to assess the costs of these proposed changes. As described above, the potential cost of the higher amounts may result in a reduction in the number of investors and projects and a lower share of EB–5 capital for some projects, which could result in capital losses, fewer jobs created, and other reductions in economic activity. DHS is not able to predict how many investors and projects will be impacted, nor can we predict the impact to the capital available for projects. DHS requests any data sources the public may provide, as well as comments on anticipated outcomes.

d. Targeted Employment Areas

Under the current regulations, a state may designate an area in which the enterprise is principally doing business as a high-unemployment TEA if that area is a geographic or political subdivision of a metropolitan statistical area (MSA) or of a city or town with a population of 20,000 or more. DHS generally defers to the state determination of the appropriate boundaries of a geographic or political subdivision that constitutes the TEA, but there is currently no limit to the number of census tracts that a state can aggregate as part of a high-unemployment TEA designation. TEA configurations that DHS has evaluated from state designations have included the census tract or tracts where the NCE is principally doing business (''project tract(s)''), one or more directly adjacent tracts, and others that are further removed, resulting in configurations resembling a chain-shape or other contorted shape. This proposed rule

[66] Allan Meltzer, *A Slow Recovery with Low Inflation,* Hoover Inst., Econ. Working Paper No. 13,110 (2013), *available at http://www.hoover.org/sites/default/files/13110_-_meltzer_-_a_slow_recovery_with_low_inflation.pdf; see also* Michael T. Kiley, *Low Inflation in the United States: A Summary of Recent Research,* FEDS Notes, Board of Governors of the Federal Reserve System (Nov. 23, 2015), *available at http://www.federalreserve.gov/econresdata/notes/feds-notes/2015/low-inflation-in-the-united-states-a-summary-of-recent-research-20151123.html*; Mary C. Daly and Bart Hobijn, *Downward Nominal Wage Rigidities Bend the Phillips Curve,* Fed. Reserve Bank S.F., Working Paper No. 2013–08 (2014), *available at http://www.frbsf.org/economic-research/files/wp2013-08.pdf.*

would remove states from the TEA designation process; instead, investors would be required to provide sufficient evidence to DHS in order to qualify for the reduced investment threshold. DHS would generally limit the number of census tracts that could be combined for this purpose.[67] Specifically, DHS is proposing that a TEA may also consist of an area comprised of the census tract(s) in which the new commercial enterprise is principally doing business, including any and all adjacent tracts, if the weighted average of the unemployment rate for all included tracts is at least 150 percent of the national average.

In order to assess the potential impact of this aspect of the proposed rule, DHS performed further analysis on the 2016 NCE sample. First, DHS determined, based on the sample, that 99 percent of regional center investments and 64 percent of non-regional center investments are made into TEAs. Because the 2016 sample significantly over-represents non-regional center investments and over-represents non-regional center NCEs by a smaller, but still noticeable, margin, DHS also determined the percentage of investments overall that were applied to TEAs. DHS found that 97 percent of investments and 85 percent of NCEs were applied to TEAs.[68] About 10 percent of investments that were made into TEAs were made into rural TEAs. This 10% was the same for regional center and non-regional center investments.

DHS then parsed the TEA filings comprising the 2016 NCE sample into specific cohorts. The first cohort is the number of non-rural high-unemployment TEA filings that did not rely on state designations to qualify. The TEAs in this cohort did not require state designations because the project was located in a specific geographical unit that met the unemployment threshold.[69] They would be unaffected by the changes proposed in this rule. The next two cohorts are the filings that relied on one or two census tracts, respectively. These too would be unaffected by this rule. The fourth cohort is the filings that relied on three or more census tracts. The proposed rule would potentially affect some of the designations in this cohort. Because of this, DHS attempted to subject these tracts to further analysis, as described further below.

DHS determined the relative size of each cohort by determining the total number of filings per cohort, and then weighting these percentages to reflect the appropriate regional center and non-regional center proportions, first for investments, and then for NCEs. The relative size of each cohort, as a share of the total number of investments in TEAs and the total number of NCEs in TEAs, are listed in Table 5 below. Note that the amounts are based on the average of filings for FY 2013–2015; potential changes in future filing patterns are discussed below. The share figures are in percentages and are provided first on the basis of all investments and NCEs and next on the basis of high-unemployment TEA investments and NCEs (the last two columns of the table). DHS could have also presented the shares on a per total-TEA basis, but since almost all investments (97 percent) were made into TEAs, little additional insight would be gained by providing figures on such a basis.

TABLE 5—TEA METRICS

TEA Cohort	Investments		NCEs		Share of high-unemployment TEA filings	
	Amount	Share (percent)	Amount	Share (percent)	Investments (percent)	NCEs (percent)
High-unemployment TEA	9,159	87	929	75	N/A	N/A
Qualify without state certification	735	7	135	11	9	18
Qualify with one Census Tract	1,883	18	177	14	20	18
Qualify with two Census Tracts	667	6	50	4	7	4
Cohort not affected by the rule because it would meet the provision	4,672	44	679	55	36	41
Qualify with three or more tracts (maximum that could be affected)	5,875	56	567	45	64	59

[67] According to USCIS policy in effect at the time of issuance of this proposed rulemaking:

A new commercial enterprise is principally doing business in the location where it regularly, systematically, and continuously provides goods or services that support job creation. If the new commercial enterprise provides such goods or services in more than one location, it will be principally doing business in the location most significantly related to the job creation.

Factors considered in determining where a new commercial enterprise is principally doing business include, but are not limited to, the location of:

- Any jobs directly created by the new commercial enterprise;
- Any expenditure of capital related to the creation of jobs;
- The new commercial enterprise's day-to-day operation; and
- The new commercial enterprise's assets used in the creation of jobs.

USCIS Policy Manual, 6 USCIS–PM G (Nov. 30, 2016).

[68] DHS used a weighted average calculation to determine these percentages because the 2016 NCE sample over-represents non-regional center investments—non-regional center investments accounted for exactly half the 2016 NCE sample but less than a tenth (9 percent) of submitted investments. This bias is not a feature of the sampling methodology but rather an inherent feature of the population, because non-regional center investments comprise 42 percent of NCEs. The 2016 NCE sample over-represents non-regional center NCEs as well, but not by as much as investments. The sample share of non-regional center NCEs is 50 percent, while the true share in the NCE population is 42 percent. Hence, the overrepresentation is about 8 percentage points but DHS feels this is significant enough that the NCE aggregate shares should be weighted as well. The weighted average for TEA investments is the sum of the regional center share of investments (.91) multiplied by the TEA share found in the sample (.99), and the non-regional share of investments (.09) multiplied by the TEA share in the sample (.64). The resulting weighting equation is .91 + .06 = .97. The weighted average for TEA NCEs is the sum of the regional center share of NCEs (.58) multiplied by the TEA share found in the sample (.99), and the non-regional share of NCEs (.42) multiplied by the TEA share in the sample (.64). The resulting weighting equation is .58 + .27 = .85.

[69] For the TEA geographies that met the high unemployment threshold in the sample analyzed, 90 percent utilized MSAs and the remaining 10 percent utilized counties.

DHS draws a number of conclusions from the metrics described above. Foremost, a large share of investments (87 percent) were made in, and three-quarters of related NCEs were located in, high-unemployment TEAs. Second, a small share of investments (7 percent) qualified as high unemployment TEAs without state certification,[70] meaning that the MSA or county in which the related project was located qualified independently for such designation. About 18 percent of the investments qualified based on a single-census-tract designation, and a small share (6 percent) qualified based on a two-tract designation. Third, more than half of investments (56 percent) and just under half of related NCEs (45 percent) relied on three or more census-tract configurations.

DHS calculated additional metrics to assess the impact of the rule. To obtain the cohort that would be unaffected by the rule, DHS added together the five subcategories representing non-TEA, rural TEA, those that qualified without state attestation, single tract configurations, and two-tract configurations. This cohort is reported in the second to last row of Table 5. Next, DHS obtained the number of investments and related NCEs that could potentially be affected by the rule. This cohort is reported in the last row of Table 5. These figures represent our maximum. In reality, some portion of the maximum cohort for projects and NCEs would have continued to qualify for TEA designation under the changes proposed by this rule. However, currently DHS does not have reliable, statistically valid information from which DHS can estimate what share would likely be impacted by the rule.

DHS obtained Census Bureau data on adjacent tracts that were utilized in studies unrelated to the current rulemaking provision.[71] From the population of 74,001 tracts provided in the Census dataset, DHS randomly sampled 390 tracts, which is slightly more than the 383 needed for 95 percent confidence and a 5 percent margin of error. The average number of adjacent tracts was 6.4 and the median was 6, with a maximum of 11, a minimum of 3, and a range of 8. Since ''partial'' tracts are not viable under the EB–5 program, the average was rounded to the nearest whole number and 1 tract was added to account for the primary tract for which the adjacencies were counted, to yield an average of 7 total tracts. This suggests that it may not be unusual for a TEA designation of three or more tracts to satisfy the adjacency requirements of this proposed rule.

The benefit of this aspect of the proposed rule is that it would prevent certain TEA configurations that rely on a large number of census tracts indirectly linked to the actual project tract(s) by multiple degrees of separation. As a result, some investments may be re-directed to areas where unemployment rates are truly high, according to the 150 percent threshold, and therefore may stimulate job creation where it is most needed.

Finally, DHS also considered an alternative provision, under which TEA designations would be subject to a twelve-tract limit. This limit is used by the State of California in its TEA certifications. DHS considered this limit as an alternative approach because it is the only case in which a state limits the number of census tracts to a specific number. Analysis of the NCE sample revealed that for tract configurations with two or more tracts, the average number of tracts aggregated was 16, but the median was 7. The figures are slightly higher at 17 and 8, respectively, when the cohort is isolated to three or more multiple tract configurations. The difference in the mean and median indicate that the distribution is right-skewed, characterized by a small number of very large-tract number compilations, evidenced by a sample range of 198 tracts. DHS notes that there is sufficient variation in the data to preclude state locational bias, as 22 states including the District of Columbia were represented in the 2016 NCE sample. Ultimately, DHS did not choose this alternative option because it is not necessarily appropriate for nationwide application, as the limitation to 12 census tracts may be justifiable for reasons specific to California but may not be apt on a national scale.

DHS stresses that the maximum cohorts presented in Table 5 overstate the number and shares of future investments and NCEs that would be impacted by the TEA reform provision because some of the configurations that relied on multiple tracts (3 or more) would be able to meet the requirements of the proposed rule. Furthermore, the number of impacted investments and NCEs is also likely to be lower because regional centers may be able to replace forgone projects in places that would not meet the high unemployment criteria under the proposed rule with other projects that would in fact qualify. For example, a regional center seeking to locate a project on one city block that would no longer qualify as a TEA may opt to locate the project on another block that could qualify as a TEA under the new rule. In that sense, the proposed rule may provide additional incentive for investments in rural areas, because such investments would be unaffected by this rule, or in areas that are more closely associated with high unemployment. In other words, if a regional center is considering a project in a specific location that would no longer qualify as a TEA, the regional center can opt to move the project to a TEA or seek another project that would fall within a TEA. DHS believes that some regional centers will not be able to make such a substitution and that there may be costs in the forms of forgone investments and projects, and accompanying reductions in job creation and other economic activity.

DHS requests any data sources or comments from the public on the estimated costs for the number of investments and projects impacted by this aspect of the proposed rule. DHS has described some of the possible negative consequences of a reduced number of investors. A decrease in investments and projects would potentially reduce some job creation and have other downstream effects.

Finally, DHS notes that because state designations will no longer be accepted, it is reasonable to expect cost savings germane to the labor time and opportunity costs of state government institutions previously involved in TEA designations. It is reasonable to expect that these cost savings to states would transfer into some additional costs for DHS in adjudication review time in order to evaluate TEA submissions. However, DHS cannot accurately predict such added time burden to the Government at this time.

e. Other Provisions

DHS has analyzed the other provisions and sub-provisions to those discussed above:

Removal of Conditions Filing. DHS is proposing to revise its regulations to clarify that, except in limited circumstances, derivative family members must file their own petitions to remove conditions from their permanent residence when they are not included in a petition to remove conditions filed by the principal

[70] State certification is currently required for high unemployment areas encompassing geographic or political subdivisions smaller than an MSA or county. *See* 8 CFR 204.(6)(i) and 204.6(j)(6)(ii).

[71] As of 2016, the Census Bureau records show 73,057 Tracts in the United States, including the District of Columbia but not counting U.S. Territories. U.S. Census Bureau, 2010 Census Tallies of Census Tracts, Block Groups and Blocks, *available at https://www.Census.gov/geo/maps-data/data/tallies/tractblock.html.* The data utilized in this analysis is currently available publicly from Brown University's (Providence, RI) American Communities Project Web site at *http://www.s4.brown.edu/us2010/Researcher/Pooling.htm.*

investor. Generally, an immigrant investor's derivatives are included in the principal immigrant investor's Form I–829 petition. However, there have been cases where the derivatives are not included in the principal's petition but instead file one or more separate Form I–829 petitions. The proposed regulation clarifies that, except in the case of a deceased principal, derivatives not included in the principal's Form I–829 petition cannot use one petition for all the derivatives combined but must each separately file his or her own Form I–829 petition. Based on EB–5 program office review of historical filings for this group, on average over a 3-year period about 24 cases per year involved such circumstances. Biometrics are currently required for the joint Form I–829 petition submissions, so the provision requiring separate filings would not impose any additional biometric, travel, or associated opportunity costs. The only costs expected from the rule would be the separate filing fee and associated opportunity cost. The filing fee for a Form I–829 petition is $3,750. DHS estimates that the form takes 3 hours to complete. DHS recognizes that many dependent spouses and children do not currently participate in the U.S. labor market, and as a result, are not represented in national average wage calculations. In order to provide a reasonable proxy of time valuation, DHS has to assume some value of time above zero and therefore uses an hourly cost burdened minimum wage rate of $10.59 to estimate the opportunity cost of time for dependent spouses. The value of $10.59 per hour represents the Federal minimum wage with an upward adjustment for benefits.[72] Each applicant would face a time cost burden of $32, which when added to the filing fee, is $3,782. Extrapolating the past number of average annual filings of 24 going forward, total applicant costs would total $90,762 annually.[73]

Removal of Conditions Interview. In addition to the separate filing requirement discussed above, DHS is proposing to improve the adjudication process relevant to the investor's Form I–829 interview process by providing flexibility in interview scheduling and location. Section 216A(c)(1)(B) of the INA, 8 U.S.C. 1186b(c)(1)(B), generally requires Form I–829 petitioners to be interviewed prior to final adjudication of the petition, although DHS may waive the interview requirement at its discretion. *See* INA section 216A(d)(3), 8 U.S.C. 1186b(d)(3). Under this rule, DHS is proposing to give USCIS greater flexibility to require Form I–829 interviews and determine the appropriate location for such an interview. Additionally, current DHS regulations allow for Form I–829 petitioners to be interviewed prior to final adjudication of a Form I–829 petition, but require the interview to be conducted at the USCIS District Office holding jurisdiction over the immigrant investor's new commercial enterprise. However, there is no requirement that the immigrant investor reside in the same location as the new commercial enterprise, and DHS has determined through some very preliminary surveys conducted by the EB–5 program office that many immigrant investors are located a considerable distance from the new commercial enterprise. Therefore, DHS proposes to clarify that USCIS has authority to schedule an interview at the USCIS office holding jurisdiction over either the immigrant investor's commercial enterprise, the immigrant investor's residence, or the location in which the Form I–829 petition is being adjudicated. DHS cannot currently determine how many petitioners would potentially be affected by these changes. From fiscal years 2011 to 2015, DHS received an average of 1,911 Form I–829 petitions. While not all of these petitioners would require an interview or face hardship to travel for an interview, some of this maximum population may be impacted.[74] Some petitioners would benefit by traveling shorter distances for interviews and thus see a cost savings in travel costs and opportunity costs of time for travel and interview time. DHS welcomes any comments by the public that may provide further data sources on the potential costs and benefits associated with this proposed change.

Process for Issuing Permanent Resident Cards. DHS also proposes to amend regulations governing the process by which immigrant investors obtain their new permanent resident cards after the approval of their Form I–829 petitions. Current regulations require the immigrant investor and his or her derivatives to report to a district office for processing of their permanent resident cards after approval of the Form I–829 petition. This process is no longer necessary in light of intervening improvements in DHS's biometric data collection program.[75] DHS now captures the required biometric data while the Form I–829 petition is pending, at the time the immigrant investor and his or her derivatives appear at an Application Support Center for fingerprinting, as required for the Form I–829 background and security checks. DHS then mails the permanent resident card directly to the immigrant investor by U.S. Postal Service registered mail after the Form I–829 petition is approved. Accordingly, there is generally no need for the immigrant investor and his or her derivatives to appear at a district office after approval of the Form I–829 petition.

DHS does not estimate any additional costs for this proposed provision. This proposed provision will likely benefit immigrant investors and any derivatives, including by providing savings in cost, travel, and time, since this regulation will no longer require them to report to a district office for processing of their permanent resident cards. DHS also benefits by removing a process that is no longer necessary.

Miscellaneous other changes. DHS is also proposing a number of other technical changes to the EB–5 regulations. First, DHS is proposing to update a reference to the former United States Customs Service, so that it will now refer to U.S. Customs and Border Protection. Second, DHS is proposing to conform DHS regulations to Public Law 107–273, which eliminated the requirement that immigrant entrepreneurs establish a new commercial enterprise from both section 203(b)(5) and section 216A of the INA. Accordingly, USCIS proposes to remove references to this requirement in 8 CFR 204.6 and 216.6. Third, DHS is proposing to further conform DHS regulations to Public Law 107–273 by removing the references to ''management'' at 8 CFR 204.6(j)(5) and 8 CFR 204.6(j)(5)(iii). Fourth, DHS is proposing to remove the phrase ''as opposed to maintaining a purely passive role in regard to the investment'' from 8 CFR 204.6(j)(5). Fifth, DHS is proposing to allow any type of entity to serve as a new commercial enterprise. Sixth, DHS is proposing to amend 8 CFR 204.6(k) to remove the requirement on USCIS to specify in the decision on the EB–5 immigrant petition whether the new commercial enterprise is

[72] *Minimum Wage,* U.S. DOL, *http://www.dol.gov/dol/topic/wages/minimumwage.htm* (indicating the Federal Minimum Wage is $7.25 per hour). The calculation for total employer costs for employee compensation for dependent spouses and children of principals with an approved Form I–140: $7.25 per hour × 1.46 = $10.59 per hour.

[73] Calculation: the burdened wage of $10.59 per hour multiplied by 3 hours. The individual fee and total cost figures are rounded from actuals of $3,781.76 and $90,762.12, respectively.

[74] USCIS, Number of I–829 Petitions by Entrepreneurs to Remove Conditions by Fiscal Year, Quarter, and Case Status 2008–2016, *available at https://www.uscis.gov/sites/default/files/USCIS/Resources/Reports%20and%20Studies/Immigration%20Forms%20Data/Employment-based/I829_performancedata_fy2016_qtr3.pdf.*

[75] DHS already has authority to collect this information under 8 CFR part 103.

principally doing business in a TEA. Finally, DHS is proposing revisions to otherwise unaffected sections of section 204.6 and 216.6 to replace the term ''entrepreneur'' with the term ''investor.'' These provisions are technical changes and will have no impact on investors or the government. Therefore, the benefits and costs for these changes were not estimated.

Miscellaneous Costs

Familiarization costs: DHS assumes that there will be familiarization costs associated with this rule. To estimate these costs, DHS relied on several assumptions. First, DHS believes that each approved regional center would need to review the rule. Other than regional centers, the NCEs would also need to be familiar with the proposed rule. Based on the 790 regional centers referenced herein as having approved Forms I–924 and 520 non-regional center NCEs, a total of at least 1,310 identified entities would likely need to review the rule. DHS believes that lawyers would likely review the rule and that it would take about 4 hours to review and inform any additional parties of the changes in this proposed rule. Based on the BLS ''Occupational Employment Statistics (OES)'' dataset, the 2015 mean hourly wage for a lawyer was $65.51.[76] DHS burdens this rate by a multiple of 1.46, consistent with other rulemakings, to account for other compensation and benefits, to arrive at an hourly cost of $95.64. The total cost of familiarization is $501,154 annually based on the current number of approved regional centers and non-regional center NCEs in the recent past.[77]

D. Executive Order 13132

This proposed rule would not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Although DHS has historically deferred to state designations of high unemployment areas, DHS is ultimately responsible for the adjudication of each petition (including TEA designations).[78] This proposed rule would not directly alter the states' rights or obligations under the EB–5 program, and is fully consistent with the federal role in administration of immigration programs. DHS is unaware of any state laws that would be preempted or otherwise affected by this proposed rule.[79] Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. DHS nonetheless welcomes public comment on possible federalism implications of this proposed rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, 110 Stat. 847 (March 29, 1996), requires Federal agencies to consider the potential impact of regulations on small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. An ''individual'' is not defined by the RFA as a small entity and costs to an individual from a rule are not considered for RFA purposes. In addition, courts have held that the RFA's regulatory flexibility analysis requirements apply to direct small entity impacts only.[80] Consequently, any indirect impacts from a rule to a small entity are not costs for RFA purposes.

However, the changes proposed by DHS to modernize and improve the EB–5 program may have the potential to affect several types of business entities involved in EB–5 projects. Therefore, DHS has prepared an Initial Regulatory Flexibility Analysis (IRFA) under the RFA because some of the entities involved may be considered small entities.

Initial Regulatory Flexibility Analysis

EB–5 investment structures are complex and can involve numerous entities involved in project financing and development. The rule proposes to raise the investment levels to account for inflation and reform the way in which TEAs are constructed. It is difficult to determine the small entity status of regional centers because there is a lack of official data on employment, income, and industry classification for these entities. Such a determination is also difficult because regional centers can be structured in a variety of different ways, and can involve multiple business and financial activities, some of which play a direct, and some an indirect, role in linking investor funds to NCEs and job-creating projects or entities. Although DHS does not know if regional centers are small entities, DHS believes some regional center NCEs and some non-regional center NCEs could be small entities. A detailed description of DHS's attempt to identify such entities is provided below. DHS welcomes public comment on the potential impact of the proposed changes on small entities.

a. A Description of the Reasons Why the Action by the Agency Is Being Considered

DHS proposes to update its EB–5 regulations to update aspects of the EB–5 program in need of reform and to reflect statutory changes and codify existing policies. Elsewhere in this preamble, DHS provides further background and explanation for the proposals contained in the rule.

b. A Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

DHS objectives and legal authority for this proposed rule are discussed in Section II of the preamble.

c. A Description and, Where Feasible, an Estimate of the Number of Small Entities to Which the Proposed Changes Would Apply

DHS believes the changes outlined in the proposed rule could affect the following types of groups that are involved in EB–5 investments: Entrepreneurs, regional centers, and new commercial enterprises (NCEs). Below, DHS identifies which of these groups may qualify as small entities under the RFA.

[76] Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm#23-0000.*

[77] Calculation: 1,310 entities × 4 hours each × burdened hourly wage of $95.64. Final figure is rounded from 501,153.6.

[78] USCIS Policy Manual, 6 USCIS–PM G at 8 (May 30, 2013) (''However, for all TEA designations, USCIS must still ensure compliance with the statutory requirement that the proposed area designated by the state in fact has an unemployment rate of at least 150 percent of the national average rate.'').

[79] For example, California's Office of Business and Economic Development notes: ''While the EB–5 visa program is administered by the U.S. Citizenship and Immigration Services and is therefore governed by federal laws and regulations, GO-Biz provides customized TEA certifications for projects that qualify under the $500,000 special TEA requirements.'' *EB–5 Investor Visa Program,* California Governor's Office of Business and Economic Development, *http://www.business.ca.gov/Programs/International-Affairs-and-Business-Development/EB-5.*

[80] *See, e.g., Mid-Tex Elec. Coop.* v. *FERC,* 773 F.2d 327, 342 (D.C. Cir. 1985) (concluding that an agency may certify a rule under Section 605(b) of the Regulatory Flexibility Act when the agency determines the rule will not directly impact small entities).

1. Entrepreneurs

An entrepreneur who wishes to immigrate to the United States must file an Immigrant Petition by Alien Entrepreneur (Form I–526). DHS analysis of filing data for the Form I–526 reveals that for FY 2013–2015 an average of 10,547 EB–5 foreign entrepreneurs filed Form I–526 petitions to DHS annually, and DHS forecasts that over the next ten years the annual average will be about 16,000. Form I–526 petitions are filed by individuals who voluntarily apply for immigration benefits on their own behalf and thus do not meet the definition of a small entity. Therefore, entrepreneurs were not considered further for purposes of this RFA.

2. Regional Centers

As previously mentioned, the small entity status of regional centers is very difficult to determine because of the lack of official data concerning employment, income, and industry classification of the regional center itself. Regional centers use Form I–924 to obtain regional center designation and use Form I–924A to demonstrate continued eligibility for regional center designation annually. The information provided by regional center applicants as part of the Form I–924 and I–924A processes does not include adequate data to allow DHS to reliably identify the small entity status of individual applicants. Although regional center applicants typically report the North American Industry Classification (NAICS) codes associated with the sectors they plan to direct investor funds toward, these codes do not necessarily apply to the regional centers themselves. In addition, information provided to DHS concerning regional centers generally does not include regional center revenues or employment.

DHS nonetheless attempted to identify how many regional centers may be small entities. DHS obtained a sample of 440 regional centers operating 5,886 projects. At the time of DHS's analysis, there were 790 approved regional centers.[81] DHS used subscription and publicly available data to identify those regional centers that may qualify as small entities by trying to obtain revenue information or information on the number of employees and the NAICS codes. Obtaining the revenue or employee count and NAICS codes would allow DHS to determine if the regional center was a small entity as recommended by the SBA. For the vast majority of the entities in the sample, DHS could not conclusively determine the entity's small entity status. For 15 of the regional centers in the sample, search queries generated preliminary results, but DHS could not confirm them as the entities of interest. This is because regional centers often utilize very broad terms, such as a combination of the term ''regional center'' and the name of the state, city, or geographic area in which the regional center is located. Non-regional center entities, such as local economic development organizations, as well as consultancies and legal units involved in the EB–5 program, often utilize very similar or even exact name syntax, and, as such, the multiple initial results could not be de-conflicted. For about 5 of the target regional centers, DHS could reasonably verify the results of the search query. However, such a low response proportion prevents DHS from drawing statistically valid conclusions.

DHS did not attempt to determine the small entity status of regional centers based on the bundled capital investment amounts available to such regional centers. Such bundled investments are not indicative of whether the regional center is appropriately characterized as a small entity for purposes of the RFA because there is no way to know, based solely on the information available, how much of these bundled investment amounts are used for the investment projects that the regional center may be affiliated with and how much may be used as administrative fees paid to the regional center. DHS assumes that some amount of the administrative fees contribute to a regional center's revenue, and if DHS were able to obtain information on administrative fees, along with industry data, DHS might be able to make a determination on whether the regional center was a small entity. DHS welcomes any public comment on data sources or information on regional centers, including their sources of revenue, their employment data, the industries in which they should be categorized, and other information relevant to their small entity status.

3. New Commercial Enterprises (NCEs)

Similar to the challenges with identifying regional centers as small entities, DHS experienced challenges when attempting to identify NCEs as small entities, whether the NCE is affiliated with a regional center or not.

First, NCEs can be involved with the job-creating activity in a variety of ways that create analytical challenges. Regional center NCEs usually are established to receive EB–5 funding, and then deploy the funding to a separate JCE. They can also engage in the job creating activity directly. Both regional center NCEs and non-regional center NCEs can fund multiple job creating activities. Under USCIS's current regulations at 8 CFR 204.6(e), an NCE can constitute a parent company and its wholly-owned subsidiaries and through these wholly-owned subsidiaries an NCE can also engage in job-creating activities in multiple industries. The multiplicity of ways in which an NCE can engage in the job creating activity make it difficult to assign a NAICS code to any particular entity that constitutes or comprises part of what is considered the NCE.

Second, DHS does not require regional center applicants or petitioners to submit on their applications or petitions the type of revenue and employment data appropriate for analysis, regardless of the type of NCE or how it is structured.[82] Although petitioners are required to submit a number of different types of documents to DHS to establish eligibility, DHS does not specifically require revenue or employment data for a specific NCE entity itself. Rather, petitioners relying on future job creation must provide a business plan for the job-creating activity (regardless of which entity is engaged in the activity), and the plan may contain projected revenues, although it is not required to. The business plan or an accompanying economic analysis will also project the expected number of jobs created by the EB–5 investment. However, these are projections only. It is not appropriate to use these projected revenues as a substitute for actual revenues in this analysis. For these reasons, although DHS recognizes that the proposed rule could result in some impacts to NCEs that may be small entities, DHS cannot feasibly or reliably estimate the number of such small entities that could be impacted. DHS requests comments from the public that provide more information how to identify the small entity status of NCEs, what the potential impacts of the rule might be on small entity NCEs, and whether and to what extent those impacts could be transferred to small entity regional centers.

[81] DHS attempted to conduct a small entity analysis on regional centers for another DHS rule in January 2016.

[82] DHS notes that regional centers and individual petitioners provide such information regarding the NCEs with which the regional centers are associated or in which the petitioners have invested.

4. Job-Creating Entities (JCEs)

Due to the complex nature of the EB–5 program and the various structures involved, DHS assumes that the proposed provisions that would increase the investment amount or change the TEA designation criteria could indirectly impact the JCEs. However, DHS requests public comment on this assumption given the various structures that are possible under the EB–5 program. Due to data capture limitations, it is not feasible for DHS to reliably estimate the number of JCEs at this time. DHS anticipates forthcoming form revisions that may collect additional data on JCEs that receive EB–5 capital, and expects to be able to examine this more closely in the future.

d. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Types of Professional Skills

The proposed rule does not directly impose any new or additional ''reporting'' or ''recordkeeping'' requirements on filers of Forms I–526, I–829 or I–924. The proposed rule does not require any new professional skills for reporting. However, the proposed rule may create some additional time burden costs related to reviewing the proposed provisions, as is discussed above. As noted above, DHS believes that lawyers would likely review the rule and that it would take about 4 hours to review and inform any additional parties of the changes in this proposed rule. Based on the BLS ''Occupational Employment Statistics (OES)'' dataset, the 2015 mean hourly wage for a lawyer was $65.51.[83] DHS burdens this rate by a multiple of 1.46, consistent with other rulemakings, to account for other compensation and benefits, to arrive at an hourly cost of $95.64, or $382.56 per entity.

While DHS has estimated these costs, and assumes that they may affect some small entities, for reasons stated previously, data limitations prevent DHS from determining how many such small entities may be impacted or the extent of the impact to the small entities.

e. An Identification of All Relevant Federal Rules, to the Extent Practical, That May Duplicate, Overlap, or Conflict With the Proposed Rule

DHS is unaware of any duplicative, overlapping, or conflicting Federal rules, but invites any comment and information regarding any such rules.

f. Description of Any Significant Alternatives to the Proposed Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

This proposed rule would modernize and make necessary updates to the EB–5 program. While DHS knows that some regional centers may be considered small entities, DHS does not have enough data to determine the impact that this proposed rule may have on those entities.

With respect to the proposal to reform the TEA designation process, DHS considered several alternatives, but found that they did not feasibly accomplish the stated objective of INA section 203(b)(5)(B)(ii). One alternative DHS considered was limiting the geographic or political subdivision of TEA configurations to an area containing up to, but no more than, 12 contiguous census tracts, an option currently used by the state of California in its TEA designation process.[84] However, DHS is not confident that this option is necessarily appropriate for nationwide application, as the limitation to 12 census tracts may be justifiable for reasons specific to California but may not be feasible on a national scale.

Another significant alternative DHS considered that would be relatively straightforward to implement and understand would be to limit the geographic or political subdivision of the TEA to the actual project tract(s). While this option would be easy to put in practice for both stakeholders and the agency, it was considered too restrictive in that it would exclude immediately adjacent areas that would be impacted by the investment.

DHS also considered options based on a ''commuter pattern'' analysis, which focuses on defining a TEA as encompassing the area in which workers may live and be commuting from, rather than just where the investment is made and where the new commercial enterprise is principally doing business. The ''commuter pattern'' proposal was deemed too operationally burdensome to implement as it posed challenges in establishing standards to determine the relevant commuting area that would fairly account for variances across the country.[85] In addition, DHS could not identify a commuting-pattern standard that would appropriately limit the geographic scope of a TEA designation consistent with the statute and the policy goals of this proposed regulation.

With respect to the minimum investment amount provision, DHS also considered an alternative to the proposed increase to the investment amount for TEAs. Specifically, DHS considered the alternative of setting the reduced TEA investment amount to $900,000 instead of $1,350,000, consistent with the existing regulatory framework.[86] DHS is proposing a 75 percent reduction rather than a 50 percent reduction to better balance the Congressional aim of incentivizing investment in TEAs with the goal of encouraging greater investment in the United States more generally. History has shown that a 50 percent reduction coincides with an extremely large imbalance in favor of TEA investments, at the expense of additional overall investment and therefore economic benefit that may accrue to the U.S. economy more generally. Removing the TEA discount entirely, although allowable by statute, would run the risk of removing the incentive to invest in TEAs altogether. Setting the reduced minimum investment at 75 percent of the standard minimum investment amount (*i.e.,* the midpoint between the maximum discount and no discount)

[83] Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm#23-0000.*

[84] *See* Cal. Governor's Office of Bus. and Econ. Dev., EB–5 Investor Visa Program, *available at http://business.ca.gov/International/EB5Program.aspx.*

[85] DHS reviewed a proposed commuter pattern analysis incorporating the data table, Federal Highway Administration, CTPP 2006–2010 Census Tract Flows, *available at* (*http://www.fhwa.dot.gov/planning/census_issues/ctpp/data_products/2006-2010_tract_flows/*) (last updated Mar. 25, 2014). DHS found the required steps to properly manipulate the Census Transportation Planning Product (CTPP) database might prove overly burdensome for petitioners with insufficient economic and statistical analysis backgrounds. Further, upon contacting the agency responsible to manage the CTPP data table, DHS was informed that the 2006–2010 CTPP data is unlikely to be updated prior to FY2018 to incorporate proposed changes to the data table. U.S. Census is currently reviewing the CTPP proposed changes. As an alternate methodology for TEA commuter pattern analysis, DHS reviewed data from the U.S. Census tool, On the Map, *http://onthemap.ces.census.gov/,* which is tied to the U.S. Census Bureau's American Community Survey. Although the interface appeared to be more user-friendly overall, using this data would be operationally burdensome, potentially requiring hours of review to obtain the appropriate unemployment rates for the commuting area.

[86] The current reduced minimum investment amount ($500,000) is 50 percent of the standard minimum investment amount ($1,000,000).

likely would produce greater investment levels in absolute terms while still providing, given the very significant imbalance in favor of TEAs produced by the 50 percent discount, a meaningful incentive to invest in TEAs.

DHS is requesting comments on other alternatives that may minimize the impacts to small entities.

F. Executive Order 12988

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

G. National Environmental Policy Act

DHS Directive (Dir) 023–01 Rev. 01 establishes the procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA. 40 CFR parts 1500–1508. The CEQ regulations allow federal agencies to establish, with CEQ review and concurrence, categories of actions (''categorical exclusions'') which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(2)(ii) and 1508.4. Dir. 023–01 Rev. 01 establishes Categorical Exclusions that DHS has found to have no such effect. Dir. 023–01 Rev. 01 Appendix A Table 1. For an action to be categorically excluded from further NEPA review, Dir. 023–01 Rev. 01 requires the action to satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the Categorical Exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Dir. 023–01 Rev. 01 section V.B(1)–(3).

DHS analyzed this action and does not consider it to significantly affect the quality of the human environment. This proposed rule would change a number of eligibility requirements and introduce priority date retention for certain immigrant investor petitioners. It would also amend existing regulations to reflect statutory changes and codify existing EB–5 program policies and procedures. DHS has determined that this rule does not individually or cumulatively have a significant effect on the human environment because it fits within Categorical Exclusion number A3(d) in Dir. 023–01 Rev. 01, Appendix A, Table 1, for rules that interpret or amend an existing regulation without changing its environmental effect.

This rule is not part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental effects. This rule is categorically excluded from further NEPA review.

H. Paperwork Reduction Act

Under the Paperwork Reduction Act (PRA) of 1995, all Departments are required to submit to OMB, for review and approval, any reporting requirements inherent in a rule. *See* Public Law 104–13, 109 Stat. 163 (May 22, 1995). USCIS is revising one information collection and requesting public comments on the proposed change as follows: Immigrant Petitioner by Alien Entrepreneur (Form I–526) to collect additional information about the new commercial enterprise into which the petitioner is investing to determine the eligibility of qualified individuals to enter the United States to engage in commercial enterprises. DHS is requesting comments on the proposed information collection changes included in this rulemaking. Comments on this revised information collection should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the 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, such as permitting electronic submission of responses.

Overview of Information Collection—Form I–526

a. *Type of information collection:* Revision to a currently approved information collection.

b. *Abstract:* USCIS uses this information collection to determine if an alien can enter the U.S. to engage in commercial enterprise.

c. *Title of Form/Collection:* Immigrant Petitioner by Alien Entrepreneur.

d. *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I–526; USCIS.

e. *Affected public who will be asked or required to respond:* Individuals.

f. *An estimate of the total number of respondents:* 15,990 respondents.

g. *Hours per response:* 1 hour and 50 minutes.

h. *Total Annual Reporting Burden:* 29,261 burden hours.

List of Subjects

8 CFR Part 204

Administrative practice and procedure, Adoption and foster care, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 216

Administrative practice and procedure, Aliens.

Proposed Regulatory Amendments

Accordingly, DHS proposes to amend chapter I of title 8 of the Code of Federal Regulations as follows:

PART 204—IMMIGRANT PETITIONS

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1151, 1153, 1154, 1182, 1184, 1186a, 1255, 1324a, 1641; 8 CFR part 2.

■ 2. Section 204.6 is amended by:

■ a. Revising the title of the section, paragraphs (a), (c), and (d); and

■ b. Amending paragraph (e) by:

■ i. Removing the terms ''Immigrant Investor Pilot'' and ''Pilot'' and adding in their place the term ''Regional Center'' in the definitions for *Employee* and *Full-time employment;*

■ ii. Removing the term ''entrepreneur'' and adding ''investor'' in the definitions for *Capital, Invest, Qualifying employee,* and *Troubled business;*

■ iii. Revising the definitions for *Rural area* and *Targeted employment area;*

Adding a new definition for *Regional Center Program;*

■ iv. *Replacing ''Form I–526'' with ''EB–5 immigrant petition'';*

■ c. Revising paragraphs (f)(1), (f)(2), and (f)(3);

■ d. Amending paragraph (g)(1) by removing the term ''entrepreneur'' and adding in its place the term ''investor'' and revising paragraph (g)(2).

■ e. Revising paragraph (i);

■ f. Revising the paragraph (j)(2)(iii), (5) introductory text and (5)(iii), (6)(i), and (6)(ii)(B);

■ g. Revising paragraph (k);

The revisions and addition read as follows:

§ 204.6 Petitions for employment creation immigrants.

(a) *General.* An EB–5 immigrant petition to classify an alien under

section 203(b)(5) of the Act must be properly filed in accordance with the form instructions, with the appropriate fee(s), initial evidence, and any other supporting documentation.

* * * * *

(c) *Eligibility to file and continued eligibility.* An alien may file a petition for classification as an investor on his or her own behalf.

(d) *Priority date.* The priority date of an approved EB–5 immigrant petition will apply to any subsequently filed petition for classification under section 203(b)(5) of the Act for which the alien qualifies. A denied petition will not establish a priority date. A priority date is not transferable to another alien. The priority date of an approved petition shall not be conferred to a subsequently filed petition if the alien was lawfully admitted to the United States for conditional residence under section 203(b)(5) of the Act based upon that approved petition or if at any time USCIS revokes the approval of the petition based on:

(1) Fraud, or a willful misrepresentation of a material fact by the petitioner; or

(2) A determination by USCIS that the petition approval was based on a material error.

(e) * * *

Regional Center Program means the program established by Public Law 102–395, Section 610, as amended.

Rural area means any area other than an area within a metropolitan statistical area (as designated by the Office of Management and Budget) or within the outer boundary of any city or town having a population of 20,000 or more based on the most recent decennial census of the United States.

Targeted employment area means an area that, at the time of investment, is a rural area or is designated as an area that has experienced unemployment of at least 150 percent of the national average rate.

(f) * * *

(1) *General.* Unless otherwise specified, for EB–5 immigrant petitions filed on or after [INSERT EFFECTIVE DATE OF FINAL RULE], the amount of capital necessary to make a qualifying investment in the United States is one million eight hundred thousand United States dollars ($1,800,000). Beginning on October 1, [INSERT YEAR FIVE YEARS AFTER EFFECTIVE DATE OF FINAL RULE], and every five years thereafter, this amount will automatically adjust for petitions filed on or after each adjustment's effective date, based on the cumulative annual percentage change in the unadjusted All Items Consumer Price Index for All Urban Consumers (CPI–U) for the U.S. City Average reported by the Bureau of Labor Statistics for the previous five years. The qualifying investment amount will be rounded down to the nearest hundred thousand. DHS may update this figure by publication of a technical amendment in the **Federal Register**.

(2) *Targeted employment area.* Unless otherwise specified, for EB–5 immigrant petitions filed on or after [INSERT EFFECTIVE DATE OF FINAL RULE], the amount of capital necessary to make a qualifying investment in a targeted employment area in the United States is one million three hundred and fifty thousand United States dollars ($1,350,000). Beginning on October 1, [INSERT DATE YEAR FIVE YEARS AFTER EFFECTIVE DATE OF FINAL RULE], and every five years thereafter, this amount will automatically adjust for petitions filed on or after each adjustment's effective date, to be equal to 75 percent of the standard minimum investment amount described in paragraph (f)(1) of this section. DHS may update this figure by publication of a technical amendment in the **Federal Register**.

(3) *High employment area.* Unless otherwise specified, for EB–5 immigrant petitions filed on or after [INSERT EFFECTIVE DATE OF FINAL RULE], the amount of capital necessary to make a qualifying investment in a high employment area in the United States is one million eight hundred thousand United States dollars ($1,800,000). Beginning on October 1, [INSERT DATE YEAR FIVE YEARS AFTER EFFECTIVE DATE OF FINAL RULE], and every five years thereafter, this amount will automatically adjust for petitions filed on or after each adjustment's effective date, based on the cumulative annual percentage change in the unadjusted All Items Consumer Price Index for All Urban Consumers (CPI–U) for the U.S. City Average reported by the Bureau of Labor Statistics for the previous five years. The qualifying investment amount will be rounded down to the nearest hundred thousand. DHS may update this figure by publication of a technical amendment in the **Federal Register**.

(g) * * *

(1) * * *

(2) *Employment creation allocation.* The total number of full-time positions created for qualifying employees shall be allocated solely to those alien investors who have used the establishment of the new commercial enterprise as the basis for a petition. No allocation must be made among persons not seeking classification under section 203(b)(5) of the Act or among non-natural persons, either foreign or domestic. USCIS will recognize any reasonable agreement made among the alien investors in regard to the identification and allocation of such qualifying positions.

* * * * *

(i) *Special designation of a high unemployment area.* USCIS may designate a particular geographic or political subdivision as an area of high unemployment (at least 150 percent of the national average rate). Such geographic or political subdivision must be composed of the census tract or contiguous census tracts in which the new commercial enterprise is principally doing business, and may also include any or all census tracts contiguous to such census tract(s). The weighted average of the unemployment rate for the subdivision, based on the labor force employment measure for each census tract, must be at least 150 percent of the national average unemployment rate.

* * * * *

(j) * * *

(2) * * *

(iii) Evidence of property transferred from abroad for use in the United States enterprise, including U.S. Customs and Border Protection commercial entry documents, bills of lading, and transit insurance policies containing ownership information and sufficient information to identify the property and to indicate the fair market value of such property;

* * * * *

(5) To show that the petitioner is or will be engaged in the new commercial enterprise, either through the exercise of day-to-day managerial control or through policy formulation, the petition must be accompanied by:

* * * * *

(iii) Evidence that the petitioner is engaged in policy making activities. For purposes of this section, a petitioner will be considered sufficiently engaged in policy making activities if the petitioner is an equity holder in the new commercial enterprise and the organizational documents of the new commercial enterprise provide the petitioner with certain rights, powers, and duties normally granted to equity holders of the new commercial enterprise's type of entity in the jurisdiction in which the new commercial enterprise is organized.

* * * * *

(6) * * *

(i) In the case of a rural area, evidence that the new commercial enterprise is

principally doing business within a civil jurisdiction not located within any standard metropolitan statistical area as designated by the Office of Management and Budget, nor within any city or town having a population of 20,000 or more as based on the most recent decennial census of the United States; or

(ii) In the case of a high unemployment area:

(A) Evidence that the metropolitan statistical area, the specific county within a metropolitan statistical area, the county in which a city or town with a population of 20,000 or more is located, or the city or town with a population of 20,000 or more, in which the new commercial enterprise is principally doing business has experienced an average unemployment rate of at least 150 percent of the national average rate; or

(B) A description of the boundaries of the geographic or political subdivision and the unemployment statistics in the area for which designation is sought as set forth in 8 CFR 204.6(i), and the reliable method or methods by which the unemployment statistics were obtained.

(k) *Decision.* The petitioner will be notified of the decision, and, if the petition is denied, of the reasons for the denial. The petitioner has the right to appeal the denial to the Administrative Appeals Office in accordance with the provisions of part 103 of this chapter.

* * * * *

PART 216—CONDITIONAL BASIS OF LAWFUL PERMANENT RESIDENCE STATUS

■ 3. The authority citation for part 216 continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1154; 1184, 1186a, 1186b, and 8 CFR part 2.

■ 4. Amend § 216.6 by

■ a. Revising paragraph (a)(1) introductory text;

■ b. Removing ''Form I–829, Petition by Entrepreneur to Remove Conditions'' from paragraph (a)(1)(i);

■ c. Removing and reserving paragraph (a)(4)(i);

■ d. Replacing ''entrepreneur'' with ''investor'' in paragraph (a)(4)(iv);

■ e. Revising paragraphs (a)(5) and (6);

■ f. Revising paragraph (b);

■ g. Removing and reserving paragraph (c)(1)(i) and revising paragraphs (c)(2); and

■ h. Revising paragraph (d).

The revisions to read as follows:

§ 216.6 Petition by investor to remove conditional basis of lawful permanent resident status.

(a) * * *

(1) *General procedures.* (i) A petition to remove the conditional basis of the permanent resident status of an investor accorded conditional permanent residence pursuant to section 203(b)(5) of the Act must be filed by the investor with the appropriate fee. The investor must file within the 90-day period preceding the second anniversary of the date on which the investor acquired conditional permanent residence. Before the petition may be considered as properly filed, it must be accompanied by the fee required under 8 CFR 103.7(b)(1), and by documentation as described in paragraph (a)(4) of this section, and it must be properly signed by the investor. Upon receipt of a properly filed petition, the investor's conditional permanent resident status shall be extended automatically, if necessary, until such time as USCIS has adjudicated the petition.

(ii) The investor's spouse and children may be included in the investor's petition to remove conditions. Where the investor's spouse and children are not included in the investor's petition to remove conditions, the spouse and each child must each file his or her own petition to remove the conditions on their permanent resident status, unless the investor is deceased. If the investor is deceased, the spouse and children may file separate petitions or may be included in one petition. A child who reached the age of 21 or who married during the period of conditional permanent residence, or a former spouse who became divorced from the investor during the period of conditional permanent residence, may be included in the investor's petition or must each file a separate petition.

* * * * *

(5) *Termination of status for failure to file petition.* Failure to properly file the petition to remove conditions within the 90-day period immediately preceding the second anniversary of the date on which the investor obtained lawful permanent residence on a conditional basis shall result in the automatic termination of the investor's permanent resident status and the initiation of removal proceedings. USCIS shall send a written notice of termination and a notice to appear to an investor who fails to timely file a petition for removal of conditions. No appeal shall lie from this decision; however, the investor may request a review of the determination during removal proceedings. In proceedings, the burden of proof shall rest with the investor to show by a preponderance of the evidence that he or she complied with the requirement to file the petition within the designated period. USCIS may deem the petition to have been filed prior to the second anniversary of the investor's obtaining conditional permanent resident status and accept and consider a late petition if the investor demonstrates to USCIS' satisfaction that failure to file a timely petition was for good cause and due to extenuating circumstances. If the late petition is filed prior to jurisdiction vesting with the immigration judge in proceedings and USCIS excuses the late filing and approves the petition, USCIS shall restore the investor's permanent resident status, remove the conditional basis of such status, and cancel any outstanding notice to appear in accordance with 8 CFR 239.2. If the petition is not filed until after jurisdiction vests with the immigration judge, the immigration judge may terminate the matter upon joint motion by the investor and DHS.

(6) *Death of investor and effect on spouse and children.* If an investor dies during the prescribed 2-year period of conditional permanent residence, the spouse and children of the investor will be eligible for removal of conditions if it can be demonstrated that the conditions set forth in paragraph (a)(4) of this section have been met.

(b) *Petition review.* (1) *Authority to waive interview.* USCIS shall review the petition to remove conditions and the supporting documents to determine whether to waive the interview required by the Act. If satisfied that the requirements set forth in paragraph (c)(1) of this section have been met, USCIS may waive the interview and approve the petition. If not so satisfied, then USCIS may require that an interview of the investor be conducted.

(2) *Location of interview.* Unless waived, an interview relating to the petition to remove conditions for investors shall be conducted by a USCIS immigration officer at the office that has jurisdiction over either the location of the investor's commercial enterprise in the United States, the investor's residence in the United States, or the location of the adjudication of the petition, at the agency's discretion.

(3) *Termination of status for failure to appear for interview.* If the investor fails to appear for an interview in connection with the petition when requested by USCIS, the investor's permanent resident status will be automatically terminated as of the second anniversary of the date on which the investor obtained permanent residence. The investor will be provided with written notification of the termination and the reasons therefore, and a notice to appear shall be issued placing the investor in removal proceedings. The investor may

seek review of the decision to terminate his or her status in such proceedings, but the burden shall be on the investor to establish by a preponderance of the evidence that he or she complied with the interview requirements. If the investor has failed to appear for a scheduled interview, he or she may submit a written request to USCIS asking that the interview be rescheduled or that the interview be waived. That request should explain his or her failure to appear for the scheduled interview, and if a request for waiver of the interview, the reasons such waiver should be granted. If USCIS determines that there is good cause for granting the request, the interview may be rescheduled or waived, as appropriate. If USCIS waives the interview, USCIS shall restore the investor's conditional permanent resident status, cancel any outstanding notice to appear in accordance with 8 CFR 239.2, and proceed to adjudicate the investor's petition. If USCIS reschedules that investor's interview, he or she shall restore the investor's conditional permanent resident status, and cancel any outstanding notice to appear cause in accordance with 8 CFR 239.2.

(c) * * *

(2) If derogatory information is determined regarding any of these issues or it becomes known to the government that the investor obtained his or her investment funds through other than legal means, USCIS shall offer the investor the opportunity to rebut such information. If the investor fails to overcome such derogatory information or evidence that the investment funds were obtained through other than legal means, USCIS may deny the petition, terminate the investor's permanent resident status, and issue a notice to appear. If derogatory information not relating to any of these issues is determined during the course of the interview, such information shall be forwarded to the investigations unit for appropriate action. If no unresolved derogatory information is determined relating to these issues, the petition shall be approved and the conditional basis of the investor's permanent resident status removed, regardless of any action taken or contemplated regarding other possible grounds for removal.

(d) Decision. (1) *Approval.* If, after initial review or after the interview, USCIS approves the petition, USCIS will remove the conditional basis of the investor's permanent resident status as of the second anniversary of the date on which the investor acquired conditional permanent residence. USCIS shall provide written notice of the decision to the investor. USCIS may request the investor and derivative family members to appear for biometrics at a USCIS facility for processing for a new Permanent Resident Card.

(2) *Denial.* If, after initial review or after the interview, USCIS denies the petition, USCIS will provide written notice to the investor of the decision and the reason(s) therefore, and shall issue a notice to appear. The investor's lawful permanent resident status and that of his or her spouse and any children shall be terminated as of the date of USCIS' written decision. The investor shall also be instructed to surrender any Permanent Resident Card previously issued by USCIS. No appeal shall lie from this decision; however, the investor may seek review of the decision in removal proceedings. In proceedings, the burden shall rest with USCIS to establish by a preponderance of the evidence that the facts and information in the investor's petition for removal of conditions are not true and that the petition was properly denied.

Jeh Charles Johnson,

Secretary.

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